

SPECIALTY DRUG AND DRUG-RELATED PRODUCTS MANAGEMENT  
ACROSS  
THE PHARMACY AND MEDICAL BENEFIT:  
EXPERIENCE OF A SELF-INSURED EMPLOYER FROM 2006 TO 2014

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## **Abstract**

**Background:** Specialty drugs are the fastest growing part of the pharmaceutical market, and this growth is expected to continue in the United States. As the specialty drug market continues to expand, questions regarding how to manage specialty drugs arise. One solution for the strategic management of specialty drugs is coordination and management across both the pharmacy benefit and the medical benefit.

**Study Goal:** The goal of this study is to examine specialty drug and drug-related product distribution and utilization across the entire health benefit plan, and by therapeutic category in both the pharmacy and the medical benefit components of the University of Minnesota's UPlan. The analysis will include identification of opportunities to coordinate and better manage safe and appropriate use of specialty medications while also managing the growth in expenditures.

**Methods:** The study design is a retrospective claims analysis. Claims data from the University of Minnesota's UPlan pharmacy and medical benefits are evaluated from 2006 to 2014.

**Results:** There was a substantial growth in total specialty drug expenditures for the UPlan from 2006 to 2014. Specialty drugs and drug-related products accounted for a relatively small volume of claims with about 2 percent to 3 percent of all drugs and drug-related claims. In contrast, the percent of total drug expenditures accounted for by specialty drugs and drug-related products grew from 26 percent to 42 percent from 2006 to 2014. Over one-half of total specialty drug expenditures in 2014 were used to treat four conditions—multiple sclerosis, oncology, hepatitis C, and drugs for autoimmune diseases. The expenditures for total specialty drugs and drug-related products through the medical

benefit more rapidly than expenditures under the pharmacy benefit. In 2013 and 2014, the top three sites of care identified under the medical benefit included physician's office, outpatient hospital, and home settings. Thirty-five drugs were provided under both the pharmacy and medical benefits.

**Implication:** This study is timely and can help payers such as employer-sponsored health plans understand the full scope of the specialty drug expenditure and management landscape. A well-rounded picture of specialty drugs and drug-related product utilization trends over time is vital for effective management of employer-sponsored health plans. Additionally, identification of pharmacy and medical benefit overlaps in specialty drugs, drug-related product coverage, and drug distribution permits more effective management opportunities.

**Conclusion:** Expenditure tracking and claims level analysis are critical for appropriate evaluation and comparison of overall and specialty drug trends across pharmacy and medical benefits. Drug management strategies are needed that include both the pharmacy benefit and the medical benefit. A small number of therapeutic categories account for greater than 50% of total specialty expenditures. Specialty drug management needs to understand market trends and specific drug utilization and expenditures through detailed claims level analysis including overlaps in benefit coverage across the pharmacy and medical benefit. Data analysis can direct management strategies by identifying and facilitating a focus on drug utilization and expenditures driven by the top therapeutic categories.

## Table of Contents

<b>Acknowledgments</b> .....	<b>i</b>
<b>Abstract</b> .....	<b>ii-iii</b>
<b>Table of Contents</b> .....	<b>iv-vi</b>
<b>List of Tables</b> .....	<b>vii-ix</b>
<b>List of Figures</b> .....	<b>x-xiv</b>
<b>List of Appendices</b> .....	<b>xv</b>
<b>Chapter 1: Introduction</b> .....	<b>1-2</b>
1.1. Background and Significance.....	2-5
1.2. Research aim and questions.....	5-6
1.2.1. Aim 1 .....	6
1.2.1.1. Research questions 1a.....	6
1.2.1.2. Research questions 1b .....	7
1.2.2. Aim 2 .....	7
1.2.2.1. Research question 2a.....	7
1.2.2.2. Research question 2b.....	7
1.2.2.3. Research question 2c.....	7
1.2.2.4. Research question 2d.....	8
1.2.2.5. Research question 2e.....	8
1.2.3. Aim 3 .....	8
1.2.3.1. Research question 3a.....	8
1.2.3.2. Research question 3b.....	8
1.3.4. Aim 4 .....	9
1.3.4.1. Research question 4a.....	9
1.3.4.2. Research question 4b .....	9
1.3.4.3. Research question 4c.....	9
1.3. Data source and research method .....	9
1.3.1. Data source .....	9
1.3.2. Research design.....	10
1.3.3. Operationalization of specialty drug definition .....	10-11
1.3.3.1. Specialty drug definition operationalization for pharmacy claims .....	11
1.3.3.2. Specialty drug definition operationalization for medical claims .....	11-12
1.3.4. Quality Assurance.....	12-13
1.3.5. Pharmacy claim data quality.....	13
1.3.6. Medical claim data quality .....	13-14
1.4. Implication of Study.....	14-15
1.5. Key terms.....	15-23
<b>Chapter 2: Literature Review</b> .....	<b>24</b>
2.1. General trends.....	24-26
2.2. Defining Specialty Drugs .....	27
2.2.1. Specialty definition by Centers for Medicare and Medicaid (CMS).....	28
2.2.2. Specialty definition by Academic of Managed Care Pharmacy (PBM Perspective) .....	29
2.2.3. Specialty definition by America’s health Insurance Plans (Health Plan Perspective) .....	30
2.2.4. Specialty definition by AARP Public Policy Institute .....	30
2.2.5. Specialty definition by Prime Therapeutics, the PBM serving the University of Minnesota’s UPlan .....	31
2.2.6. Specialty definition by University of Minnesota’s UPlan .....	32
2.2.7. Specialty definition developed for this study .....	32
2.3. Specialty drug vs. traditional drugs .....	32-34
2.4. Biosimilar vs. traditional generics.....	34-41
2.5. Specialty drug under pharmacy benefit verses medical benefit .....	42-45
2.5.1. Specialty drugs under pharmacy benefit .....	46-47
2.5.2. Specialty drugs under medical benefit .....	47-49
2.5.3. Specialty drugs that flow across pharmacy and medical benefit.....	50-52
2.6. Specialty drug management strategies under pharmacy and medical benefit.....	53

2.6.1.	Control of specialty drug definition .....	53
2.6.2.	Utilization management .....	54-56
2.6.3.	Distribution channel and site of care management.....	56-59
2.6.4.	Patient engagement and management.....	60
2.6.5.	Provider engagement .....	61
2.6.6.	Continued evaluation and monitoring of data and trends.....	61-62
<b>Chapter 3: Conceptual Framework and Research Methodology .....</b>		<b>63</b>
3.1.	Data source .....	63-64
3.2.	Study aims and research questions .....	64
3.2.1.	Aim 1 .....	64
3.2.1.1.	Research questions 1a.....	65
3.2.1.2.	Research questions 1b .....	65
3.2.2.	Aim 2 .....	65
3.2.2.1.	Research question 2a.....	65
3.2.2.2.	Research question 2b.....	66
3.2.2.3.	Research question 2c.....	66
3.2.2.4.	Research question 2d.....	66
3.2.2.5.	Research question 2e.....	66
3.2.3.	Aim 3 .....	67
3.2.3.1.	Research question 3a.....	67
3.2.3.2.	Research question 3b.....	67
3.2.4.	Aim 4.....	67
3.2.4.1.	Research question 4a.....	67
3.2.4.2.	Research question 4b.....	68
3.2.4.3.	Research question 4c .....	68
3.3.	Claims data characteristics .....	69
3.3.1.	Pharmacy claims data elements .....	70
3.3.1.1.	Pharmacy data element.....	70-71
3.3.1.2.	Distribution channels or places of services under pharmacy benefit .....	71-74
3.3.1.3.	Product identifiers under pharmacy benefit.....	74-76
3.3.1.4.	Date identifiers under pharmacy benefit .....	76-77
3.3.1.5.	Utilization data elements under pharmacy benefit .....	77
3.3.1.6.	Financial data elements under pharmacy benefit .....	78
3.3.2.	Medical claims data elements.....	78-80
3.3.2.1.	Unique claim vs. claim line .....	81
3.3.2.2.	Drug and drug-related claims.....	81-83
3.3.2.3.	Medical claims data elements 2006-2014 .....	83-86
3.3.2.4.	Place of service data elements under medical benefit .....	86-90
3.3.2.5.	Product identifiers under medical benefit.....	91-95
3.3.2.6.	Date identifier under medical benefit .....	95
3.3.2.7.	Utilization data elements under medical benefit .....	96
3.3.2.8.	Financial data elements under pharmacy benefit .....	96-97
3.4.	Data quality, data linking, and data enhancements .....	97
3.4.1.	Data quality.....	97-100
3.4.1.1.	Pharmacy claims data quality.....	100-101
3.4.1.2.	Medical claims data quality.....	101
3.4.2.	Data enhancements.....	101-103
3.4.2.1.	Pharmacy claims data enhancement .....	103-105
3.4.2.2.	Medical claims data enhancement.....	105-108
3.4.2.3.	Combining pharmacy and medical claims data.....	108-109
3.5.	Operationalization of specialty drug definition .....	110
3.5.1.	Specialty drug operationalization under pharmacy claims.....	110-111
3.5.2.	Specialty drug operationalization under medical claims.....	111-112
3.6.	Statistical analysis process for each study aim and research question .....	112
3.6.1.	Aim 1 .....	113
3.6.2.	Aim 2 .....	113

3.6.3.	Aim 3 .....	113
3.6.4.	Aim 4 .....	113
3.7.	Study limitations.....	113-114
3.7.1.	Study limitations under pharmacy benefit.....	114-115
3.7.2.	Study limitations under medical benefit .....	115-116
<b>Chapter 4: Results .....</b>		<b>117</b>
4.1.	General trends.....	117
4.1.1.	Over all trends .....	117-152
4.1.2.	General trends specialty versus traditional drugs .....	152-166
4.2.	Aim one results .....	167
4.2.1.	Question 1a.....	167-191
4.2.2.	Question 1b.....	192-193
4.3.	Aim two results .....	193-203
4.3.1.	Question 2a results.....	203-210
4.3.2.	Question 2b results .....	210-213
4.3.3.	Question 2c results.....	213-229
4.3.4.	Question 2d results .....	229-232
4.3.5.	Question 2e results.....	233-252
4.4.	Aim three results.....	253
4.4.1.	Question 3a results.....	253-262
4.4.2.	Question 3b results .....	262-273
4.5.	Aim four results.....	273
4.5.1.	Question 4a results.....	273
4.5.2.	Question 4b results .....	274-277
4.5.3.	Question 4c results.....	278-312
<b>Chapter 5: Discussion and Conclusion .....</b>		<b>313</b>
5.1.	UPlan general trends .....	313-316
5.2.	UPlan specialty trends (Aim 1 and Aim 2) .....	316-318
5.2.1.	Specialty drug utilization vs expenditures .....	319-320
5.2.2.	Growth of specialty drug expenditures .....	320-322
5.2.3.	Top specialty drugs contributing to trend .....	322-323
5.2.3.1.	Top specialty drugs under pharmacy benefit.....	323-324
5.2.3.2.	Top specialty drugs under medical benefit .....	324-325
5.3.	Specialty drug utilization and expenditures by therapeutic category (Aim 2) .....	325-327
5.4.	Specialty drug utilization and expenditures by site of services under medical benefit (Aim 3) .....	327-330
5.5.	Specialty drugs used across pharmacy and medical benefit (Aim 4).....	331-333
5.6.	Study limitation .....	333-334
5.7.	Study implication and conclusion.....	334-337
<b>Reference .....</b>		<b>338-348</b>
<b>Appendices .....</b>		<b>349-364</b>



## LIST OF TABLES

1. Table 2.1: Biosimilars Approved & Market Status as of July 2018 (39)
2. Table 2.2: Approved Biosimilars & Reference Biologics AWP Unit Prices as of: July 12, 2018 (40)
3. Table 3.1: UPlan 2006 to 2014 Average Number of Covered Lives (64)
4. Table 3.2: Pharmacy Claims Data Elements (71)
5. Table 3.3: Total Pharmacy Claims Drug Distribution Channels (73)
6. Table 3.4: Pharmacy Type Code and Description per NCPDP (74)
7. Table 3.5: Illustration of medical claims, unique claim vs. claim line (80)
8. Table 3.6: Medical Claim Classification Codes (82)
9. Table 3.7: Grouping of Drug and Drug Related Claims (83)
10. Table 3.8: Medical Claims Data Elements: 2006 to 2014 (84-86)
11. Table 3.9: Unique Claim Counts by Place of Service (88-89)
12. Table 3.10: Unique Claim Counts by Consolidated Place of Service (90)
13. Table 3.11: HCPCS/CPT versus NDC (94-95)
14. Table 3.12: Prices of NDCs under HCPCS Codes C9129 (95)
15. Table 3.13: Data Elements for Combined Pharmacy and Medical Claims Summary Data (108-109)
16. Table 4.1: PMPY Expenditures under Pharmacy & Medical Benefits: 2006 to 2014 (136)
17. Table 4.2: Percentage Growth Year to Year in PMPY Expenditure for Drugs under Pharmacy & Medical Benefit: 2006 to 2014 (139)
18. Table 4.3: PMPM Expenditures under Pharmacy & Medical Benefits: 2006 to 2014 (141)
19. Table 4.4: PMPY Expenditures for Specialty & Traditional Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014 (158)
20. Table 4.5: Percent Growth PMPY Expenditures Year to Year for Specialty & Traditional Expenditures across Pharmacy & Medical Benefits: 2006 to 2014 (161)
21. Table 4.6: PMPY Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014 (172)
22. Table 4.7: Percentage Growth in PMPY Specialty Expenditure Year to Year Pharmacy & Medical Benefits: 2006 to 2014 (173)
23. Table 4.8: PMPM Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014 (175)
24. Table 4.9: PMPY for Specialty Expenditures across Pharmacy & Medical Benefits by Therapeutic Category: 2006 to 2014 (179-180)
25. Table 4.10: PMPY Expenditure for Specialty under the Pharmacy Benefit: 2006 to 2014 (182)
26. Table 4.11: PMPY Expenditure for Specialty Drugs under the Medical Benefit by Therapeutic Category: 2006 to 2014 (185)
27. Table 4.12: Year to Year Change in Expenditures for Specialty Drugs and Drug-related Products in Aggregate for the Pharmacy Benefit and Medical Benefit from 2006 to 2014 (192)
28. Table 4.13: Year to Year Change in Claims for Specialty Drugs and Drug-related Products in Aggregate that Flow Through the Pharmacy Benefit and the Medical Benefit: 2006 to 2014 (193)

29. Table 4.14: PMPY Specialty Drug Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2013 (197)
30. Table 4.15: PMPY Total Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2014 (201)
31. Table 4.16: Number of NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Drug and Drug-Related Expenditures for the UPlan (210)
32. Table 4.17: Percent of NDCs/HCPCS Accounting for 50%, 75%, 90% of Total Specialty Expenditures for the UPlan: 2006 to 2014 (212)
33. Table 4.18: Drugs with the Highest Average Expenditures per Claim for Specialty Drugs under the Pharmacy and Medical Benefits: 2006 to 2014 (217)
34. Table 4.19: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2006 (217)
35. Table 4.20: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2007 (218)
36. Table 4.21: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2008 (219)
37. Table 4.22: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2009 (221)
38. Table 4.23: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2010 (222)
39. Table 4.24: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2011 (223)
40. Table 4.25: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2012 (224)
41. Table 4.26: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2013 (225)
42. Table 4.27: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2014 (226)
43. Table 4.28: Percent of Total Specialty Expenditures Accounted for by Each Therapeutic Category Each Year Across the Pharmacy and Medical Benefits: 2006 to 2014 (230)
44. Table 4.29: PMPY Expenditure for Multiple Sclerosis Drugs under the Pharmacy & Medical Benefits: 2014 (243)
45. Table 4.30: PMPY Expenditures for Specific Hepatitis C Drugs under the Pharmacy Benefit: 2014 (245)
46. Table 4.31: PMPY & Total Expenditures for Top 10 Oncology Drugs under the Pharmacy & Medical Benefits: 2014 (247)
47. Table 4.32: PMPY and Total Expenditures for Autoimmune Drugs under the Pharmacy & Medical Benefits: 2014 (249)
48. Table 4.33: PMPY and Total Expenditures for Top 10 Immunomodulators & Immune Serums under the Medical Benefit: 2014 (252)
49. Table 4.34: Number of Total Medical Claims Accounted for by Site of Care (258)
50. Table 4.35: Percent of Total Medical Claims Accounted for by Site of Care (258)
51. Table 4.36: Number of Total Medical Specialty Claims Accounted by Site of Care (259)

52. Table 4.37: Percent of Total Medical Specialty Claims Accounted for by Each Site of Care (259)
53. Table 4.38: Number of Total Medical Traditional Claims Accounted by Site of Care (262)
54. Table 4.39: Percentage of Total Medical Traditional Claims Accounted for by Each Site of Care (262)
55. Table 4.40: Percent Change in Average Specialty Expenditure by Site of Care under Medical Benefit: 2006 to 2014 (271)
56. Table 4.41: Percent Change in Number of Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014 (273)
57. Table 4.42: Specialty Drugs Present under Both the Pharmacy Benefit and the Medical Benefit for the UPlan: 2006 to 2014 (275)
58. Table 4.43: PMPY Expenditures for Dual Channel Specialty Drugs Used under the Pharmacy and Medical Benefit: 2006 to 2014 (281)
59. Table 4.44: PMPY Expenditures for Orencia (abatacept) under Pharmacy and Medical Benefit from 2006 to 2014 (283)
60. Table 4.45: PMPY Expenditures for Cytoxan (cyclophosphamide) under Pharmacy & Medical Benefits from 2006 to 2014 (285)
61. Table 4.46: PMPY Expenditures for Lovenox (enoxaparin sodium) under Pharmacy & Medical Benefit from 2006 to 2014 (287)
62. Table 4.47: PMPY Expenditures for Epogen & Procrit (Epoetin Alfa) under the Pharmacy & Medical Benefits from 2006 to 2014 (290)
63. Table 4.48: PMPY Expenditures for Neupogen (filgrastim) under Pharmacy & Medical Benefit from 2006 to 2014 (292)
64. Table 4.49: PMPY Expenditures for Supprelin LA (histrelin acetate) under Pharmacy & Medical Benefit from 2006 to 2014 (294)
65. Table 4.50: PMPY Expenditures for Remicade (infliximab) under the Pharmacy & Medical Benefits from 2006 to 2014 (296)
66. Table 4.51: PMPY Expenditures for Leuprolide Acetate under the Pharmacy & Medical Benefits from 2006 to 2014 (298)
67. Table 4.52: PMPY Expenditures for Xolair under Pharmacy & Medical Benefit from 2006 to 2014 (300)
68. Table 4.53: PMPY Expenditures for Stelara (Ustekinumab injection) under the Pharmacy and Medical Benefits from 2006 to 2014 (302)
69. Table 4.54: PMPY Expenditures for Sandostatin (Octreotide inj) under the Pharmacy & Medical Benefits from 2006 to 2014 (304)
70. Table 4.55: PMPY Expenditures for Vivitrol under the Pharmacy and Medical Benefits from 2006 to 2014 (306)
71. Table 4.56: PMPY Expenditures for Neulasta (pegfilgrastim) under the Pharmacy and Medical Benefits from 2006 to 2014 (308)
72. Table 4.57: PMPY Expenditures for Mycophenolate Mofetil under Pharmacy & Medical Benefits from 2006 to 2014 (310)
73. Table 4.58: PMPY Expenditures for Prograf (tacrolimus) under the Pharmacy & Medical Benefits from 2006 to 2014 (312)

## LIST OF FIGURES

1. Figure 2.1 Specialty Drug Approvals vs. Traditional Drug Approvals: 2005 to 2014 (25)
2. Figure 3.1: Example of NDC Components (76)
3. Figure 4.1: Total Annual Expenditures under Pharmacy & Medical Benefit: 2006 to 2014 (119)
4. Figure 4.2: Total Monthly Expenditure under Pharmacy & Medical Benefit: 2006 to 2014 (120)
5. Figure 4.3: Total Monthly Claims under Pharmacy & Medical Benefits: 2006 to 2014 (121)
6. Figure 4.4: Pharmacy & Medical Expenditures as % of Total Expenditures: 2006 to 2014 (123)
7. Figure 4.5: Pharmacy & Medical Claims as percentage of Total Claims: 2006 to 2014 (124)
8. Figure 4.6: Total Expenditures under the Medical Benefit By Category 2006 to 2014 (126)
9. Figure 4.7: Percentage of Total Expenditures under the Medical Benefit by Category: 2006 to 2014 (127)
10. Figure 4.8: Percentage of Total Claims under the Medical Benefit by Category: 2006 to 2014 (129)
11. Figure 4.9: Total Expenditures under Pharmacy Benefit by Category: 2006 to 2014 (130)
12. Figure 4.10: Percentage of Total Expenditures for Pharmacy Benefit by Category: 2006 to 2014 (132)
13. Figure 4.11: Percentage of Total Claims under the Pharmacy Benefit by Category: 2006 to 2014 (133)
14. Figure 4.12: PMPY Expenditures under Pharmacy & Medical Benefit: 2006 to 2014 (135)
15. Figure 4.13: PMPY Expenditures under Pharmacy & Medical Benefits as Percentage of Total PMPY Expenditures: 2006 to 2014 (137)
16. Figure 4.14: Percentage Growth Year to Year in PMPY Expenditure under Pharmacy & Medical Benefit: 2006 to 2014 (138)
17. Figure 4.15 PMPM Expenditures under Pharmacy & Medical Benefit: 2006 to 2014 (140)
18. Figure 4.16: Total Number of Claims under Pharmacy & Medical Benefits: 2006 to 2014 (142)
19. Figure 4.17: Percentage of Pharmacy & Medical Claims as Percentage of Total Claims: 2006 to 2014(144)
20. Figure 4.18: Monthly Number of Pharmacy & Medical Claims: 2006 to 2014 (146)
21. Figure 4.19: Monthly Total Average Expenditure per Claim under Pharmacy & Medical Benefit: 2006 to 2014 (147)
22. Figure 4.20: Annual Average Expenditure per Pharmacy & Medical Claim: 2006 to 2014 (148)
23. Figure 4.21: Percentage Change in per Claim Expenditures Year to Year under Pharmacy & Medical Benefits: 2006 to 2014 (149)
24. Figure 4.22: Immunization & Immunization Administration Claims under

- Medical Benefit by Month: 2004 to 2014 (150)
25. Figure 4.23: Immunization & Immunization Administration Expenditures under Medical Benefit by Month: 2004 to 2014 (151)
26. Figure 4.24: Total Specialty & Traditional Expenditures across Pharmacy & Medical Benefits: 2006 to 2014 (153)
27. Figure 4.25: Specialty vs. Traditional Expenditures as Percentage of Total Expenditures under Pharmacy & Medical Benefits: 2006 to 2014 (154)
28. Figure 4.26: PMPY Expenditures for Specialty & Traditional Expenditures across Pharmacy & Medical Benefit: 2006 to 2014 (156)
29. Figure 4.27: PMPY Expenditures for Specialty & Traditional Drug Expenditures under Pharmacy & Medical Benefit: 2006 to 2014 (157)
30. Figure 4.28: PMPY Expenditures for Specialty & Traditional Expenditures as a Percentage of Total PMPY Expenditures across Pharmacy & Medical Benefits: 2006 to 2014 (159)
31. Figure 4.29: Percentage Growth PMPY Expenditures Year to Year for Specialty & Traditional Drugs & Drug-Related Claims across Pharmacy & Medical Benefits: 2006 to 2014 (160)
32. Figure 4.30: Specialty vs. Traditional Drug Claims as Percentage of Total Drug Claims under Pharmacy & Medical Benefits: 2006 to 2014 (162)
33. Figure 4.31: Specialty Expenditures & Utilization as a Percentage of Total Expenditures & Utilization: 2006 to 2014 (164)
34. Figure 4.32: Traditional Expenditures & Utilization as a Percentage of Total Expenditure & Utilization: 2006 to 2014 (166)
35. Figure 4.33: Total Expenditures on Specialty Drugs and Drug-Related Expenditures across Pharmacy & Medical Benefits: 2006 to 2014 (168)
36. Figure 4.34: Total Specialty Expenditures under Pharmacy & Medical Benefit: 2006 to 2014 (169)
37. Figure 4.35: PMPY Expenditure for Specialty Drugs under Pharmacy & Medical Benefits: 2006 to 2014 (171)
38. Figure 4.36: Percentage Growth in PMPY Expenditure Year to Year for Specialty Drugs and Drug-Related Expenditures under Pharmacy & Medical Benefits: 2006 to 2014 (172)
39. Figure 4.37: PMPM Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014 (174)
40. Figure 4.38A: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Higher Cost Categories: 2006 to 2014 (176)
41. Figure 4.38B: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Mid-Range Cost Categories: 2006 to 2014 (177)
42. Figure 4.38C: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Lowest Cost Categories: 2004 to 2014 (178)
43. Figure 4.39: PMPY Expenditure for Specialty under the Pharmacy Benefit by Therapeutic Category: 2006 to 2014 (181)
44. Figure 4.40: PMPY Expenditure for Specialty Drugs under the Medical Benefit by Therapeutic Category: 2006 to 2014 (183)
45. Figure 4.41: Average Specialty Expenditure per Claim under Pharmacy & Medical Benefits: 2006 to 2014 (186)

46. Figure 4.42: Specialty Pharmacy vs. Specialty Medical Expenditures as Percentage of Total Specialty Expenditures: 2006 to 2014 (187)
47. Figure 4.43: Specialty Pharmacy & Specialty Medical Claims as Percentage of Total Specialty Claims: 2006 to 2014 (188)
48. Figure 4.44: Expenditures & Utilization for Specialty Drugs under the Pharmacy Benefit as a Percentage of Total Pharmacy Expenditures & Utilization: 2006 to 2014 (189)
49. Figure 4.45: Expenditures & Utilization for Specialty Drugs under the Medical Benefit as a Percentage of Total Medical Expenditures & Utilization: 2006 to 2014 (190)
50. Figure 4.46: Total Specialty Drug and Drug-Related Expenditures under Pharmacy and Medical Benefits by Therapeutic Category: 2013 (194)
51. Figure 4.47: PMPY Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2013 (195)
52. Figure 4.48: Total Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2014 (198)
53. Figure 4.49: PMPY Total Specialty Expenditures under the Pharmacy & Medical Benefits by Therapeutic Category: 2014 (200)
54. Figure 4.50: PMPY Total Specialty Expenditures under the Pharmacy & Medical Benefits by Therapeutic Category: 2006 vs. 2014 (202)
55. Figure 4.51: Percent of Total Specialty Expenditures Accounted for by The Top 10, 25, and 50 drugs for the UPlan Each Year: 2006 to 2014 (204)
56. Figure 4.52: Top 10 Specialty Drugs by Total Expenditure as a Percent of Total Specialty Expenditures by Pharmacy Benefits & Medical Benefits: 2006 to 2014 (206)
57. Figure 4.53: Top 25 Specialty Drugs by Total Expenditure as a Percent of Total Specialty Expenditures by Pharmacy Benefits & Medical Benefits: 2006 to 2014(208)
58. Figure 4.54: Top 50 Specialty Drugs by Total Expenditure as Percentage of Total Specialty Drug and Drug-Related Expenditures: 2006 to 2014 (209)
59. Figure 4.55: Number of Specialty NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Expenditures:2006 to 2014 (211)
60. Figure 4.56: Percentage of Specialty NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Expenditures: 2006 to 2014 (213)
61. Figure 4.57: Average Expenditure per Claim under Pharmacy & Medical Benefits: 2006 to 2014 (214)
62. Figure 4.58: Highest Average Expenditure per Claim for Specialty Drugs under the Pharmacy Benefit & the Medical Benefit: 2006 to 2014 (216)
63. Figure 4.59: Top 10 Specialty Drugs by Average Expenditures per Claim under the the Pharmacy Benefit: 2014 (228)
64. Figure 4.60: Top 10 Specialty Drugs by Average Expenditures per Claim under the Medical Benefit: 2014 (229)
65. Figure 4.61: Percentage of Total Specialty Claims and Expenditures Accounted for by Each Therapeutic Category in 2006 vs. 2014 (232)
66. Figure 4.62: Five Specialty Therapeutic Categories as Percent of Total Specialty Drug Expenditures: 2014 (233)
67. Figure 4.63: Five Specialty Therapeutic Categories as Percent of Total Specialty Drug Expenditures: 2014 (235)
68. Figure 4.64: PMPY by Selected Therapeutic Category under the Pharmacy Benefit: 2006 to 2014 (236)

69. Figure 4.65: PMPY by Selected Therapeutic Category under the Medical Benefit: 2006 to 2014 (237)
70. Figure 4.66: PMPY by Selected Therapeutic Category under the Pharmacy & Medical Benefits: 2006 to 2014 (238)
71. Figure 4.67: Total Specialty Expenditure by Selected Therapeutic Category under Pharmacy & Medical Benefit: 2006 to 2014 (240)
72. Figure 4.68: Total Multiple Sclerosis Specialty Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014 (241)
73. Figure 4.69: Total Expenditures on Hepatitis C Agents under the Pharmacy & Medical Benefits: 2006 to 2014 (244)
74. Figure 4.70: Total Specialty Oncology Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014 (245)
75. Figure 4.71: Total Specialty Inflammatory Agents (Autoimmune Disease) Expenditures under the Pharmacy and Medical Benefits: 2006 to 2014 (248)
76. Figure 4.72: Total Specialty Immunomodulator and Immune Serum Expenditures under the Pharmacy and Medical Benefits: 2006 to 2014 (251)
77. Figure 4.73: Total Drug Expenditures by Place of Service under Medical Benefit: 2006 to 2014 (254)
78. Figure 4.74: Total Specialty Expenditures by Place of Service under the Medical Benefit: 2006 to 2014 (255)
79. Figure 4.75: Traditional Expenditures by Place of Service under the Medical Benefit: 2006 to 2014 (256)
80. Figure 4.76: Total Claims by Place of Service under Medical Benefit: 2006 to 2014 (257)
81. Figure 4.77: Specialty Claims by Place of Service under the Medical Benefit: 2006 to 2014 (259)
82. Figure 4.78: Traditional Claims by Place of Service under Medical Benefit: 2006 to 2014 (261)
83. Figure 4.79: Average Expenditure per Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014 (263)
84. Figure 4.80: Percent Change from Year to Year in Average Expenditure per Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014 (264)
85. Figure 4.81: Overall Percentage Change from 2006 to 2014 in Average Expenditure per Specialty Claim under the Medical Benefit by Site of Care (265)
86. Figure 4.82: Specialty Medical Expenditures by Site of Care as a Percent of Total Medical Specialty Expenditures (268)
87. Figure 4.83: Specialty Medical Claims by Site of Care as a Percent of Total Medical Specialty Claims (269)
88. Figure 4.84: Percent Year to Year Change in Expenditures for Specialty Drugs under Medical Benefit by Site of Care: 2006 to 2014 (270)
89. Figure 4.85: Percent Year to Year Change in Number of Claims for Specialty Drugs under the Medical Benefit by Site of Care: 2006 to 2014 (272)
90. Figure 4.86: Specialty Drug Claims for Specialty Drugs Found in Both the Pharmacy Benefit & the Medical Benefit: 2006 to 2014 (276)
91. Figure 4.87: Dual Channel Specialty Drug Claims as a Percent of Total Claims for Specialty Drugs across Pharmacy and Medical Benefits: 2006 to 2014 (277)

92. Figure 4.88: Expenditures for Dual Channel Specialty Products that were Used Under Both Pharmacy & Medical Benefits from 2006 to 2014 (278)
93. Figure 4.89: Dual Channel Specialty Drug Expenditures under Pharmacy and Medical Benefits as a Percent of Total Expenditures across Pharmacy and Medical Benefits from 2006 to 2014 (279)
94. Figure 4.90: Average Expenditures per Claim for Dual Channel Specialty Drugs Used Under Both Pharmacy & Medical Benefits: 2006 to 2014 (280)
95. Figure 4.91: Average Expenditure per Claim for Orenzia (abatacept) under the Pharmacy & Medical Benefits: 2006 to 2014 (282)
96. Figure 4.92: Average Expenditure per Claim for Cytoxan (cyclophosphamide) under Pharmacy & Medical Benefits: 2006 to 2014 (284)
97. Figure 4.93: Average Expenditure per Claim for Lovenox (enoxaparin sodium) under Pharmacy & Medical Benefit: 2006 to 2014 (286)
98. Figure 4.94: Average Expenditure per Claim for Epogen & Procrit (epoetin alfa) under the Pharmacy & Medical Benefits: 2006 to 2014 (289)
99. Figure 4.95: Average Expenditure per Claim for Neupogen (filgrastim) under the Pharmacy & Medical Benefits: 2006 to 2014 (291)
100. Figure 4.96: Average Expenditure per Claim for Supprelin LA (histrelin acetate) under the Pharmacy & Medical Benefits: 2006 to 2014 (293)
101. Figure 4.97: Average Expenditure per Claim for Remicade (infliximab) under the Pharmacy & Medical Benefits: 2006 to 2014 (295)
102. Figure 4.98: Average Expenditure per Claim for Lupron Depot (leuprolide acetate) under the Pharmacy & Medical Benefits: 2006 to 2014 (297)
103. Figure 4.99: Average Expenditure per Claim Xolair (Omalizumab injection) under Pharmacy & Medical Benefits: 2006 to 2014 (299)
104. Figure 4.100: Average Expenditure per Claim for Stelara (Ustekinumab injection) under the Pharmacy & Medical Benefits: 2006 to 2014 (301)
105. Figure 4.101: Average Expenditure per Claim for Sandostatin (Octreotide inj) under Pharmacy & Medical Benefits: 2006 to 2014 (303)
106. Figure 4.102: Average Expenditure per Claim Vivitrol (naltrexone Injection) under Pharmacy & Medical: 2006 to 2014 (305)
107. Figure 4.103: Average Expenditure per Claim Neulasta (Pegfilgrastim) under the Pharmacy & Medical Benefits: 2006 to 2014 (307)
108. Figure 4.104: Average Expenditures per Claim for Cellcept (Mycophenolate mofetil) under Pharmacy and Medical Benefits: 2006 to 2014 (309)
109. Figure 4.105: Average Expenditure per Claim for Prograf (tacrolimus) under the Pharmacy & Medical Benefits: 2006 to 2014 (311)



## **List of Appendices**

1. Appendix 1. Pharmacy Claims Data Elements
2. Appendix 2. CMS Place of Service Code Set for Facility Based Claims
3. Appendix 3. CMS Place of Service Code Set for Professional Based Claims
4. Appendix 4: Primary Dispenser Type Codes

## CHAPTER 1: INTRODUCTION

### 1 Introduction

Spending on specialty drugs, which are generally identified as drugs typically used to treat complex conditions requiring special handling, and associated with high cost, are growing in the United States. This growth is expected to continue. Current drug development and expenditure trends show a shift away from traditional small molecule drugs and toward specialty drugs. In the past seven years, specialty drugs have been the most rapidly growing segment of the pharmaceutical market. From 2009 to 2013, about two-thirds of the new drug entities approved by the FDA were considered specialty drugs rather than traditional small molecule agents.<sup>1</sup> With more than 900 biologic drugs in the pipeline, advances and innovations in the pharmaceutical market are moving from traditional drugs to specialty drugs.<sup>2</sup>

Trend analysis reports from the top three pharmacy benefit managers (PBMs) in 2014 show that the specialty drug market is growing in absolute dollars and in the percentage of total drug spending.<sup>1,3</sup> Currently, specialty drugs are a small percentage of total prescriptions by number of claims, but they account for a much larger share of total prescription expenditures. Expenditures on specialty drugs are significant and continue to account for a larger portion of annual drug spending for both public and private payers.<sup>1,4,5</sup>

In 2012, spending on specialty drugs in the U.S. was \$87 billion, and this spend is projected to more than quadruple by 2020, reaching an estimated \$400 billion. That is roughly 9.1 percent of total national health spending.<sup>3</sup> However, this estimation only accounts for drugs flowing through the pharmacy benefit and typically dispensed in retail

chains, independent pharmacies, or specialty pharmacies. A study completed in the state of Minnesota using the Minnesota All Payers' Claims Database (MN-APCD) found that when considering drugs on the medical side of the benefit along with drugs flowing through the pharmacy benefit, drug expenditures are a much larger share of total health expenditures than is traditionally reported. In Minnesota in 2013, it is estimated that drugs accounted for 20.1 percent of total healthcare expenditures rather than the 9.7 percent to 10.3 percent often reported in national health spending reports from 2010 to 2014.<sup>6</sup>

## **1.1 Background and significance**

The growing specialty drug trend has become one of the biggest concerns for employers who offer health benefits to their employees and dependents. A 2017 survey of 298 employers representing 10 million covered individuals found that while employers acknowledge the benefit of specialty drugs for their members, they are struggling to keep up and manage costs associated with specialty drugs.<sup>7</sup> Some of the challenges facing employers include lack of in-house expertise, lack of transparency, lack of appropriate data, and a lack of standard definitions for specialty drugs. Specialty drug definitions may vary depending on different stakeholders. Many employers, pharmacy benefit managers (PBMs), health plans, and other health care stakeholders may define specialty drugs differently. Each stakeholder has differing perspectives and business interests and these differences may influence how they define specialty drugs.<sup>1</sup> With that in mind, a

discussion of specialty drug definitions from various stakeholders is provided in Chapter 2.

Confounding these challenges for employers is how specialty drugs are distributed in the market. Specialty drugs flow under both pharmacy and medical benefits. Data shows that in recent years, specialty drug spend is growing faster under the medical benefit than under the pharmacy benefit. A study on specialty drug expenditures and utilization, based on 2012 data for 83 million covered lives, found that the total specialty drug expenditures paid under medical benefits accounted for 53 percent, compared to 47 percent under pharmacy benefits.<sup>4</sup> Specialty drugs represented 6 percent of medical benefit allowed costs, and 24 percent of pharmacy benefit allowed costs.<sup>4</sup> Drug expenditures under medical benefits may take place through different sites of care. The top three sites of care accounted for 91 percent of total medical specialty expenditures. The hospital outpatient setting accounted for the largest share of the expenditures at 43 percent, followed by physician's offices at 35 percent, and patient's homes at 13 percent.<sup>4</sup> Another study compared costs between the hospital outpatient setting and physician's office visits for specialty cancer drugs using Truven Marketscan®, and found higher cost per episode in the hospital outpatient setting.<sup>7</sup> The cost per episode in the hospital outpatient setting was 28 percent to 53 percent higher than physician office cost per episode.<sup>1,7</sup>

One source of variation in expenditures among sites of care comes from drug administration and drug administration supply charges, in addition to the drug product cost. Currently employers don't have much access to the utilization and expenditure trends for drug administration services, and drug administration supplies that they are

paying for along with drug products under the Medical benefit. Employers providing medical benefits are not only responsible for the cost of the drug, they are also paying for drug administration supplies and drug administration services. When considering drug expenditures under pharmacy benefits, drug dispensing fees are included as part of the total cost of each dispensed prescription. Likewise, it is important for employers to understand that it is not only the drug expenditure trend, but also the drug administration and drug administration supply trend, which increasingly contributes to total drug expenditure growth under medical benefits. However, there are few, if any, studies published that address this issue.

The trends observed in the specialty drug market indicate the need for appropriate management of specialty drugs across both pharmacy and medical benefits, including drug and drug-related expenditures. Employers usually work with Pharmacy Benefit Managers (PBMs) to manage drugs flowing under the pharmacy benefit. Similarly, they should work with Health Plans or medical plan administrators to manage drugs flowing under the medical benefit. Specialty drug benefit management becomes complex for employers due to differences and difficulties with tracking specialty drug distribution and utilization across both the pharmacy and medical benefits. The way claims are processed and paid is considerably different between pharmacy and medical benefit providers.

Claims processed under pharmacy benefits are processed in real time and tend to have more detail on the actual drugs provided in comparison to claims processed under medical benefits. The latter tend to have delayed claims processing, sometimes taking up to six months, along with less detail on the actual drug provided and billed and the quantity utilized and reported on a given claim (this variation is discussed in depth in

Chapter 3). Although it has been shown that specialty drugs have been a rapidly growing part of the overall pharmaceutical market, it is difficult to identify their utilization, pricing, and appropriateness.

There are many questions about how specialty drugs and associated products and services are managed across the pharmacy and medical benefits programs within a specific employer-sponsored health plan. These include: What specialty drugs flow through the pharmacy benefit? What specialty drugs flow through the medical benefit? Are there specialty drugs that are flowing through both the pharmacy and the medical benefit? What is the best way to assure appropriate utilization and effective cost management for specialty drugs? How can specialty drug utilization and cost trends be managed by the employer-sponsored health plan? How does specialty drug distribution and management differ by therapeutic category? What is the contribution of drug administration services and drug administration supplies to the total drug costs? This study is timely and needed to help payers such as employer-sponsored health plans understand the full scope of specialty drug management, including drug-related expenditures. Evaluating specialty drug and drug-related product management across pharmacy and medical benefits allows for a more complete picture of the specialty drug management landscape.

## **1.2 Research aims and questions**

Specialty drugs are the fastest growing part of the pharmaceutical market. As the specialty drug market continues to expand, questions regarding how to manage specialty drugs in health benefit programs continue to arise. The need for strategic management of specialty drugs is critical to ensuring safe and appropriate use while effectively managing

the cost. The overall aim of this project is to determine the patterns of specialty drug use over the past few years and to examine the channels of distribution and payment for these drugs. This study will dramatically improve the scope with which an employer-sponsored health benefit program can effectively and appropriately manage specialty drugs use across pharmacy and medical benefits.

The goal of this study is to examine specialty drug distribution and utilization trends across the entire health benefit plan, including both the pharmacy and the medical benefit components of the University of Minnesota's UPlan. This study has identified patterns of specialty drug distribution and utilization by therapeutic category across both the pharmacy and the medical benefits. In addition, this study outlines the use and expenditure trends of drug administration supplies and drug administration services. The analysis includes identification of opportunities to coordinate and better manage safe and appropriate drug use, while also managing the growth in expenditures. To accomplish the overall goal, this study will address several specific aims.

### **1.2.1 Aim 1**

Describe specialty drug and drug-related product trends including expenditures and utilization under the pharmacy benefit and the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

#### **1.2.1.1 Research question 1a**

What is the total utilization and expenditures of specialty drugs and drug-related products under the pharmacy benefit and medical benefit from 2006 to 2014?

### **1.2.1.2 Research question 1b**

What are the changes year to year in utilization and expenditures for specialty drugs and drug-related products in aggregate for those that flow through the pharmacy benefit and medical benefit from 2006 to 2014?

### **1.2.2 Aim 2**

Describe specialty drug and drug-related product trends including expenditures, and utilization by therapeutic category and other characteristics from 2006 to 2014 for the University of Minnesota's UPlan.

#### **1.2.2.1 Research question 2a**

What percent of total specialty drug and drug-related expenditures are accounted for by the top 10, 25, and 50 drugs for the UPlan each year?

#### **1.2.2.2 Research question 2b**

What number of specialty drugs and drug-related products account for 50%, 75%, 90% of total specialty drug and drug-related expenditures for the UPlan?

#### **1.2.2.3 Research question 2c**

What is the average total price paid per claim of each specialty drug under the UPlan by year?



#### **1.2.2.4 Research question 2d**

What percent of total specialty drug and drug-related expenditures are accounted for by each therapeutic category each year?

#### **1.2.2.5 Research question 2e**

From 2013 to 2014 what percent of total specialty drug expenditures do the following four therapeutic categories account for in the UPlan? Categories include: (1) Immune Modulators; Multiple Sclerosis; Oncology; and Hepatitis C.

### **1.2.3 Aim 3**

Identify and assess the utilization and expenditures by channels of distribution of specialty drugs and drug-related products that flow through the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

#### **1.2.3.1 Research question 3a**

What are total expenditures by year for specialty drug and drug-related products utilized in outpatient hospital, physician's office, home infusion, and all other sites of care identified in UPlan medical claims data?

#### **1.2.3.2 Research question 3b**

What channel of distribution has the highest year-to-year growth in expenditures for specialty drug and drug-related products utilized under the medical benefit from 2006 to 2014?

#### **1.2.4 Aim 4**

Identify and assess utilization and expenditures of specialty drugs and drug-related products that are covered by both the pharmacy and the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

##### **1.2.4.1 Research question 4a**

How many specialty drugs were distributed under both the pharmacy and the medical benefit each year?

##### **1.2.4.2 Research question 4b**

What specialty drugs are utilized under both the pharmacy and medical benefit?

##### **1.2.4.3 Research question 4c**

What are the expenditures for specialty drugs and drug-related products that are used under both pharmacy and medical benefit?

### **1.3 Data source and Research Methods**

#### **1.3.1 Data source**

This study evaluates all drug and drug-related claims provided to covered individuals under the University of Minnesota's UPlan. This study evaluates both pharmacy and medical claims data for a period of nine years (2006 to 2014).

### **1.3.2 Research design**

The research design for this study is a retrospective descriptive analysis of administrative pharmacy and medical claims data. This study evaluates several variables, including those that may have slight variations in meaning when applied to pharmacy versus medical claims. A detailed description of the retrospective descriptive analysis conducted is provided in Chapter 3. For pharmacy claims, expenditure is the dependent variable. Independent variables include utilization identified as number of claims and drug characteristics. A detailed description of the variables for pharmacy claims is provided in Chapter 3, and a list is provided in Appendix 1. For medical claims, expenditure is the dependent variable. Independent variables include utilization identified as the number of drug characteristics, and site of service. A detailed description of the variables for medical claims is provided in Chapter 3, and a list is provided in Appendix 2.

### **1.3.3 Operationalization of specialty drug definition**

Specialty drug classifications were developed by experts in the pharmaceutical market and in clinical expert review completed by four pharmacists and one physician. Specialty drug classification of drugs and drug-related products flowing under medical benefits were completed at the Health Care Procedural Coding System (HCPCS) code level. Specialty drug classification for drugs flowing under pharmacy benefits were completed at the Generic Product Identifier (GPI) level. Manual review and validation were completed to ensure that specialty drug classification at the drug name level was the same when flowing under pharmacy and medical benefits. The expert review panel

identified several characteristics associated with specialty drug classification. The drug class, dosage form, product handling, product administration, site of care, clinical indication, orphan drug status, and need for clinical monitoring were characteristics identified to be associated with individual drugs having specialty status. Several specific drug types were also associated with specialty status including radiopharmaceuticals and antidote drugs. Cost was considered in determining specialty status, in particular high cost. But high cost alone did not determine specialty status.

#### **1.3.3.1 Specialty drug definition operationalization for pharmacy claims**

First, identify the universe of GPI codes considered to be drugs and drug-related codes for the study. This identification was completed using Medi-Span's GPI dataset which, included a crosswalk of GPI to NDCs. Second, drug or drug-related products were classified at the GPI level by expert reviewers to assign their status as a specialty drug or specialty drug-related product. Each reviewer completed an independent review of the drugs and scored each drug as "specialty" or "non-specialty". The reviewers then met as a group to reach consensus on the specialty status of each product at the GPI code level. This process was repeated a second time on a different date for data validation purposes. Finally, the list of GPIs with specialty classification information was then linked to UPlan pharmacy claims data at the NDC level.

#### **1.3.3.2 Specialty drug definition operationalization for medical claims**

First, identify the universe of HCPCS codes considered to be drugs and drug-related codes for study. This identification was initially completed for a study completed

for the Minnesota Department of Health using the Minnesota All Payer Claims Database (MN-APCD). A list of HCPCS codes identified in the MN APCD database were cross walked to Medi-Span's HCPCS-NDC crosswalk database, which was then linked to the Medi-Span PriceRx Pro database that included GPI-level data. Second, the HCPCS list linked to GPI was used to identify and define specialty drugs. Drug or drug-related products were defined at the HCPCS level and assigned their status as a specialty drug or specialty drug-related product by expert reviewers of the list. Each reviewer completed an independent review of the drugs and scored each drug as "specialty" or "non-specialty". The reviewers then met as a group to reach consensus on the specialty status of each product at the HCPCS code level. Finally, the list of HCPCS codes with GPIs and specialty classification information was then linked to UPlan data at the HCPCS level.

#### **1.3.4 Quality assurance**

Each variable in this study needs a level of precautionary controls to ensure appropriate operationalization of the variable from the data source. Appendix 1 and Appendix 2 describe some of the data elements. Ensuring the quality and accuracy of data sources is critical for a retrospective claims analysis. Key steps to ensure quality of data include checking for relevance, reliability, and validity of the data source. To ensure relevance, each of the data attributes was described. Steps were taken to ensure reliability and validity of the data, including data quality checks and data cleaning procedures. The data for this study was originally collected for reimbursement purposes and not research. Rather, it was collected for claims processing and payment. Quality checks are important

with administrative databases and were performed to prevent unreliability of data that may occur due to changes in reporting or coding over time.

### **1.3.5 Pharmacy claims data quality**

The aggregated pharmacy claims data held in the University of Minnesota's UPlan data set was reviewed and evaluated. All pharmacy claims data fields were examined, and descriptive statistics run to assess patterns and outliers. A key focus was on completeness of data for important variables such as National Drug Code (NDC) number, amount paid (total, plan, and member), number of units, number of days, and number of clean paid claims (as opposed to test claims or reversed claims). Variables were examined for the presence of valid codes for categorical variables, and/or the range and distribution of responses for continuous variables. Once, this initial assessment was complete, the pharmacy claims were linked to a drug information database (i.e., Medi-Span Rx Pro+) to provide enhancement of the claims data with other drug product variables and data.

### **1.3.6 Medical claims data quality**

The aggregated medical claims data held in the University of Minnesota's UPlan data set was reviewed and evaluated. All medical claims data fields were examined to determine if they represent claims for drug products administered as a medical benefit. The primary method to identify drug claims in the medical claims data set was the use of the Healthcare Common Procedure Coding System (HCPCS) codes on claims. The most

common HCPCS codes for drugs are known as “J codes”. However, there are other codes that also represent drugs and drug-related products, including A, B, C, Q, P, S and others. A key focus was on completeness of data for important variables, such as HCPCS codes, site of care codes, date of service, amount paid (total, plan, and member), and number of unique claims (as opposed to test claims or reversed claims). Variables were examined for the presence of valid codes for categorical variables, and/or the range and distribution of responses for continuous variables. Once this initial assessment was complete, the medical claims were linked to a drug information database (i.e., Medi-Span Rx Pro+) to provide enhancement of the claims data with other drug product variables and data.

#### **1.4 Implication of study**

There is a need for evidence-based research to address the lack of published studies related specialty drug management by self-insured employers. Not only does this study bring value to the UPlan, but its findings can be applied to other key stakeholders in medical and pharmacy benefits management. This study provides a well-rounded picture of specialty drug distribution and utilization trends over time for an employer-sponsored health plan. In addition to providing insight into drug trends across pharmacy and medical benefits, this study allows employers to see the role drug administration supplies and drug administration services play in total drug expenditures, especially in the medical benefits.

Prior to this study, no publications were identified that have examined drug-related product and service utilization and expenditures to this degree. This study provides insights into possible approaches to better manage both the distribution and the safe and

appropriate use of specialty drugs. This study identifies where the pharmacy benefits and the medical benefits overlap in terms of specialty drug coverage and distribution, and will provide insight into how to most effectively manage these real or potential overlaps. The findings of this study identified areas to improve the appropriate utilization and the effective cost management of specialty drugs and drug-related products and services.

### **1.5 Key terms**

Definition of the key terms used in this study is important to provide a common understanding of the research aims and questions. The definitions provided for the listed key terms are unique to how the key terms are used in this study.

**Pharmacy Benefits:** The prescription drug benefit that is administered by the pharmacy benefit manager that generally covers drugs that are self-administered orally, topically, by injection, or inhaled and provided by community, mail order or specialty pharmacies.

**Medical benefits:** Benefit that is administered by a health plan that generally cover drugs that are injected or infused by a healthcare provider in the physician's office, patient's home, infusion center, hospital outpatient, and other healthcare settings.

**Self-Insured Plan:** This type of plan is sometimes present in larger companies, but not exclusively, where the employer itself collects premiums from enrollees and takes on the responsibility of paying employees' and dependents' medical and pharmacy benefit claims. These employers can contract for insurance services such as enrollment, claims



processing, and provider and pharmacy networks with a third-party administrator, or they can be self-administered.

**Self-Insured Employer:** A corporation that administers a self-insured plan.

**Drug Product:** A substance approved by the FDA as a drug or biologic with specific dosage form, strength, and package size that has a designated NDC number.

**Drug:** A drug substance approved by the FDA through a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) process and sold in the form of one or more drug products.

**Biologic:** A drug substance approved by the FDA through the Biological License Application (BLA) process and sold in the form of one or more biologic products.

**Drug- Related:** Any product, supply or service used in the administration of a drug product.

**Prescription:** A drug order that is written or printed on paper, an oral order written out by a pharmacist, or an electronic order. To be valid, a prescription must be issued for an individual patient by a practitioner within the scope and usual course of the practitioner's practice, and must contain the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, the name and address of the

practitioner, and a telephone number at which the practitioner can be reached. A prescription may include a written or printed document that is given to the patient or an agent of the patient or that is transmitted by fax and must contain the practitioner's manual signature. An electronic prescription must contain the practitioner's electronic signature. A prescription may be written for over-the-counter drug products.

**Prescription drug product:** A drug product that must be prescribed by an authorized prescriber and cannot be sold to consumers directly without an authorized provider's prescription.

**Over the counter product:** A drug product that does not require a prescription from an authorized provider and which can be sold directly to consumers.

**Specialty drug:** A drug product that is used to treat complex diseases (e.g., an autoimmune disorder, cancer, orphan conditions), is a complex product (e.g., biological product, but not exclusively), requires complex drug administration (e.g., injectable, requires provider administration under medical benefit, but not exclusively), or has complex handling (i.e. preparation, storage, and distribution) and which is usually associated with high cost.

**Traditional drug:** All other drugs that do not meet the definition of a specialty drug.

Therapeutic category: The classification of drug products in regards to the therapeutic purpose. If a drug product has multiple uses, the most common indication typically becomes the basis for the therapeutic category. To group drug products in this study into therapeutic categories the coding scheme of MediSpan, known as the Generic Product Indicator (GPI) code, was used.

Healthcare Common Procedure Coding System (HCPCS): Level I and Level II codes. Level I codes are a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II codes are a standardized coding system that is used primarily to identify products, supplies, and services not included with Level I codes.

Current Procedural Terminology (CPT): The code set providers use to report medical procedures and professional services furnished in ambulatory and outpatient settings, including physician visits to inpatients.

National Drug Code: A unique 11-digit, three-segment number, that serves as a universal product identifier for human drug products in the United States. The three segments of the NDC identify the labeler, the product, and the commercial package size and type.

Generic Product Identifier (GPI): a 14-digit code that organizes drug products in terms of active ingredients(s), route of administration, dosage form, strength or concentration,

therapeutic use, and pharmaceutical equivalence. Each unique 14-digit GPI code groups all NDCs for any package type and size and from all manufactures, marketers, or distributors for drug products with the same active ingredients(s), route of administration, dosage form, strength or concentration.

Pharmacy benefit manager (PBM): An organization that manages pharmacy benefits and related services. PBM activities may include some or all the following: Benefit plan design, creation and administration of pharmacy network, operation of a mail service or specialty pharmacy, claims processing, rebate negotiation with drug manufacturers, and managed prescription drug services such as drug utilization review, formulary management, generic substitution and maximum allowable costs, prior authorization, and disease and health management.

Health plan: An organization that manages the medical benefit. Health plan activities may include some or all of the following: negotiate and contract with health care providers and health systems, creation and administration of provider networks, claims processing, rebate negotiation with drug manufacturers, and managed care services such as utilization review, prior authorization, and disease and health management.

Place of service (site of service) codes: Two-digit codes used on provider claims and facility claims to specify the entity where services were rendered. Place of service codes for provider claims are maintained by the Centers for Medicare and Medicaid (CMS).

Appendix 3 and Appendix 4 provide a list of place of service codes from CMS for facility claims and for provider claims.

**Pharmacy:** A place of business where prescription drugs are prepared, compounded, or dispensed by or under the supervision of a pharmacist, and from which related clinical pharmacy services are delivered.

**Utilization Measures:** A metric used to measure utilization of drug products and drug-related products. Utilization measures are based on claims, unique claims, and claim lines.

**Claim:** A documentation of a specific drug product or related service and supplies reported as a transaction that is submitted for payment under a pharmacy or medical benefit. Under the medical benefit, a claim may be identified as a unique claim or a claim line. Under the pharmacy benefit each drug product is usually an independent and unique claim for a specific quantity of the drug product.

**Unique claim:** One unique claim that includes a single or multiple products and services as a part of a single transaction submitted for payment.

**Claim line:** Is an itemization of individual products and services billed on the same unique claim with each claim line individually numbered beginning with one and with

additional lines being incremented by one for each additional service lines on that specific unique claim.

Medical claims: Submissions by a health care provider or institution of information related to products and services delivered to a covered patient under the medical benefit.

Medical claims are submitted to a third-party administrator or a health plan for payment.

Medical claims may be professional claims or facility claims.

Professional claims: A submission to a payer using the CMS-1500 standard claim form.

CMS-1500 is used by non-institutional physicians and other suppliers for non-institutional claim submission.

Facility claims: A submission to a payer by a hospital or institutional provider using a CMS-1450 (AKA UB-04) standard claim forms.

Pharmacy claims: Claim submissions for a drug product by a pharmacy under the pharmacy benefit to a third-party administrator or PBM.

Financial Measures: A metric used to measure drug and drug related expenditures.

Financial measures include total expenditures per claim, total expenditures, plan paid amount, coordination of benefit, member paid amount, copay, coinsurance, deductible, per member per month (PMPM) amounts, and per member per year (PMPY) amounts.

Total Expenditures per claim: The sum of all payments made for each claim. Expenditures include member paid, plan paid, and other source paid amounts.

Total expenditures: The sum of expenditures including member paid, plan paid, and other source paid amounts for all claims.

Plan paid: The amount paid by a health benefit plan such as a self-insured employer for a claim.

Coordination of Benefits (COB): For members with secondary insurance, COB represents the amount paid by the secondary plan or other sources.

Member paid: The amount paid by a member for a claim in the form of coinsurance, copayment, or deductible.

Coinsurance: A form of cost sharing under the pharmacy or medical benefits that requires a covered person to pay a stated percentage of expenses after the deductible amount, if any, is paid.

Copayment: A form of cost sharing under the pharmacy or medical benefits that requires a covered person to pay a stated fixed dollar amount of expenses after the deductible amount, if any, is paid.

Deductible: A fixed dollar amount during a specified benefit period — usually a year — that a covered person pays before the self-insured employer starts to make payments for covered pharmacy and medical services. Plans may have both per individual and family deductibles.

Per member per month (PMPM): Expenditures divided by the total number of members for a given month.

$$\text{PMPM} = (\text{Expenditure}/\text{Total Number of Members for a Given Year})/(12 \text{ Months})$$

or

$$\text{PMPM} = \text{Expenditures}/(\text{Total Number of Members for a Given Month})$$

Per member per year (PMPY): Expenditures divided by total number of members for a given year.

$$\text{PMPY} = \text{Expenditures}/(\text{Total Number of Members for a Given Year})$$



## CHAPTER 2: LITERATURE REVIEW

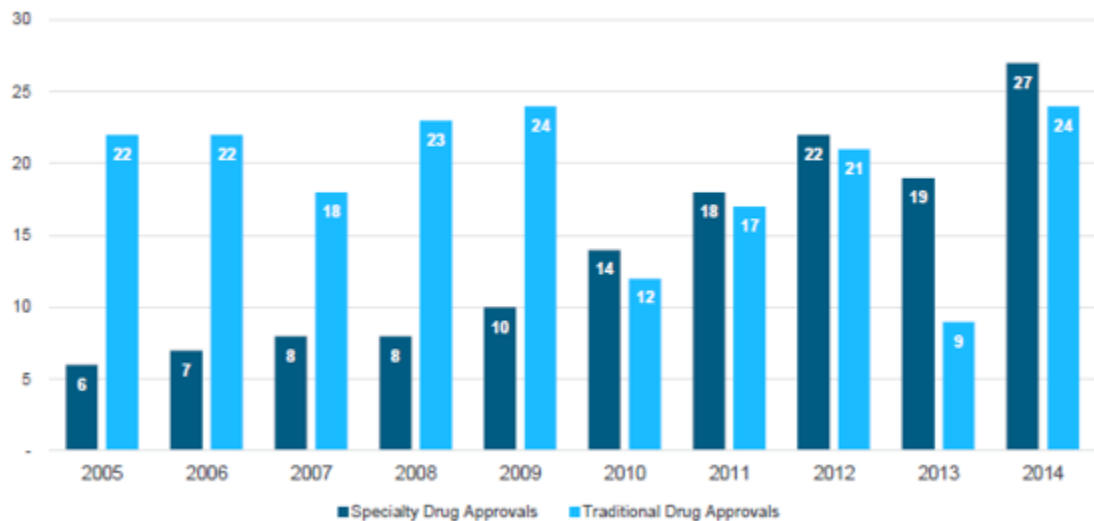
### 2 Introduction

This literature review chapter includes six sections. The first section provides an overview of general drug trends related to FDA approvals of traditional and specialty drugs. The second section provides definitions of specialty drugs from the perspective of different stakeholders in the marketplace. The third section describes drug characteristics that differentiate specialty drugs from traditional drugs. The fourth section describes the differences between biosimilars and traditional generics. The fifth section explains differences between specialty drugs flowing through pharmacy benefits and medical benefits. The sixth, and final, section outlines specialty drug management strategies across pharmacy and medical benefits.

#### 2.1 General trends

In the last decade, the number of traditional drug approvals has gone down, while specialty drug approvals have been steadily increasing. From 2006 to 2014, the number of specialty drug approvals has nearly quadrupled, from 7 in 2006 to 27 in 2014.<sup>8</sup> In contrast, traditional drug approvals have either stayed steady or gone down from 2005 to 2014. It was estimated that in 2016, three out of every five new drug approvals was a specialty drug.<sup>9</sup>

**Figure 2.1 Specialty Drug Approvals vs. Traditional Drug Approvals: 2005 to 2014**



The impact of growth in the number of specialty drug approvals can be observed in specialty drug expenditure trends. In 2014, specialty drugs accounted for one-third of total drug expenditures.<sup>10</sup> In 2014, expenditures for outpatient prescription drugs in the United States were between \$360.7 billion and \$373.9 billion.<sup>10,11</sup> In 2015, spending on specialty drugs reached an estimated \$121 billion based on net price alone.<sup>12</sup> While specialty drugs continue to grow in the number of drug approvals as well as the share of total drug expenditures, they still only account for a very small portion of total drug utilization. In 2015, specialty drugs accounted for 38 percent of total health care expenditures, but only accounted for 1 to 2 percent of utilization (i.e., number of prescriptions).<sup>13</sup> Specialty drug expenditures are anticipated to reach as high as \$400 billion by 2020. However, with the entry into the market of biosimilars, and with more in the pipeline, some suggest that projection might be too high. If the uptake of

biosimilars goes as anticipated, it is expected that total specialty drug spending will be closer to \$262 billion by 2019.<sup>9</sup>

Specialty drugs may offer treatment solutions for disease states that previously had limited or complex treatment solutions, and in some cases no treatment solution at all.<sup>9</sup> Specialty drugs tend to come with a very high price tag. An example is sofosbuvir, which had a price tag of \$84,000 per 12 week course of therapy. In 2014, sofosbuvir, an antiviral agent, had an estimated total of \$6.6 billion in expenditures.<sup>11</sup> Sofosbuvir is used to treat hepatitis C and reached the top spending spot after being on the market less than a year.<sup>11</sup> According to IMS, health expenditures for hepatitis C treatment reached \$12.3 billion in 2014.<sup>10</sup> However, such a high price tag for drugs is not only true for specialty drugs, but it is sometimes present for traditional drugs as well.

Looking at trends for traditional drugs used to treat common chronic conditions, we see expenditures are continuing to rise without a proportional increase in utilization. For example, insulin glargine had the third-highest expenditures in 2014 at \$5.7 billion.<sup>11</sup> Insulin is typically categorized as a traditional drug, but it can also fall under the specialty category depending on how specialty is defined. Other traditional drugs such as aripiprazole, an antipsychotic; esomeprazole a proton pump inhibitor used for various gastrointestinal indications; fluticasone salmeterol, a bronchodilator used for Asthma and COPD; and sitagliptin DPP-IV-I, used to treat type II diabetes were among the traditional drugs represented in the top 15 drugs by expenditure in 2014.<sup>11</sup> Expenditures for diabetes increased 30.5 percent from the previous year to \$32.2 billion in 2014.<sup>10</sup>

## **2.2 Defining specialty drugs**

Defining specialty drugs is a challenge. The definition may vary depending on different stakeholders; including employers, pharmacy benefit managers (PBMs), health plans, and other health care stakeholders. Each stakeholder has differing perspectives and may define specialty drugs somewhat differently. For example, the Centers for Medicare and Medicaid Services (CMS) defines specialty drugs solely based on the amount of monthly expenditure for a 30-day prescription of that drug. As of this writing there is not a set industry standard definition of what specialty drugs are. However, there are specific characteristics generally used within the industry. Thus, some or all of the following characteristics of specialty drug definitions have been used in the market.<sup>14</sup>

- How they are made? (Biological process)
- How they are approved by FDA? (Biologics License Application)
- Conditions they treat. (Chronic, complex, genetic)
- How they are used? (Injection, implant, infusion, or other special administration.)
- Special features (Safety, monitoring, storage, etc.)
- How much do they cost ( e.g. > \$600/month for Medicare Part D)

### **2.2.1 Specialty definition by Centers for Medicare and Medicaid (CMS)**

According to CMS's Medicare Part D Specialty Tier policy, only drugs for which the majority of prescription drug events (PDE) exceed a set dollar threshold are referred to as specialty drugs.<sup>12</sup> As of this writing, the specialty drugs threshold outlined by CMS is \$600 per month for PDE.<sup>15</sup>

### **2.2.2 Specialty definition by Academy of Managed Care Pharmacy (PBM Perspective)**

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists, health care practitioners and others who develop and provide clinical, educational and business management services.<sup>16</sup> According to AMCP specialty drugs are:

- high-cost drugs,
- usually prescribed for people with complex or chronic medical conditions, or
- drugs that typically exhibit one or more of the following characteristics:
  - drugs that are injected or infused. However, some may be taken by mouth
  - drugs that have unique monitoring
  - special storage or shipment requirements
  - additional education needed for patients and providers
  - support from a health care professional is essential.

### **2.2.3 Specialty definition by American Health Insurance Plans (Health Plan Perspective)**

The American Health Insurance Plans (AHIP) is a national trade association representing the health insurance industry whose members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid.<sup>17</sup> According to the AHIP, specialty drugs are those drugs “...which are generally understood to be drugs that are structurally complex and often require special handling or delivery mechanism — and are priced much higher than traditional drugs”.<sup>17</sup>

### **2.2.4 Specialty definition by AARP Public Policy Institute<sup>18</sup>**

According to AARP, specialty drugs are those drugs that are “...administered by injection, such as intravenous, intramuscular, sub-cutaneous, or other injection sites (not including insulin); any dosage form that has a total average prescription cost greater than \$1,000 per prescription; or any dosage form that has a total average cost per day of therapy greater than \$33 per day.”<sup>18</sup>

### **2.2.5 Specialty definition by Prime Therapeutics, the PBM serving the University of Minnesota's UPlan <sup>19</sup>**

Prime Therapeutics is the PBM that manages the prescription drug benefit for the University of Minnesota's UPlan. According to Prime Therapeutics, drugs are considered specialty drugs if they meet one of two criteria.<sup>15</sup> First, a drug is considered specialty if it is used to treat a disease on Prime Therapeutic's "Broad Specialty Drug list". Second, it is considered high cost, with a projected cost of greater than \$1,000 per month for ongoing therapy or projected cost of greater than \$5,000 per year or over the course of therapy, and an evaluation of the following:

- Special drug administration considerations (infusion, injection, etc.)
- Unique delivery and dispensing considerations (shipping, and storage considerations)
- Patient support considerations
  - Health and safety monitoring, compliance assistance and training
  - Monitor for contraindications or safety concerns
  - Monitor for appropriate dosing and duration
  - Monitor for adverse reactions (e.g., neutropenia, anemia, or severe skin rash)



### **2.2.6 Specialty definition by the University of Minnesota's UPlan**

The University of Minnesota's UPlan defines specialty drugs as those drugs generally prescribed for people with complex or ongoing drugs, conditions, or drugs that are high cost with unique storage or shipment requirements, or with complexity requiring additional education and support from health care professionals for their appropriate use.

### **2.2.7 Specialty definition developed for this study**

A drug that is used to treat complex diseases (e.g., autoimmune disorder, cancer, orphan conditions), is a complex product (e.g., biological product, but not exclusively), requires complex drug administration (e.g., injectable, requires provider administration under medical benefit, but not exclusively), or has complex handling (i.e., preparation, storage, and distribution), and is associated with high cost. The operationalization of this specialty definition to UPlan data is discussed in Chapter 3, in Section 3.5.

## **2.3 Specialty drug vs. traditional drugs**

Several differences have been outlined between specialty and traditional drugs.<sup>31</sup> Chief among the differences is the difference that exists in molecular and chemical structures. Traditional drugs are typically small molecules that are chemically synthesized, and are generally orally administered.<sup>32</sup> In contrast, specialty drugs tend to be biologic drugs that are large, complex molecules typically derived from living organisms.<sup>32</sup> Biologic drugs are developed through a complex biologic process, and generally require special handling and delivery systems. In addition, compared to traditional drugs, biologic drugs are often more sensitive to environmental change and

conditions. While not all specialty drugs are biologics, biologic drugs require a more robust and rigorous production and distribution process, as demonstrated by the particular handling, distribution, and administration requirements outlined in the various definitions of specialty drugs.

Advances in the biologic drug market continue at an increasingly fast pace. The biologic drug market that was once considered a small and insignificant portion of the drug market is now increasing at a rapid pace and is no longer considered insignificant. In fact, many biologic drugs have reached blockbuster status.<sup>33</sup> This growth is partly due to an increased interest in biologics after patent expirations of many blockbuster drugs in the traditional drug market.<sup>34</sup> <sup>35</sup> Advances in diagnostics and drug development technologies have also played a role in the increased consideration of biologics in the market place. Compared to traditional drugs, biologic drugs are significantly more costly. For example, Remicade was one of the top 5 biologic drugs used by recipients of Medicare Part B in 2010, costing more than \$20,000 annually.<sup>32,36</sup> Other biologic drugs, such as Soliris for paroxysmal nocturnal hemoglobinuria (PNH), may yield costs up to \$400,000 annually.<sup>37</sup>

Drug utilization as well as spending is growing at a greater rate than what traditionally is observed in the drug market. A report by Express Scripts indicates that, from 2012 to 2013, utilization of traditional prescriptions grew 0.5 percent while utilization of specialty drugs grew 2.5 percent.<sup>38</sup> In addition, the report noted that the unit cost of specialty drugs increased by 11.6 percent from 2012 to 2013, but only increased 1.9 percent for traditional drugs.<sup>38</sup> In 2007, biologic drug sales were estimated at \$75 billion.<sup>39</sup> Advances in the biologic drug market offer improved efficacy, without

reduced patient outcomes. However, with current national budget constraints and a growing national deficit, the long term sustainability of biologic drug prices has become a growing concern. To help combat these unsustainable costs the Biologics Price Competition and Innovation Act was passed in 2009 and enacted in 2010. The act provides an abbreviated pathway for getting biosimilars approved and on the market.

#### **2.4 Biosimilars vs. traditional generics**

Traditional drugs can be brand name and generic drugs. Non-biological specialty drugs may be brand name and/or generics as well. However, if the specialty drug is a biological drug, then it will not have a generic, but it could have a biosimilar or an interchangeable biosimilar. There are two key differences between biosimilars and traditional generics. One is the naming and the other is the ability to substitute the generic for the brand or the biosimilar for the biologic.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendment) amended the Food, Drug and Cosmetic (FD&C) Act to provide an abbreviated pathway for the approval of traditional generic drugs.<sup>41</sup> While traditional generics faced challenges in the early years after the Hatch-Waxman Amendment, the amendment has been in large part a success. Under the Hatch-Waxman Amendment, generic drugs have to show therapeutic equivalency (i.e., bioequivalence) to their branded counterparts.<sup>42</sup> Traditional generic drugs are widely used, and now account for more than 80 percent of the outpatient prescription drugs used in the traditional pharmaceutical market. Traditional generics have been effective at increasing competition, access and affordability within the traditional drug market.

The success of traditional generic drugs can be attributed to naming of traditional generic drugs, and state substitution laws that govern the substitution of traditional generic drugs. Traditional generic drugs share the exact same International Nonproprietary Name (INN) as their brand name counterpart. According to the World Health Organization (WHO), international nonproprietary names, also known as generic names, identify active pharmaceutical ingredients.<sup>43,44,45</sup> Each INN is a unique name that is globally recognized and is public property.<sup>43</sup> For example, Lipitor (with an INN of atorvastatin) is a statin drug used to treat high cholesterol. In this example, the brand name is Lipitor. The brand name is also the trademarked name of this drug. The INN or generic name which identifies the active ingredient name of this drug is 'atorvastatin'. When Lipitor went off patent, the generic version of the drug could be marketed and sold under the INN name 'atorvastatin' by various generic manufacturers. The common INN name between traditional brand and generic drugs allows for uncomplicated substitution between the brand and generic names. However, state substitution laws also add to the ease of substitution between brand and generic traditional drugs.

Traditional generic drug substitution is governed by a combination of federal and state laws. The same holds true for substitutability of biosimilars for biologic drug products. Therefore, states vary one from another on how substitution takes places. The key to substitution between brand and generics is the FDA's publication of Approved Drug Products with Therapeutic Equivalence Evaluations (also known as The Orange Book). Most states rely on the FDA's Orange Book of therapeutic ratings for a generic drug product to determine which drugs can be automatically substituted by the pharmacist. The FDA uses a two letter rating system. The first letter indicates

pharmaceutical equivalence. The second letter provides additional information based on evaluation from the FDA. The FDA has two categories, A and B (first Letters). An A-rated drug is one that is considered to be therapeutically equivalent to a reference listed drug product. A B-rated<sup>46</sup> drug is a drug product that the FDA considered not to be therapeutically equivalent to a reference listed drug product.<sup>47</sup>

Generic drug substitution laws differ from state to state. However, there are some key similarities and differences.<sup>48</sup> Many states require the use of the Orange Book, but there are still other states that don't refer to the Orange Book<sup>48</sup> in reference to generic substitution. Another example is mandatory or permissive substitution.<sup>48</sup> Although some states require mandatory substitution by pharmacists if a generic prescription meets all requirements, several states have a permissive substitution approach. A third area involves a situation where the patient may object to the substitution and/or has to be notified of the substitution.<sup>48</sup> A few additional considerations among state substitution laws for traditional drugs may include a state drug formulary (that is drugs is a positive or negative list of drugs that may be considered interchangeable based on bioequivalence to a reference listed drug), cost saving requirements (drug dispensed to be less than, or no more expensive than, the drug prescribed) and narrow therapeutic index special categorization.<sup>48</sup>

Although many state substitution laws vary, a vast majority encourage substitution of a generic drug for a brand name drug when appropriate. In the traditional drug market, state substitution laws generally do not add extra steps for pharmacists to take if a prescription fits the stated requirements. Thus, traditional substitution laws and naming of traditional generics allow essentially automatic substitution to take place with

efficiency and with ease. This ensures that patients get their drug in an efficient and timely manner, while ensuring that the drug they are receiving is clinically safe and effective, as well as less costly.

In 2009, the Biologics Price Competition and Innovation Act was passed as part of the Affordable Care Act and was signed into law in 2010. The act provides an abbreviated pathway for getting biologic products known as ‘biosimilars’ approved and on the market. Interchangeability between reference biologic drugs and their biosimilars is one of the key components of the Act (i.e., The Biologics Price Competition and Innovation Act) and the Act opens the door for lower cost but equally safe and effective biosimilar and alternatives for reference biologic drugs similar to what was done with the Hatch-Waxman Amendment for traditional brands and generics. From 2014 to 2020, as many as 26 reference biologic drugs are anticipated to come off patent.<sup>43</sup> The pharmaceutical industry anticipates that the entry of biosimilars into the biologics market will increase market competition and thus both reduce prices and improve accessibility. However, the full impact of biosimilars on competition and cost burden reduction may not be realized, as the issues of naming and substitution laws are not the same as what is observed with traditional drugs. In part, this may be due to the fact that biologic drugs are complex and chemically function very differently from traditional drugs. Determining equivalency between a reference biologic and a biosimilar is a very complex scientific issue. In fact, biologics are so complex, the reference biologic itself may have slight variation from batch to batch. That’s why generic drug manufacturers must demonstrate that the generic is bioequivalent to the brand name drug. But manufacturers of biosimilars “must demonstrate the biosimilar is highly similar to the reference product,

except for minor differences in clinically inactive components. Biosimilar manufacturers must also demonstrate that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.”<sup>52</sup>

Looking at the issues of naming and substitution for biosimilars, we observe some differences that may impact how effective biosimilars will be in helping bring competition to the market. Similar to the FDA Orange Book, used for traditional drugs to provide drug therapeutic equivalence information regarding brand and generic drug products, the FDA has started publishing the Purple Book listing biologic products and related biosimilars. The Purple Book provides a list of all biological products with reference product exclusivity and biosimilarity or interchangeability evaluations of the biosimilar products.<sup>53</sup>

Demonstrating interchangeability of biosimilars with a reference biologic product is not a simple matter. As of July 2018, FDA had approved 11 biosimilar products, and zero interchangeable biosimilar products. Of those that have been approved, there are only five biosimilar products currently being marketed. The reason there is a difference between the number of biosimilars approved, compared with those being marketed is due to litigation over intellectual property claims and pay for delay tactics are being employed by the some of the reference biologic manufacturers. This behavior is similar to anti-competitive behavior seen between originator brand name products and their respective generic drug products in the traditional drug market.

**Table 2.1 Biosimilars Approved & Market Status as of July 2018**

BLA Number	Generic(INN) Name (strength & product packaging)	Proprietary Name	Date of Licensure (mo/day/yr)	Interchangeable (I)/ Biosimilar (B)	Reference Biologic	Active Ingredient	On the Market
761058	adalimumab-adbm	Cyltezo	8/25/2017	B	Humira	adalimumab	No
761024	adalimumab-atto	Amjevita	9/23/2016	B	Humira	adalimumab	No
761028	bevacizumab-awwb	Mvasi	9/14/2017	B	Avastin	bevacizumab	No
125545	epoetin alfa-epbx, 2000 u/1 ml pkg 10s & 1ml	Retacrit	5/15/2018	B	Epogen & Procrit	epoetin alfa	Yes
125545	epoetin alfa-epbx 4000 u/1 ml	Retacrit	5/15/2018	B	Epogen & Procrit	epoetin alfa	Yes
125545	epoetin alfa-epbx 3000 u/1 ml	Retacrit	5/15/2018	B	Epogen & Procrit	epoetin alfa	Yes
125545	epoetin alfa-epbx 10000 u/1 ml	Retacrit	5/15/2018	B	Epogen & Procrit	epoetin alfa	Yes
761042	etanercept-szszs	Erelzi	8/30/2016	B	Enbrel	etanercept	No
125553	filgrastim-sndz 300mcg/0.5ml	Zarxio	3/6/2015	B	Neupogen	filgrastim	Yes
125553	filgrastim-sndz 480mcg/0.8ml	Zarxio	3/6/2015	B	Neupogen	filgrastim	Yes
761054	infliximab-abda	Renflexis	4/21/2017	B	Remicade	infliximab	Yes
125544	infliximab-dyyb	Inflectra	4/5/2016	B	Remicade	infliximab	Yes
761072	infliximab-qbtx	Ixifi	12/13/2017	B	Remicade	infliximab	No
761075	pegfilgrastim-jmdb	Fulphila	6/4/2018	B	Neulasta	pegfilgrastim	Yes
761074	trastuzumab-dkst	Ogivri	12/1/2017	B	Herceptin	trastuzumab	No



**Table 2.2 Approved Biosimilars & Reference Biologics AWP Unit Prices as of July 12, 2018**

Proper Name	Brand Name	Biosimilar AWP Unit Price	Active Ingredient	Reference Biologic AWP Unit Price	Reference Biologic AWP Unit Price (Procrit)	% Biosimilar Unit Price is Lower From Reference Biologic	% Biosimilar (Procrit) Unit Price is Lower From Reference Biologic
Epoetin alfa-epbx 2000 u/1m	Retacrit	\$26.47	epoetin alfa	\$59.69	\$61.74	56%	57%
epoetin alfa-epbx 4000 u/1m	Retacrit	\$52.94	epoetin alfa	\$79.58	\$92.78	33%	43%
epoetin alfa-epbx 3000 u/1m	Retacrit	\$39.71	epoetin alfa	\$59.69	\$69.59	33%	43%
epoetin alfa-epbx 10000 u/1m	Retacrit	\$132.36	epoetin alfa	\$198.96	\$308.66	33%	57%
filgrastim-sndz 300mcg/0.5ml	Zarxio	\$661.58	filgrastim	\$800.88		17%	
filgrastim-sndz 480mcg/0.8ml	Zarxio	\$658.48	filgrastim	\$797.14		17%	
infliximab-abda	Renflexis	\$904.07	infliximab	\$1,401.38		35%	
infliximab-dyyb	Inflectra	\$1,135.54	infliximab	\$1,401.38		19%	
pegfilgrastim-jmdb	Fulphila	\$8,350.00	pegfilgrastim	\$12,462.12		33%	

Biosimilars have the potential to bring competition to the specialty drug market by providing lower cost alternatives to high-priced reference biologic drugs. Biosimilars, however, are presented with a few obstacles that may hinder their uptake, unlike traditional generics. One is that biosimilars don't have the same generic active ingredient name as the reference biologic product. While they may share a component of the name, the fact that a biosimilar has a 4-letter suffix attached to the generic name makes that name unique to each manufacturer. The difference in name makes it more difficult for substitution of biosimilars versus the reference biologic. In addition, proving interchangeability is difficult, but it is necessary to ensure safety and efficacy similarities between a reference biologic and a biosimilar.

According to the FDA, an interchangeable product is a biosimilar product that meets additional requirements outlined by the Biologics Price Competition and Innovation Act. As part of fulfilling these additional requirements, information is needed to show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Also, for products administered to a patient more than once, the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product will have been evaluated. An interchangeable product may not be substituted for the reference product without the involvement of the prescriber. The FDA's high standards for approval should assure health care providers that they can be confident in the safety and effectiveness of an interchangeable product, just as they would be for an FDA-approved reference product.<sup>5</sup>

## **2.5 Specialty drugs under pharmacy benefit verses medical benefit**

Pharmacy and medical benefits differ in several ways, including how drugs are acquired, how and where drugs are administered, how they are reimbursed, and how patients pay their cost share.<sup>54</sup> Specialty drugs under medical benefits are typically administered by a provider. The most common sites of where drugs are administered under the medical benefit are hospital outpatient clinics, a physician's office, and home infusion. The provider or provider organization is the purchaser of the drug product under the medical benefit, rather than the specialty, mail, or retail pharmacy under the pharmacy benefit. The way drugs are billed and how claims data is organized is different between pharmacy and medical benefits. Under pharmacy benefits, drugs are billed using the National Drug Code (NDC). The NDC code provides detailed information on the drug, including the labeler of the drug, the product name and strength, and product package type and size.

On the other hand, the Healthcare Common Procedure Coding System (HCPCS) used to identify drugs under medical benefits, does not provide product specific details like NDCs. The HCPCS codes used to identify drugs under medical benefits are a standardized coding system that is used primarily to identify products, supplies and services. The HCPCS codes that are used to identify drug products lump all versions of a drug product under the same general code. For example, the HCPCS code S0090 is the code for Sildenafil citrate, 25 mg. However, there are both brand name and generic versions of Sildenafil citrate 25 mg, with many NDCs and very different drug costs. What a HCPCS code does is combine all of those various NDCs associated with Sildenafil citrate, both brand and generic, into one code, S0090. Thus, every time a patient is administered Sildenafil citrate 25mg, whether it is brand or generic, we will only see HCPCS code S0090. There will be no detail on the actual product that was used, including manufacturer (labeler) and package information, such as package type and size. In this example, we know the product's generic name and strength, but we don't know if what was used was brand or generic or how many units were administered.

In some cases, there may be 50 or more NDCs for one HCPCS code. This is an issue because drug prices vary based on who manufactures or markets the drug, as well as by the package type and size. So, it is important to know more detail about drugs being provided for a HCPCS code including which NDC was used. That's why one of the goals set forth by employers who are a part of Minnesota Health Action Group's (MN-HAG) Specialty Drug Guiding Coalition is requiring that NDC codes be required on claim submissions under medical benefits. This effort is one that is being spearheaded by the UPlan as part of the Guiding Coalition, where the UPlan is a part of a pilot study with its health plan, as its health plan implements this requirement.

The way drugs are reimbursed is different between pharmacy and medical benefits. Typically, pharmacy benefit reimbursement is based on Average Wholesale Price (AWP) minus some percentage of AWP, based on contracted rates between the employer and PBM, as well as between the PBM and the pharmacy. Medical benefit reimbursements for drugs under Medicare Part B are based on Average Sales Price (ASP). The ASP is an average of actual prices paid for drugs, and ASP is calculated based on a formula from CMS. It is often the net of most discounts and rebates [excludes rebates, other than those obtained through the Medicaid drug rebate program; excludes sales that are nominal in amount and sales excluded from the Medicaid "best price" calculation (e.g., VA, DOD, PHS)].<sup>56</sup> Commercial medical benefit plans may or may not use an ASP based pricing method. They may also use an AWP or WAC based pricing method. AWP is a published list price that was reportedly created in the late 1960s by the California Medicaid program as a way to standardize the basis for pharmacy drug cost reimbursement. Historically, AWP was the generally accepted drug payment benchmark for many payers because it

was standardized and readily available. However, AWP is only a “sticker price” and is not the real transaction price. AWP does not account for discounts or rebates or contract prices. Most payers base provider payment rates for drugs covered under the pharmacy and medical benefits on a percentage off of AWP.<sup>27</sup>

Section 303(c) of the Medicare Modernization Act (MMA) revised the drug payment methodology for Medicare Part B drugs by creating a new pricing system based on a drug’s average selling price (ASP). Effective on January 1, 2005, Medicare began paying for the vast majority of Part B covered drugs and biologicals using a drug payment methodology based on the ASP. Manufacturers submit the ASP data for their products to the Centers for Medicare & Medicaid Services (CMS), and CMS updates ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Medicare Part B drugs and biologicals not paid on a cost or prospective payment basis are paid based on the ASP methodology, and payment to providers is 106 percent of the ASP, minus applicable beneficiary deductible and coinsurance payments.<sup>27</sup>

### **2.5.1 Specialty drugs under pharmacy benefit**

According to Schumock, et al, in 2014, 51 percent of prescription drug expenditures were accounted for by the retail pharmacy setting at \$184 billion. Expenditures in mail-order pharmacy and clinics were \$74.6 billion (20.7 percent) and \$46.9 billion (13.0 percent) respectively.<sup>11</sup> The 2014 prescription drug trend report from Prime Therapeutics, the PBM for the University of Minnesota's UPlan, notes that expenditures for specialty drugs under the pharmacy benefit book of business (BOB) increased 25.8 percent while expenditures for traditional drugs only increased by 4.2 percent from the previous year.<sup>57</sup> For Express Scripts (ESI), the top PBM in the U.S. representing one-third of the nation's covered lives, specialty drug expenditures accounted for more than 31 percent of total drug expenditures for 2014.<sup>58</sup> For Prime Therapeutics, five of the top 10 therapeutic category drivers of total expenditures were categories commonly considered specialty. Prime's top therapeutic categories were hepatitis C, diabetes, biologic anti-inflammatory, HIV, multiple sclerosis (MS), pain, cancer (pills), hemophilia, psychosis, high cost other, seizures, and blood thinners.<sup>57</sup> Similar categories were noted in ESI's top 10 specialty therapeutic classes by expenditure under their pharmacy benefits for 2014. The top 10 specialty list for ESI included inflammatory conditions, multiple sclerosis, oncology, hepatitis C, HIV, miscellaneous specialty conditions, growth deficiency, hemophilia, pulmonary arterial hypertension and transplant.<sup>58</sup>

A study by EMD Serono based on data from 70 commercial health plans in the U.S. representing more than 100 million covered lives, found that Prime Therapeutics and ESI had similar specialty drug expenditures by therapeutic category.<sup>59</sup> For both pharmacy benefit managers, the top three drivers of expenditures were immune modulators, oncology, and MS.<sup>59</sup>

According to CVS Caremark, also known as CVS Health, the second largest PBM in the U.S., the 2012 expenditures for specialty drugs under their pharmacy benefit were \$47.9 billion.<sup>60</sup> CVS Health projected<sup>61</sup> that expenditures for specialty drugs under the pharmacy benefit would reach as high as \$200.9 billion by 2020.

## **2.5.2 Specialty drugs under medical benefit**

Drug expenditures under the medical benefit accounted for less than 10 percent of total expenditures.<sup>11</sup> The medical settings included non-federal hospitals, long-term care facilities, federal facilities, staff-model HMOs, home health care facilities, and other settings. Drugs administered in the hospital or clinic setting commonly are covered under medical benefit. Over the last decade, there has been a growth in drugs flowing through the medical benefit. In the state of Minnesota, a study by Minnesota Department of Health on the Minnesota All Payer Claims Database, looking at pharmaceutical spending and use from 2009 to 2013, found that spending on drugs flowing through medical benefits increased nearly three-fold from 2009 to 2013.<sup>62</sup> In addition, "... overall spending on prescription drugs rose from \$6.1 billion in 2009 to \$7.4 billion in 2013, an increase of 20.6 percent. More than one-half (55.0 percent) of this spending growth was driven by medical claims for prescription drugs in health care settings, such as



physicians' offices and hospital outpatient clinics, even though medical claims accounted for only about one-fifth (19.2 percent) of all drug claims.”<sup>62</sup>

“The faster growth in spending for medical claims across various health care settings is largely due to the nature and price of prescription drugs used in each setting. Pharmacy claims for prescription drugs represent ‘traditional prescription drugs’ (i.e., drugs taken on a routine basis for a chronic condition or for a short-term infection or pain). More than 80 percent of these pharmacy claims are for lower-priced generics.”<sup>62</sup>

In line with what was observed in the Minnesota study, CVS health observed that specialty drug expenditures under the medical benefit were \$39.2 billion in 2012.<sup>61,63</sup> It is projected<sup>61</sup> that the specialty drug expenditures under the medical benefit are expected to reach as high as \$200.9 billion by 2020.<sup>63</sup> Of those drugs flowing through non-federal hospitals in 2014, infliximab, rituximab and pegfilgrastim represented the top three drugs by expenditure, accounting for \$2.1 billion collectively.<sup>64</sup> The largest expenditure increases from 2013 to 2014 in the non-federal hospital setting were noted for natalizumab at 116.5 percent, pegfilgrastim at 13.1 percent and trastuzumab at 12.0 percent.<sup>64</sup> For those drugs flowing through the clinic setting, infliximab, pegfilgrastim, and epoetin held the top three positions for expenditures, collectively accounting for \$6.3 billion of the total expenditures going through the clinic setting.<sup>64</sup> The top ten drugs from the clinic setting accounted for \$14.4 billion of the \$46.9 billion total expenditure.<sup>64</sup> The drugs with the highest price increase from 2013 to 2014 in the clinic setting included natalizumab at 277.4 percent, immune globulin at 32.5 percent and denosumab at 21.7 percent.<sup>64</sup> According to Schumock, et al, injectable products represented the majority of drug expenditures in the clinic setting, accounting for \$37.4 billion of the \$46.9 billion

total clinic spending in 2014. In the non-federal hospital setting, a similar trend was observed as in clinic settings in regards to injectable products, with \$21.9 billion of the \$29.7 billion of the total non-federal hospital expenditures going towards injectable products. <sup>64</sup> Schumock, et al, noted that expenditure growth in non-federal hospitals was primarily due to price increases of drugs, while growth in expenditures in the clinic setting was attributed to volume and mix of drugs.

The top 10 therapeutic drug categories by expenditure in non-federal hospitals in 2014 include antineoplastic agents, hemostatic modifiers, anti-infective (systemic), blood growth factors, gastrointestinal agents, biologics, anesthetics, immunologic agents, hospital solutions, and respiratory therapy agents. <sup>64</sup> The top 10 drugs in the non-federal hospital setting in 2014 include Infliximab (Remicade), Rituximab (Rituxan), Pegfilgrastim (Neulasta), Immune globuline, Alteplase (Activase, Cathflo Activase), Natalizumab (Tysabri), Bevacizumab (Avastin), Daptomycin (Cubicin), Bivalirudin (Angiomax) and Trastuzumab (Herceptin). <sup>64</sup>

### **2.5.3 Specialty drugs that flow across pharmacy and medical benefit**

Specialty drugs flow under both pharmacy and medical benefits. Under the pharmacy benefit, most specialty drugs flow through a specialty pharmacy. However, since there is not a set definition of what specialty drugs are, the drugs that flow through a specialty pharmacy may vary based on the employer. Depending on what definition of specialty drug is used, the percent of total drug utilization and spending that are accounted for under specialty pharmacy will vary. Some concerns have been raised by consumers and employers regarding the definition of specialty drugs. The cases where employers solely rely on their PBM to manage their specialty drugs have raised some concerns, as the PBM is incentivized to shift drugs from independent community pharmacies into their own PBM-owned and operated specialty pharmacy. This is particularly concerning in the cases where a pharmacy benefit manager owns the specialty pharmacy. By simply changing the definition of specialty drugs to include a larger list of drugs, the PBM can channel a greater number of drugs through its own specialty pharmacy. For an employer such as the UPlan, paying the bills this way can be concerning, as the dispensing fees and reimbursement structure for specialty drugs are higher for specialty drugs than for traditional drugs.

Specialty pharmacies may add value in some cases where there is certainty in the definition of specialty drugs. Specialty pharmacies can work with providers and patients to help ensure that the patient is on the appropriate drug and dosage. In addition, they can help patients with drug use and administration as well as with monitoring drug use and adherence.<sup>65</sup> The growth of specialty drugs in the market has resulted in the growth of specialty pharmacies. Initially, specialty pharmacies were owned and operated by independent firms. However, there have been many mergers and acquisitions of specialty pharmacies by large, traditional chain pharmacies and PBM firms.

The growth in specialty pharmacies raised some questions regarding the drugs that flow through traditional retail or mail pharmacies vs. the drugs that flow through a specialty pharmacy. This is particularly concerning in the case where a pharmacy benefit manager owns the specialty pharmacy. By simply changing the definition of specialty drugs to include a larger list of drugs, the PBM can channel a greater number of drugs through its own specialty pharmacy. For an employer such as the UPlan, this can be concerning, as dispensing fees and the reimbursement structure for specialty drugs are controlled by the PBM, itself, and are usually higher through the specialty pharmacy than through community pharmacies.

Under the medical benefit, the most common sites of care where specialty drugs are administered are hospital outpatient clinics, physicians' offices, patients' homes, and other settings. However, there is variation among the sites of care on the cost to the plan associated with specialty drug administration. Typically, employers pay about two to three times more per infusion of a specialty drug at a hospital outpatient clinic compared with other sites of care.<sup>7</sup> As a result, in recent years employers have been seeking site of

care strategies to help ensure that they are not overpaying for specialty drugs. The most common site of care strategies presented to employers in the market encourage shifting patients from hospital outpatient clinics to either a physician's office or to home infusion. However, a different approach is being presented to employers in Minnesota by the Minnesota Health Action Group (MN-HAG). Since 2014, the University of Minnesota's UPlan, as an employer, has been a part of MN-HAG's Specialty Drug Learning Network, an employer learning network and Specialty Drug Guiding Coalition, a multi-stakeholder group. The Specialty Drug Guiding Coalition, which has representatives from health plans, PBMs, provider organizations, specialty pharmacies, pharmaceutical companies, manufacturers, and employers, works to address and develop solutions for various goals set out by employers regarding specialty drug management. One of the goals set forth by employers for health plans who manage the medical benefit and drugs that flow under medical benefit is a "Contract with providers to assure cost parity of all sites of care for the same drugs and services."<sup>66</sup> The idea of "cost parity" is different from what has been presented in the market. However, the rationale of MN-HAG's approach stems from employers who were frustrated with the mergers and acquisitions of physicians' offices and hospitals and health systems in the market. Thus, a physician's office today may be considered a hospital outpatient clinic tomorrow. In addition, site of care strategies that move patients from one site to the other cause member distribution and administrative expenses employers want to avoid.

## **2.6 Specialty drug management strategies under pharmacy and medical benefit**

While most employers are still working on figuring out specialty drug management under the medical benefit, many have adopted some specialty drug management strategies with varying degrees of complexity. Specialty drug management strategies are multifaceted and differ slightly between pharmacy and medical benefits. The primary specialty drug management strategies across benefits include appropriate definition of specialty drugs, utilization management (UM), distribution channel or site of care management and patient and provider engagement. The most common management strategies employed under pharmacy benefits include utilization management strategies, such as prior authorization, step therapy, quantity limits, NDC blocks, and restrictions on drug distribution channels. Similar strategies can be employed under medical benefits, but there are additional management options, such as site of care management, where members are restricted to only one or two sites of care.<sup>67</sup>

### **2.6.1 Control of specialty drug definition**

Appropriately defining specialty drugs is a critical first step to ensure proper management of specialty drugs. As discussed previously, there is not a set definition for specialty drugs. Thus, employers must be actively engaged in determining the definition that best fits their employees. Using the set definition of specialty drugs, a list of drugs created to meet the definition. The list will make up the specialty drug formulary. While drug formularies are most commonly utilized by PBMs under a pharmacy benefit, employers should consider deploying a specialty drug formulary on the medical benefit side, with management strategies imbedded.

### **2.6.2 Utilization management**

Utilization management strategies are the most common specialty drug management tools deployed by employers. They include — but are not limited to — prior authorization, step therapy, quantity limits, age limits, gender restriction and NDC blocks. While some or all of these UM strategies can be deployed under both pharmacy and medical benefits, they are more commonly seen under pharmacy benefits. This is because of the differences in billing and claim process discussed in earlier sections, as well as the fact that most employers are still unaware of their drug management needs on the medical side of the benefit.

Prior authorization and step therapy are ways for employers to ensure that the drug that has been prescribed is being used according to appropriate criteria. For prior authorization, the criteria may include a requirement for use of the drug for specific FDA approved indication, along with other parameters, such as the presence of a biomarker or lab values, limitation of use to a specific age group or gender, and so on. Step therapy is a UM strategy that ensures that a patient has tried a lower cost but equally safe and effective alternative for the same indication prior to the use of that particular specialty drug. The operationalization of prior authorization and step therapy will vary slightly between pharmacy and medical benefits. Under pharmacy benefit, prior authorization and step therapy can be addressed at the point of sale at the pharmacy. When a pharmacy puts in the order for a prescription, the PBM will send back a message to the pharmacy stating that a prior authorization or step therapy is required. For step therapy, included within the message sent to the pharmacy is typically a list of alternative products that

must have been tried prior to the ordered specialty drug. The pharmacist can then contact the prescribing provider to make the change. For prior authorization, the pharmacist notifies the prescribing provider of the prior authorization requirement, and the prescribing provider will follow up with the PBM to complete the prior authorization process.

In all, the process for prior authorization and step therapy can take a hours to days to implement for a specific case. Under medical benefits, prior authorization and step therapy take place at the point of care, and typically the prescribing provider has to submit the required documents prior to administering the drug to the patient. The process under a pharmacy benefit is automated for the most part and is much more efficient. However, under medical benefits this process is not always simple. In fact, many health plans don't have the capability to perform these utilization management strategies for drugs and have to sub-contract with another vender for these capabilities.

Other utilization management strategies, such as quantity limits, an age limit, a gender restriction, or an NDC block are also possible under both pharmacy and medical benefits. These utilization management strategies are automated and easily deployed under pharmacy benefits at the point of purchase at the pharmacy. The implementation of these strategies is not as easy on the medical side due to limitations addressed above. The most challenging limitations are NDC blocks, as most health plans do not currently require the use of NDC codes for billing of drug claims processed under the medical



benefit. However, it is possible to still employ NDC blocks under medical benefits with the use of a vendor with capabilities to utilize HCPCS-NDC crosswalks.

### **2.6.3 Distribution channel and site of care management**

Two other specialty drug management strategies deployed by employers are the distribution channel management under pharmacy benefits, and site of care management under medical benefits. Under pharmacy benefits, specialty drugs can flow through retail pharmacy (e.g., chain, grocery store, independent, and so on), mail order pharmacy, and specialty pharmacies. One management strategy under pharmacy benefits is restricting which pharmacies a patient can use to obtain specialty drugs. Many PBMs recommend restricting the distribution of specialty drugs only through a specific specialty pharmacy (which they usually own). PBMs argue that this approach is justified because the PBM and its specialty pharmacy provide the patient care and management tools recommended for provision of specialty drugs. However, restricting the flow of all specialty drugs to a specialty pharmacy may not always be the most cost-effective option for an employer. Some experts in the industry argue that PBMs' recommendations to require the flow of specialty drugs through their own specialty pharmacies may be financially motivated, and may not always be in the best interests of their clients. This is because most of the major PBMs own their own specialty pharmacies. So when they require specialty drugs to flow through their own specialty pharmacy, they are essentially driving business away from other pharmacies and toward themselves. This represents a major potential conflict of interest and one that employers who want to deploy a distribution channel strategy under pharmacy benefits should take into account. In addition, the contracted rates for

drugs flowing through the various pharmacy distribution channels are different. Typically, the discount off of AWP is much less for specialty drugs flowing through the specialty pharmacy. In addition, drugs flowing through the specialty pharmacy have higher dispensing fees. Thus, employers must be aware of details associated with an arrangement that will restrict the flow of drugs strictly to a specific specialty pharmacy. For many oral, and some injectable specialty drugs, it is not necessary for the drugs to be dispensed by a specialty pharmacy, as long as other management strategies are in place, such as utilization management tools.

Under medical benefits, employers can deploy a site of care (i.e. place of service) strategy. This is a critical strategy that employers should not ignore, particularly under a medical benefit. Depending on what site of care is used for a particular drug, there can be significant differences in the charges associated with the same services, same drug and same amount of the drug. The most common sites of care where drugs are administered under medical benefits are at a physician's office, patient's home and in hospital outpatient facilities. Among the three, the most expensive site of care is typically the hospital outpatient clinic. It is commonly seen that similar claims flowing through hospital outpatient clinics can be two to ten times more expensive than what is observed if the same drug was administered at a physician's office or at the patient's home.

To address this challenge, a site of care strategy that restricts or limits where a patient can get a drug administered under the medical benefit can be deployed. One approach is requiring that patients can only get a drug administered at the physician's office or patient's home. However, there is a risk associated with such a strategy because prices at the physician's office and patient's home can start to go up. Secondly, what has been

observed in the marketplace is an increased acquisition of physician's practices by hospital outpatient facilities. When these acquisitions happen, it limits the number of options patients have within a community to have their drugs administered. An alternative to limiting access to a particular site of care is known as site of care parity. In this approach, employers can place a limit on how much they will pay for a particular drug and its administration, and any site of care that is willing to accept that amount would be able to administer the drug. While appealing, the site of care parity concept has not yet taken off. Most of the strategies currently being deployed focus on restriction of site of care or moving patients from one site of care to another.

While distribution channel and site of care management strategies may be deployed strictly on each side of the benefit, it is important to note that employers need to also consider managing the distribution of drugs across the pharmacy and medical benefits. There are some drugs that flow on both sides of the benefit. However, either the pharmacy or medical benefit may provide a better distribution channel for a particular drug. Thus, it is important to consider possible distortions across the two types of benefits and across sites of care.

While the above discussed channel and site of care management options are available to employers, there are drugs that can only be obtained at selected specialty pharmacies or sites of care. Drugs that have this type of restriction are called "Limited Distribution Drugs", which are determined by the manufacturer of the drug. The manufacturer determines which limited channels and sites of care can be used for the purchase or administration of the drug. A manufacturer may determine limited distribution status of a drug for various reasons. One reason noted is that the target

population is too small, making it more efficient to dispense the drug from a limited number of pharmacies rather than allow the over 64,000 retail pharmacies to have access to dispense.<sup>9</sup> Other reasons for limited distribution status may include safety and monitoring requirements as well as special handling. In addition, some limited distribution drugs may have additional requirements by the FDA as part of the approval process. Thus, limited distribution status is required of manufacturers to ensure that the use of their drug is compliant with FDA's requirements.<sup>9</sup>

#### **2.6.4 Patient engagement and management**

In the case of specialty drugs, patient engagement is critical. If patients are not taking their specialty drugs properly, they will not be getting the desired outcomes — at significant cost to them and the employer. An example of this is drugs for hepatitis C or HIV. In both of these cases, if the patient misses doses regularly, the effectiveness of the drugs are diminished, because resistance to a particular virus strain may develop. Thus, care programs that connect with patients to make sure they are taking their drugs properly and to monitor their adherence over time become critical. In addition to this type of patient engagement, additional efforts can revolve around ensuring that a particular specialty drug is working for the patient. For rheumatoid arthritis, for example, tracking a patient's American College of Rheumatology (ACR) improvement criteria to assess improvement with the use of a biologic drug is an example of tracking patient outcomes and improvement. Based on information from this type of tracking, recommendations can be made to the prescriber to change the patient's drug if needed. Under the pharmacy benefit, patient engagement and management is typically undertaken by a specialty pharmacy. However, there are small carve-out vendors that also focus solely on patient engagement and management aspects of specialty drug utilization. Under medical benefits, patient engagement and management is left to the provider, or a vendor assigned this task by the health plan.

### **2.6.5 Provider engagement**

Provider engagement is another management strategy that can be deployed. By engaging the providers that prescribe and administer specialty drugs within the community, an employer can take a proactive approach to managing specialty drugs. Providers determine what drug they want to order for a patient. If prior to the ordering of a specialty drug an employer, with the help of their PBM, specialty pharmacy, or health plan, engage a provider and relay information regarding what is covered and what is not covered, a lot of time can be saved and administrative burden can be avoided. Providers who receive targeted information prior to seeing a patient are more likely to consider the information before ordering.

### **2.6.6 Continued evaluation and monitoring of data and trends**

Finally, a key part of specialty drug management is the continued monitoring and evaluation of claims data for trends. This continued monitoring and evaluation can be deployed for drugs flowing through both pharmacy and medical claims. To have a complete picture of specialty drug trends, it is important that employers monitor and evaluate across both benefits. Based on findings from this continued monitoring, specialty drug management strategies discussed above can be deployed. Without this type of monitoring many issues that need attention and related management opportunities can be missed. This is particularly important for management of drugs across both pharmacy and medical benefits. In addition, because there are many market dynamics that create reverse, perverse, and misaligned incentives for the vendors that employers trust to

manage their benefits, it is critical that employers have claims data to monitor and validate the execution of contractual agreements with their vendors. The misaligned incentives create situations where, for example, drugs that may not need to be utilized are covered, and drugs that should not be administered at a particular site are administered. Along with misaligned incentives, there is huge lack of transparency within the drug supply chain under both pharmacy and medical benefits. To combat this issue and ensure that the vendors hired to manage drug benefits under pharmacy and medical benefits are doing what they agreed to do in contracts, a process for monitoring and evaluation of claims data is critical.

## CHAPTER 3:

### CONCEPTUAL FRAMEWORK AND RESEARCH METHODOLOGY

#### 3 Introduction

This chapter consists of seven sections. The first section describes the data source. The second section presents study aims and research questions. The third section explains the claims data characteristics. The fourth section details data quality, data linking and data enhancements. The fifth section operationalizes the definition of specialty drugs within pharmacy and medical claims. The sixth section explains the statistical analysis process for each research aim and research question. The seventh section outlines the limitations of this study.

#### 3.1 Data source

Data for this study was provided by the University of Minnesota UPlan. Data included pharmacy and medical claims data from 2006 to 2014. The data provided for this study was grouped and aggregated at the NDC level for pharmacy claims and at the HCPCS level for medical claims. The data was also grouped by month and year. Thus, data provided for this study has aggregated data for each NDC and HCPCS summarized by month and year. The aggregated claims data provided for this study was clean paid claims data used for business services. The pharmacy data was provided by UPlan from their data warehouse, while medical data was obtained from two sources. Medical data from 2006 to 2012 was obtained from the UPlan's data warehouse vendor. The data for 2013 and 2014 was obtained from the UPlan's health plan, the vendor administering medical benefits. The average number of lives covered by year is listed in Table 3.1.



**Table 3.1: UPlan 2006 to 2014 Average Number of Covered Lives**

<b>Year</b>	<b>Average Number of Members</b>
2006	35,066
2007	35,752
2008	37,157
2009	38,576
2010	39,066
2011	39,276
2012	38,748
2013	38,632
2014	38,754

### **3.2 Study aims and research questions**

The goal of this study is to examine specialty drug distribution and utilization across the entire health benefit plan, including both the pharmacy and the medical benefit components of the University of Minnesota’s UPlan. This study identifies patterns of specialty drug distribution and utilization by therapeutic category across both the pharmacy and the medical benefits. To accomplish the overall goal, this study will address several specific aims.

#### **3.2.1 Aim 1**

Describe specialty drug and drug-related product trends including expenditures and utilization under the pharmacy and medical benefits from 2006 to 2014 for the University of Minnesota’s UPlan.

### **3.2.1.1 Research question 1a**

What is the total utilization and expenditure of specialty drugs and drug-related products under the pharmacy benefit and medical benefit from 2006 to 2014 for the University of Minnesota's UPlan?

### **3.2.1.2 Research question 1b**

What are the changes year to year in utilization and expenditures for specialty drugs and drug-related products in aggregate for those that flow through the pharmacy benefit and medical benefit from 2006 to 2014 for the University of Minnesota's UPlan?

### **3.2.2 Aim 2**

Describe specialty drug and drug-related product trends including expenditures, and utilization by therapeutic category and other characteristics from 2006 to 2014 for the University of Minnesota's UPlan.

### **3.2.2.1 Research question 2a**

What percent of total specialty drug and drug-related expenditures are accounted for by the top 10, 25 and 50 drugs for the University of Minnesota's UPlan each year?

### **3.2.2.2 Research question 2b**

What number of specialty drugs and drug-related products account for 50%, 75% and 90% of total specialty drug and drug-related expenditures for the for the University of Minnesota's UPlan?

### **3.2.2.3 Research question 2c**

What is the average total price paid per claim of each specialty drug each year under the University of Minnesota's UPlan?

### **3.2.2.4 Research question 2d**

What percent of total specialty drugs and drug-related expenditures are accounted for by each therapeutic category each year for the University of Minnesota's UPlan?

### **3.2.2.5 Research question 2e**

From 2013 to 2014 what percent of total specialty drug expenditures do the four therapeutic categories comprise for each year for the University of Minnesota's UPlan? The therapeutic categories include are: Immune Modulators; Multiple Sclerosis; Oncology ; and Hepatitis C.

### **3.2.3 Aim 3**

Identify and assess the utilization and expenditures by channels of distribution of specialty drugs and drug-related products that flow through the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

#### **3.2.3.1 Research question 3a**

What are total expenditures by year for specialty drug and drug-related products in the medical claims data utilized in outpatient hospital, physician's office, home infusion, and all other sites of care identified in the University of Minnesota's UPlan?

#### **3.2.3.2 Research question 3b**

What channel of distribution has the highest year to year growth in expenditures for specialty drug and drug-related products utilized under the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan?

### **3.2.4 Aim 4**

Identify and assess utilization and expenditures of specialty drugs and drug-related products that are covered by both the pharmacy and the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

#### **3.2.4.1 Research question 4a**

How many specialty drugs were distributed under both the pharmacy and the medical benefit each year for the University of Minnesota's UPlan?

#### **3.2.4.2 Research question 4b**

What specialty drugs are utilized under both pharmacy and medical benefit for the University of Minnesota's UPlan?

#### **3.2.4.3 Research question 4c**

What are the expenditures for specialty drugs and drug-related products that are used under both pharmacy and medical benefit for the University of Minnesota's UPlan?

### **3.3 Claims data characteristics**

The claims data provided by the UPlan for this study was data that was not collected for research purposes. Rather, the data provided is transactional administrative claims data collected for business purposes. While the UPlan has individual claims level data, the data provided for this study was aggregated clean paid claims data. That is data used to provide business reporting to the UPlan. Pharmacy claims data was aggregated at the NDC level, while medical claims data was aggregated at the HCPCS/CPT level. Both pharmacy and claims data contained key data variables types, including product identifiers, utilization measures, financial measures, place of service identifiers and date of service identifiers. Historically, drug utilization and expenditures under the pharmacy benefit accounts for drug products, drug administration supplies (e.g., syringes), and drug administration costs (dispensing fees). However, under the medical benefit, costs outside of actual drug products have not been widely studied and reported. This study evaluates and reports on drug products, drug administration supplies and drug administration services, allowing for a more complete picture of use and spend trends associated with drug use and administration under the medical benefit.

### **3.3.1 Pharmacy claims data elements**

Pharmacy claims data for the UPlan was provided in aggregate at the NDC level. The pharmacy claims data provided was a clean set of paid claims data used by the UPlan for business purposes. Pharmacy claims data provided contained key data elements necessary for answering study objectives. The pharmacy claims data also contained additional data elements beyond what was needed to answer the objectives of this study. A complete list of data elements is provided in Appendix 1. Table 3.2 shows the data elements utilized from pharmacy claims data for this study. The key pharmacy claims data elements used for this study included product identifiers, utilization measures, financial measures, place of service identifiers and date of service identifiers.

#### **3.3.1.1 Pharmacy data elements**

The UPlan pharmacy claims data was provided aggregated at the month and year level from 2006 to 2014. The unique claims and all financial fields for each NDC code were aggregated at the month and year level by the distribution channel discussed below. The findings for this study are reported at the year level. When appropriate, some results are reported at the month and year level. Table 3.2 outlines the aggregated pharmacy claims data elements used in this study.

**Table 3.2: Pharmacy Claims Data Elements**

Data Element Type	Short Name	Long Name	Description
Data	Yr Mo	Year -Month	Code indicating the year and month of the claim (i.e., 2017 01)
Date	Year	Year	Indicates the year the prescription claim was submitted
Date	Month	Month	Indicates the month the prescription claim was submitted
Distribution channel (Place of service)	ClamType	Claim type	S=Specialty pharmacy M=Mail order MR=Mail at Retail R=Retail
Financial	Total \$	Total paid	Total amount paid (plan paid amount plus member paid amount)
Financial	Plan Pd	Plan paid	Plan amount paid per claim
Financial	Mbr Pd	Member Paid	Member amount paid per claim
Financial	COB	Coordination of Benefits	Amount paid by other third party payers for this claim
Financial	Copay	Copay	Copay amount paid per prescription claim
Utilization	# Utilizers	Number of Utilizers	Number of Utilizers per Claim (should be 1)
Utilization	# Claims	Number of Claims	Number of Claims per Line (should be 1)
Utilization	Qty	Quantity	Amount (units) of drug dispensed per claim
Utilization	Days	Day supply	Days' supply dispensed per claim
Product Identifier	Label Name	Brand Name	Official brand name of a drug product (if any).
Product Identifier	Generic Name	Generic Name	The active ingredient name, also called generic name
Product Identifier	NDC	National Drug Code	NDCs are an 11-digit code uniquely identifying the drug product. When there is no NDC code, this field may contain a UPC or an HRI code. These codes are converted to 11-character codes according to NCPDP standards.
Product Identifier	GPI	Generic Product Identifiers	Generic Product Identifier (GPI)* defines pharmaceutically equivalent drug products that are identical in terms of: active ingredient(s), route of administration, dosage form, strength or concentration, and therapeutic use.

\*Definition of GPI is obtained from Medi-Span Electronic Drug File (MED-File) v2. Published 11/11. Revised 05/15.

**3.3.1.2 Distribution channels or places of service under pharmacy benefits**

The UPlan pharmacy claims data identifies four distribution channels associated with each claim. The pharmacy claims data aggregated at the NDC level by month or by year was distributed through a retail pharmacy, mail order pharmacy, specialty pharmacy, or mail at retail. Table 3.3 provides a summary of total claims flowing



through each distribution channel for the UPlan from 2006 to 2014. Table 3.4 provides a definition of the distribution channels listed in Table 3.3 from the National Council for Prescription Drug Program (NCPDP), which maintains pharmacy type codes. A drug flowing through a specialty pharmacy doesn't necessarily mean the drug is a specialty drug. Likewise, a drug flowing through the other channels does not indicate that the drug is not a specialty drug. Many specialty drugs can be dispensed through non-specialty pharmacies. A complete list of pharmacy type codes from NCPDP is provided in Appendix 2. The UPlan has designated all claims flowing through the pharmacy benefit as one of the four channels, grouping like pharmacy types together. Mail at retail is not technically a separate distribution channel or a pharmacy type, but rather a dispensing strategy that is similar to a mail order pharmacy. Typically, mail order pharmacies fill prescriptions with a 90-day supply of drug. The ability to fill a 90-day supply, or three month supply, in the retail setting is called 'mail at retail'.

**Table 3.3.: Total Pharmacy Claims Drug Distribution Channels**

<b>Distribution Channel</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Mail	12,405	13,315	14,229	14,633	13,007	12,975	12,672	12,046	101,402
Mail at Retail						69,554	77,767	93,978	
Retail	313,262	333,108	349,294	359,244	352,298	278,989	245,995	226,237	222,215
Specialty	2,072	2,153	2,133	2,141	2,877	3,201	2,909	2,724	
Grand Total	327,739	348,576	365,656	376,018	368,182	364,719	339,343	334,985	323,617

**Table 3.4: Pharmacy Type Code and Description per NCPDP<sup>1</sup>**

Code	Code Name	Pharmacy Type Code Description
1	Community/Retail	defined as a pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes. Associated taxonomy code is "3336C0003X".
5	Mail Order	defined as a pharmacy where pharmacists compound or dispense prescriptions or other drugs in accordance with federal and state law, using common carriers to deliver the drugs to patients or their caregivers. Mail order pharmacists counsel patients and caregivers (sometimes independent of the dispensing process) through telephone or email contact and provide other professional services associated with pharmaceutical care appropriate to the setting. Mail order pharmacies are licensed as a Mail Order Pharmacy in the state where they are located and may also be licensed or registered as nonresident pharmacies in other states. Associated with taxonomy code "3336M0002X".
15	Specialty	defined as a pharmacy that dispenses generally low volume and high cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex and potentially life threatening. Often these therapies require specialized delivery and administration. Associated with taxonomy code "3336S0011X".
1	Mail at Retail	See Community/Retail

**3.3.1.3 Product identifiers under pharmacy benefits**

The UPlan pharmacy claims data contained key product identifiers, including but not limited to NDC, drug name (both brand and generic) and GPI. The data was aggregated at the NDC level. When a prescription drug claim is processed under the pharmacy benefit, drugs are billed using the NDC. The NDC code is an 11-digit code (and sometimes a 10-digit UPC or HRI code) or that provides detailed information about

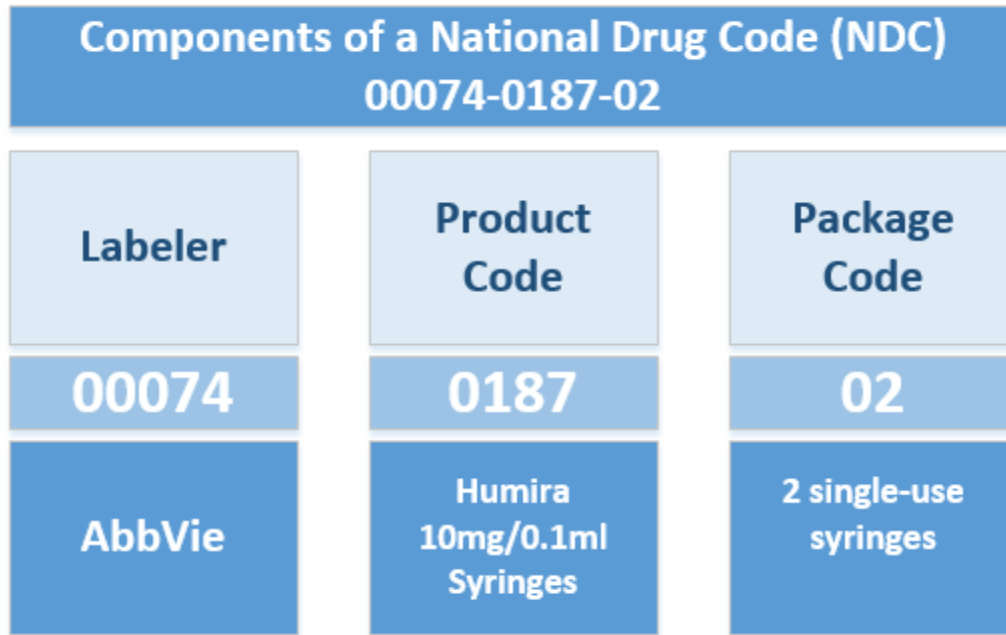
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<sup>1</sup> ResDAC. Primary Dispenser Type Code. Retrieved on: 1/25/2016. Retrieved from: <http://www.resdac.org/cms-data/variables/Primary-Dispenser-Type-Code>.

the drug, including the labeler, product name and strength, and product package type and size.

Figure 3.1 shows an example of an NDC code: 00074-0817-02 for Humira (adalimumab), and the information provided. The NDC code may also be used for non-drug products. An example is surgical supplies. When an product code (i.e., NDC, HRI, or UPC) is only 10 characters it is converted to an 11-digit code by adding a zero at the beginning of it to comply with National Council on Prescription Drug Program (NCPDP) standards. The 11-digit NDC is divided into three segments. The first five digits represent the labeler or manufacturer. These first five digits are assigned by the FDA. The remaining digits are assigned by the manufacturer or labeler. In the example below, the manufacturer, AbbVie, is represented by the first five digits. The next four characters represent the drug product, including name, strength and dosage form. In the example below, the drug is Humira, the strength is 10mg/0.1ml, and the dosage form is syringes. The final two digits identify the package size and type. In the example below, we see that one package has two syringes in it. This package size is '02'.

**Figure 3.1 Example of NDC Components\***



The GPI is a 14-digit number which at the most detailed level identifies pharmaceutically equivalent drug products that are identical in active ingredient(s), dosage form, route and strength or concentration. Thus, one GPI code may include many NDC codes. The GPI provides a way to group drug products that are pharmaceutically equivalent (and which may usually be generically substituted for each other) without taking into account their labeler and brand name. The importance of GPI to enhance pharmacy claims data is discussed in detail in section 3.4.2.1.

#### **3.3.1.4 Date identifiers under pharmacy benefits**

The UPlan pharmacy claims data was provided aggregated at the month and year level from 2006 to 2014. The unique claims and all financial fields for each NDC code were aggregated at the month and year level by distribution channel, be it retail pharmacy, mail order pharmacy, specialty pharmacy, or mail at retail. The findings

for this study are reported at the year level. When appropriate, some results are reported at that month and year level.

### **3.3.1.5 Utilization data elements under pharmacy benefits**

Pharmacy claims utilization data elements include the number of claims, number of units dispensed, units of measure, number of utilizers, number of days' supply, number of prescriptions or clean claim transactions, number of units dispensed (e.g., unit may be tablet, capsule, milliliter, gram, or other), and number of days of therapy. To maintain consistency between pharmacy and medical claims data, the data elements that were present across both data sets were ultimately used as the utilization data element. As discussed below, under medical benefit utilization, data element "claim count" aggregated at the HCPCS level is what is used as a utilization measure. Under pharmacy benefit, claims counts aggregated at the NDC level are used as measure of utilization to provide consistency between the pharmacy and medical benefits. Ideally, medical benefit claims would contain NDC-level drug information, which includes detailed information about the drug product and the amount of drug product utilized. As discussed in Chapter 2, the use of NDC codes for both pharmacy and medical claims data is important for a detailed and accurate assessment of drug spending and utilization across pharmacy and medical benefits. Obtaining these NDC codes under the medical benefit, and reporting at the NDC level across pharmacy and medical benefit has been an effort undertaken by a certain health plans in Minnesota. It is the result of demands by employers in the state over the course of several years.

### **3.3.1.6 Financial data elements under pharmacy benefits**

Several primary financial variables are present in the UPlan pharmacy claims data. The UPlan data contains both charged amount and paid amount financial variables. However, to answer the objectives of this study, only paid amounts were examined. The primary financial variables used in this study were paid financial variables aggregated at the NDC level by month and year and distribution channel. The paid financial variables include member, employer (plan), and secondary payer cost share. Member cost share data elements include copay, coinsurance and deductible. Employer (plan) cost share includes paid amount and secondary payer cost share coordination of benefit (COB). The total paid is the sum of all of the paid financial variables, including member paid, employer paid and secondary payer paid.

To obtain total paid amount the paid financial variables were added together in the following equation:

$$\text{Total Paid Amount} = \text{Copay} + \text{Coinsurance} + \text{COB} + \text{Deductible} + \text{Plan Paid}$$

### **3.3.2 Medical claims data elements**

Medical claims data provided for the UPlan was aggregated at the HCPCS/CPT level. The aggregated UPlan medical claims data was evaluated and assessed at the unique claim level discussed in Table 3.5. The medical claims data was provided from two different sources. Data for 2006 to 2012 was provided from the data warehouse vendor for the UPlan. Data for 2013 and 2014 was provided directly from the medical benefit administrator for the UPlan's health plan. The aggregated medical claims data

provided included key data elements needed to answer objectives outlined in this study. The final medical claims data used for this study included key data elements such as product identifiers, utilization measure, financial measures, place of service identifiers and date of service.

Medical claims are unlike pharmacy claims, where one unique claim number represents each claim line. For medical claims, one unique claim number may represent multiple claim lines. One unique claim number is associated with all service lines on a given date or visit and represented on the same bill. Therefore, multiple medical records may share the same claim number. Those multiple records that share the same claim number are referred to as claim lines. Within claims data, “claim line,” sometimes referred to as “claim line counter” or “line counter,” is a data element, and it contains the line number for service within unique claim. The claim line begins with 1 and is incremented by 1 for each additional service line of a claim. Each claim line within a unique claim number represents a specific product or service rendered under that unique claim. Claim lines within a unique claim may include HCPCS codes, CPT codes and revenue codes associated with that unique claim. Table 3.5 represents an illustrative relationship between a unique claim number (unique claim) and claim lines within a unique claim.



**Table 3.5: Illustration of medical claims, unique claim vs. claim line\***

Number ID	Claim Number	Claim Line	Principal Diagnosis (ICD.10)	Procedure Code (HCPCS or CPT)	Procedure Code Description	Date of Service	Charge Amount	Paid Amount
1234	887744	1	G35	J2350 <sup>¶</sup>	Injection, ocrelizumab, 1 mg	4/01/2018	\$\$	\$\$
1234	887744	2	G35	96413	Chemotx Admin IV NFS TQUP 1hr 1/1st sbst/drug	4/01/2018	\$	\$
1234	887744	3	G35	99211	Office outpatient visit 5 minutes	4/01/2018	\$	\$
1234	887744	4	G35	J2350 <sup>¶</sup>	Injection, ocrelizumab, 1 mg	4/01/2018	\$\$\$\$	\$\$\$\$
5555	998877	1	G35	J2350	Injection, ocrelizumab, 1 mg	5/5/2018	\$\$\$\$	\$\$\$\$
5555	998877	2	G35	96413	Chemotx Admin IV NFS TQUP 1hr 1/1st sbst/drug	5/5/2018	\$	\$
5555	998877	3	G35	99211	Office outpatient visit 5 minutes	5/5/2018	\$	\$

\*This illustrative figure only contains limited number of data elements available for medical claims. This figure is only used to illustrate the relationship between a unique claim number and claim line. The data elements used are not only for illustration purposes and are not inclusive of all possible data elements available for medical claims. This illustration does not address the complexities imbedded within medical claims.

<sup>¶</sup>In this example J2350 appears twice within one unique claim. There are two claims. This is because it is possible that when administering a drug, provider first administers a test dose to ensure patient can tolerate the full prescribed dose

In the example depicted in Table 3.5, claim number 887744 (unique claim) has four claim lines associated with it. Of the four claim lines for claim number 887744, two of the claim lines are for the drug ocrelizumab, HCPCS code J2350. This example demonstrates the two possible ways to evaluate and report drug claims within medical claims data, which was discussed in section 3.3.2.1

### **3.3.2.1 Unique claim vs. claim line**

There are two ways to evaluate claims for drugs under the medical benefit. One is at the unique claim level, and the other at the claim line level. The data for this study is aggregated at the HCPCS/CPT level, and claims are counted at the unique claim level, and not at the claim line level. Using the example above, this study would count the number of claims associated with J2350 to be two claims, claim number 887744 (with two claim lines) and claim number 998877 (with one claim line), even though there are a total of three claim lines for J2350. However, when calculating the total expenditures (Total Paid) associated with J2350, the total paid for each claim line is added up to provide total paid for each of the two unique claims. For claim number 887744 the two claim lines for J2350 would be added up, and for claim number 998877, there is only one claim line for J2350, so only that line will be counted.

### **3.3.2.2 Drug and drug-related claims**

When considering utilization and expenditures for drugs, it is important to include the actual drug product, but also the drug-related supplies and services to capture the full financial exposure for employers. For claims flowing through the pharmacy benefit, everything that flows through the pharmacy claims is counted in total estimations of drug utilization and spending. This is the case even though within the pharmacy claims there may be products that are not technically drugs, but rather they are supplies such as needles, test strips, syringes, and other durable medical equipment. Drug-related claims, while present, are limited on the pharmacy side. However, on the medical benefit side there is a significant amount of drug-related claims, such as drug administration supplies,

drug administration services, durable and non-durable medical equipment and supplies traditionally not called out or separately reported. The reason for the difference in drug-related claims between pharmacy and medical benefit is that under medical benefit, the benefit allows a provider drug administration charge and payment for drug administration supplies.

To capture both drug and drug-related claims, a manual and iterative process by expert reviewers (a pharmacist and physician) was conducted to manually classify each HCPCS and CPT code either as a drug or drug-related claim.

**Table 3.6: Medical Claim Classification Codes**

<b>Medical Classification Code</b>	<b>Claim</b>	<b>Medical Claim Classification</b>
D		Drug
DA		Drug and Drug Administration
DD		Diagnostic Drug
IM		Immunization and Immunization Administration
ESRD		End Stage Renal Disease
A		Drug Administration
MM		Drug Monitoring
MTM		Drug Therapy Management
NDMS		Non-Durable Medical Supplies
OST		Ostomy care products
WC		Wound Care
DME		Durable medical equipment (DME)

For reporting purposes the sub-categories created will be used in limited cases. Rather, reporting for this study will be summarized as “Drugs” and “Drug Related and Other” used for claims.

**Table 3.7: Grouping of Drug and Drug Related Claims**

Summary Title	Description
Drugs	Summary reporting titled “Drugs” represents drug products found within medical claims data. “Drugs” are level one claims and include codes developed for the purposes of this study. The codes included in “Drugs” are D, DA, DD, IM, and ESRD.
Drug Related and Other	Summary reporting titled “Drug Related and Other” represents drug related and other products found within medical claims data. “Drug Related and Other” are level two claims and include codes developed for the purposes of this study. The codes included in “Drug Related and Other” are A, MM, MTM, NDMS, OST, WC, and DME.

**3.3.2.3 Medical claims data elements 2006 to 2014**

There were variations in the data elements presented for “2006 to 2012” and for “2013 and 2014”. The variations were addressed, and a study data set was created — “Medical Claims Data 2006 to 2014” — combining the two data sets with data elements that were consistent across the “2006 to 2012” and “2013 to 2014” medical claims data sets. Table 3.8 shows the list of data elements, along with descriptions for UPlan medical claims data for all three data sets “2006 to 2012”, “2013 to 2014” and the combined data set for “2006 to 2014.” The UPlan medical claims data used for this study contained key descriptive data elements used to answer the study objectives outlined in Section 3.2. Data elements includes place of service identifiers, product identifiers, date, utilization and financial elements.

**Table 3.8: Medical Claims Data Elements: 2006 to 2014.**

<b>Medical Claims Data 2006 to 2014</b>				
<b>Data Element Type</b>	<b>2006 to 2012 Data Element</b>	<b>2013 to 2014 Data Element</b>	<b>Combined 2006 to 2014 Data Elements</b>	<b>Data Element Description</b>
Place of service identifier	place_serv_cd	Place of Service Code	Place of Service Code	Place of service codes are two digit codes used on professional claims and facility claims to specify the type of entity where service(s) were rendered.
Place of service identifier	place_service_descrip	Place of Service	Place of Service	A unique identifier for the site where the service was rendered
Product identifier	HCPCS	HCPCS	HCPCS	This field contains the HCPCS or CPT code for the product administered or the procedure performed.
Product identifier	proc_cd	Primary Procedure Code (HCPCS/CPT Codes)	Primary Procedure Code (HCPCS/CPT Codes)	This field contains the HCPCS or CPT code for the procedure performed.
Product identifier	proc_cd_descrip	HCPCS Code Description	HCPCS Code Description	Provides the description (name) for the HCPCS or CPT code used
Date	serv_yr	Year	Year	Year of claim
Date	serv_mth	Month	Month	Month of claim
Utilization	claim_line_count			Claim line count begins with 1 and is incremented by 1 for each additional service line of a claim.
Utilization	unique_claim_count	Unique Claim Count	Unique Claim Count	The number of unique claims submitted and paid

				by the UPlan under medical benefit
Financial	med_allow_chg_amt			Is the amount of total charges submitted by provider
Financial	med_paid_amt	Paid Amount (Plan Paid)	Plan Paid	The amount paid by payer (e.g employer like UPlan) for a claim
Financial	med_coins_amt	Coinsurance Amount	Coinsurance Amount	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a stated percentage of medical and pharmacy expenses after the deductible amount, if any, was paid
Financial	med_deduct_amt	Deductible Amount	Deductible Amount	A fixed dollar amount during the benefit period - usually a year - that an insured person pays before the insurer starts to make payments for covered medical and pharmacy services. Plans may have both per individual and family deductibles.
Financial	med_cob_amt	Coordination of Benefits (COB) Amount	Coordination of Benefits Amount	For members with a secondary insurance plan, COB represents the amount paid by the secondary plan
Financial	med_copay_amt	Copayment Amount	Copayment Amount	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a fixed dollar amount when a medical and pharmacy

				service is received. The insurer is responsible for the rest of the reimbursement
Financial	Total_Paid (Including COB)	Total Paid (including COB)	Total Paid (including COB)	The amount paid by plan and member including all member (e.g employer like UPlan) for a claim

### 3.3.2.4 Place of service data elements under medical benefits

There are many places of service under medical benefits where drugs are administered. Depending on what place of service the care was delivered, the claim is submitted using a different claim form. The majority of drug claims under medical benefit are submitted under professional and facility claim forms. Professional claims are claims submitted using the CMS-1500 standard claim form and are submitted by non-institutional physicians and other suppliers for non-institutional claim submission. Facility claims are those claims submitted using CMS-1450, also known as UB-04 standard claim forms. The CMS-1450 (UB-04) is used by institutional providers for billing institutional claims. Table 3.9 lists all the places of services present in the UPlan medical claims data from 2006 to 2014. As can be observed in Table 3.9, there are a few places of service with the majority of the claims. These include hospital outpatient (outpatient hospital), patient home (home), and office (other physician’s office). Given the two different data sources, the place of service names varied slightly between “2006 to 2012” and “2013 to 2014”. For example, for the place of service “Home”, the 2006 to 2012 data refer to it as “Patient Home”, while just “Home” is used for 2013 to 2014. To

address these slight differences in place of service names and also to consolidate the data in the table, a new summary classification and grouping was created that combined “like” places of service together, as shown in Table 3.10.



**Table 3.9: Unique Claim Count by Place of Service**

Place of Service	2006	2007	2008	2009	2010	2011	2012	2013	2014
AmbSurg - Free Standing	5	14	10	15	20	15	12	0	0
Ambulance-Land	0	0	0	0	0	0	0	7	6
Ambulatory Surgical Center	0	0	0	0	0	0	0	19	40
Birthing Center	0	0	0	0	0	0	0	3	6
Chiropractors Office	8	26	16	19	14	13	2	0	0
Clinic	2	13	18	27	7	10	7	0	0
Day Care/Night Care	0	0	0	0	0	2	0	0	0
Dentist Office	2	8	3	3	9	4	0	0	0
Emergency Room	0	0	0	0	0	0	0	1,373	1,293
Emergency Treatment Center	479	775	957	877	899	1,425	590	0	0
End-Stage Renal Disease Treatment Facility	0	0	0	0	0	0	0	71	103
Extended Care Facility	0	0	0	0	0	0	0	0	0
Federally Qualified Health Centers	0	0	0	0	0	0	0	6	2
Group Home	0	0	0	0	0	0	0	1	0
Home	0	0	0	0	0	0	0	6166	6084
Hospice	0	0	0	0	0	0	0	0	0
Hospital Emergency Room	39	195	196	106	35	20	6	0	0
Hospital Inpatient	74	81	127	144	155	103	22	0	0
Hospital Outpatient	132	238	236	242	343	319	217	0	0
Independent Clinic	0	0	0	0	0	0	0	0	12
Independent Lab	217	277	248	323	329	326	172	0	0
Independent Laboratory	0	0	0	0	0	0	0	398	773
Inpatient Hospital	0	0	0	0	0	0	0	222	228
Mass Immunization Center	0	0	0	0	0	0	0	466	379
Medical Rehab Center	0	4	0	0	0	0	0	0	0
Medical Rehabilitation - Outpatient	4	2	1	0	0	1	0	0	0
Nursing Facility	0	0	0	0	0	0	0	4	27
Nursing Home	0	0	6	1	0	0	0	0	0
OB/GYN Office	412	1762	1979	1939	1381	1521	887	0	0
Office	0	0	0	0	0	0	0	23,934	22,508
Other	212	279	102	156	131	170	56	0	0

Other Physician's Office	22,172	49,419	49,472	56,657	50,599	43,737	22,443	0	0
Outpatient Hospital	0	0	0	0	0	0	0	4,905	5,002
Patient's Home	4050	5,268	6248	6,884	7,602	7,326	4,817	0	0
Pharmacy	0	0	0	0	0	2	0	7	2
Podiatrist Office	122	168	222	210	198	160	143	0	0
Psychiatric Facility	0	0	0	0	0	0	5	0	0
Psychiatric Facility - Outpatient	0	0	0	0	0	0	0	0	0
Psychiatric Facility - Partial Hospitalization	0	0	0	0	0	0	0	2	0
Psychiatrist/Psychologist Office	8	3	7	7	4	9	21	0	0
Rural Health Clinic	0	0	0	0	0	0	0	20	8
School	0	0	0	0	0	0	0	21	22
Skilled Nursing Facility	73	39	11	2	0	2	0	0	0
State or Local Public Health Clinic	0	0	0	0	0	0	0	10	8
Unknown	4	337	247	528	879	727	1,058	0	0
Urgent Care Facility	0	0	0	0	0	0	0	1,007	825
Walk-In Retail Health Clinic	0	0	0	0	0	0	0	1,228	1,330
Grand Total	28,015	58,908	60106	68,140	62,605	55,892	30,458	39,870	38,658

**Table 3.10: Unique Claim Counts by Consolidated Place of Service**

<b>Place of Service</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Hospital Outpatient	136	240	237	242	343	320	217	4,905	5,002
Other Physicians Office	22,716	51,365	51,698	58,840	52,189	45,437	23,501	23,934	22,520
Home	4,050	5,268	6,248	6,884	7,602	7,326	4,817	6,166	6,084
Urgent Care & Emergency	518	970	1,153	983	934	1,445	596	2,380	2,118
Other	595	1,065	770	1,191	1,537	1,364	1,327	2,485	2,934
Total	28,015	58,908	60,106	68,140	62,605	55,892	30,458	39,870	38,658

### **3.3.2.5 Product identifiers under medical benefits**

The UPlan medical claims data contained two key product identifier data elements. These identifiers were “Primary Procedure Code”, also called HCPCS or CPT codes, and HCPCS and CPT code description. Healthcare Common Procedure Coding System (HCPCS) codes are divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I codes are comprised of Current Procedural Terminology (CPT-4), a numeric coding system maintained by the American Medical Association (AMA). The CPT-4 is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. These health care professionals use the CPT-4 to identify services and procedures for which they bill public or private health insurance programs. Level I of the HCPCS, the CPT-4 codes, does not include codes needed to separately report medical items or services that are regularly billed by suppliers other than physicians. Level II codes are a standardized coding system that is used primarily to identify products, supplies and services not included in the CPT-4 codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), when used outside a physician's office. Because Medicare and other insurers cover a variety of services, supplies and equipment that are not identified by CPT-4 codes, the Level II HCPCS codes were established for submitting claims for these items.

Most HCPCS Codes are Level 1 Current Procedural Terminology (CPT) codes. These are procedures performed by health care individuals billed using CPT codes typically not drugs. Other HCPCS codes that are typically not drugs include Level III

Local Codes. Level III codes are alphanumeric and begin with a letter that is followed by four numbers, and range from W0000 to Z0000. Local Medicare carriers assign and maintain Local Level III codes that vary from carrier to carrier. The codes that identify the majority of drugs and drug related services are Level II National Codes. Level II National Codes are alphanumeric and start with a letter followed by four numbers. The codes range from A0000 to V0000. In addition to the Level II codes, there are National Level II Modifiers. A modifier indicates that the reporting provider can indicate that a service or procedure that has been performed has been altered somehow, but not changed in its definition or code. Currently, there are over 2,400 HCPCS National Level II codes that cover supplies, materials, injections and services. The HCPCS National Level II code descriptions are all uniform throughout the United States. Level II National HCPCS

Codes include:

A0000-A0999	Transportation Services
A4000-A7509	Medical and Surgical Supplies
A9000-A9999	Miscellaneous and Experimental
B0000-B9999	Enteral and Parenteral Therapy
C0000-C9999	Temporary Hospital Outpatient PPS
D0000-D9999	Dental Procedures
E0000-E9999	Durable Medical Equipment (DME)
G0000-G9999	Temporary Procedures and Professional Services
H0000-H9999	Rehabilitative Services
J0000-J8999	Drugs Administered Other than Oral Method
J9000-J9999	Chemotherapy Drugs
K0000-K9999	Temporary Codes for DMERCS
L0000-L4999	Orthotic Procedures
L5000-L9999	Prosthetic Procedures
M0000-M9999	Medical Services
P0000-P9999	Pathology and Laboratory
Q0000-Q9999	Temporary Codes
R0000-R9999	Diagnostic Radiology Services
S0000-S9999	Private Payer Codes
T0000-T9999	State Medicaid Agency Codes
V0000-V2999	Vision Services

While useful in identifying drugs and drug-related claims, HCPCS and CPT codes don't provide detailed information about drug products like the information linked to NDC codes under pharmacy claims. The use of HCPCS and CPTs to identify drug products under medical benefit significantly limits the employer's ability to do an in-depth assessment of drug products used and their cost. Table 3.11 provides a comparison between HCPCS/CPT code and NDC codes for Mycophenolic acid. When comparing NDCs to HCPCS to identify drug products, there are some key differences. The NDC code provides the primary data representation for drugs flowing through pharmacy benefit, with the classification code based on drug labeler (manufacturer or distributor), the product code (identifying the drug strength, dosage and formulation) and package code (package size and type). The NDC codes are defined based on the labeler and Food and Drug Administration assignments. Thus, while NDC codes provide product, manufacturer, and packaging details, HCPCS only provide limited product information.

Under the pharmacy benefit the NDC code of the product that was dispensed to the patient is the same NDC code used for billing, and that NDC code shows up in the claims data. The use of HCPCS for identifying drugs within medical claims creates a data granularity problem, which is a major concern since the codes may not fit well with the actual drug packaging or typical dosing regimens used at point of care. This is because there may be multiple NDCs that are represented by one HCPCS code. The addition of a higher degree of data granularity to HCPCS code data could improve the specificity of dosing-related information and could enhance data quality. In part, the one (HCPCS) to many (NDCs) problem occurs as a result of the effort to make the HCPCS function for a

variety of products and dosages that may be used in clinical practice. Thus, an employer does not know what NDC or what price is associated with the drug product used at the point of care. As a result the price associated with HCPCS/CPT code within claims data is not necessarily reflective of the actual drug product administered, but rather what the institution bills. While CMS sets payment limits for each HCPCS/CPT code, this might not necessarily be followed for commercial payers such as the UPlan. Table 3.12 displays all the NDC codes under HCPCS C9219, along with the prices associated with each NDC. The example of C9219 demonstrates that there is much more granular information about the drug product at the NDC level than at HCPCS/CPT level.

**Table 3.11. HCPCS/CPT versus NDC**

Drug Information From HCPCS/CPT		Drug Product Information from NDC							
HCPCS	HCPCS Description	NDC	Labeler Name	Drug Name	Generic Name	Strength	Unit of Measure	Total Package Quantity	Package Quantity
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID, ORAL, PER 180 MG	60505296507	APOTEX	Mycophenolic Acid	Mycophenolate Sodium Tab	180	MG	120	1
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID, ORAL, PER 180 MG	00378420178	MYLAN	Mycophenolic Acid	Mycophenolate Sodium Tab	180	MG	120	1
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID, ORAL, PER 180 MG	00378420278	MYLAN	Mycophenolic Acid	Mycophenolate Sodium Tab	360	MG	120	1
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID, ORAL, PER 180 MG	51079050920	MYLAN INSTITUTIONAL	Mycophenolic Acid	Mycophenolate Sodium Tab	360	MG	100	1
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID,	00078038566	NOVARTIS	Myfortic	Mycophenolate Sodium Tab	180	MG	120	1

	ORAL, PER 180 MG								
C9219	Mycophenolic acid, oral MYCOPHENOLIC ACID, ORAL, PER 180 MG	00078038666	NOVARTIS	Myfortic	Mycophenolate Sodium Tab	360	MG	120	1

**Table 3.12: Prices of NDCs under HCPCS Code C9129**

NDC	Product Name	Active Ingredient	Manufacturer/Distributor	Strength	Package Size	WAC Package Price	AWP Package Price	AWP Unit Price
16729-0261-29	MYCOPHENOLIC ACID	mycophenolate sodium	ACCORD HEALTHCARE, INC.	180 mg	120s ea	\$438.60	\$548.26	\$4.57
60505-2965-07	MYCOPHENOLIC ACID	mycophenolate sodium	APOTEX CORP.	180 mg	120s ea	\$438.60	\$548.26	\$4.57
00378-4201-78	MYCOPHENOLIC ACID	mycophenolate sodium	MYLAN PHARMACEUTICALS, INC.	180 mg	120s ea		\$548.26	\$4.57
51079-0508-20	MYCOPHENOLIC ACID	mycophenolate sodium	MYLAN INSTITUTIONAL, INC.	180 mg	100s ea	\$405.17	\$506.46	\$5.06
00078-0385-66	MYFORTIC	mycophenolate sodium	NOVARTIS PHARMACEUTICALS CORP.	180 mg	120s ea	\$624.42	\$749.30	\$6.24
16729-0189-29	MYCOPHENOLIC ACID	mycophenolate sodium	ACCORD HEALTHCARE, INC.	360 mg	120s ea	\$877.20	\$1,096.50	\$9.14
60505-2966-07	MYCOPHENOLIC ACID	mycophenolate sodium	APOTEX CORP.	360 mg	120s ea	\$877.20	\$1,096.50	\$9.14
00378-4202-78	MYCOPHENOLIC ACID	mycophenolate sodium	MYLAN PHARMACEUTICALS, INC.	360 mg	120s ea		\$1,096.50	\$9.14
68084-0918-25	MYCOPHENOLIC ACID	mycophenolate sodium	AMERICAN HEALTH PACKAGING	360 mg	30s ea	\$228.24	\$300.00	\$10.00
51079-0509-20	MYCOPHENOLIC ACID	mycophenolate sodium	MYLAN INSTITUTIONAL, INC.	360 mg	100s ea	\$810.34	\$1,012.92	\$10.13
00078-0386-66	MYFORTIC	mycophenolate sodium	NOVARTIS PHARMACEUTICALS CORP.	360 mg	120s ea	\$1,248.85	\$1,498.62	\$12.49

### 3.3.2.6 Date identifier under medical benefits

The UPlan medical claims data was provided aggregated at the month and year level from 2006 to 2014. The unique claims and all financial fields for each HCPCS or CPT code were aggregated at the month and year level. The findings for this study are reported at the year level. When appropriate, some results are reported at that month and year level.



### **3.3.2.7 Utilization data elements under medical benefits**

Utilization for this study is represented by unique claim counts for each HCPCS or CPT code. Ideally, utilization is measured by “units” of the particular product or service utilized, as represented by the HCPCS or CPT code. While “units” could have been provided for this study, the major limitation in using units is the lack of consistency in reporting the units of measure associated with units reported. Different providers may report units and units of measure associated with the same HCPCS code or CPT code differently. This is a major limitation of this study and current marketplace reporting on drug utilization under medical benefits with the use of HCPCS and CPT codes. To combat this limitation, the use of NDC codes, along with units and units of measure as observed under pharmacy claims is recommended. In fact, the health plan provider for the UPlan is currently developing this capability as of this writing. However, for this retrospective study the use of unique claims as a measure of utilization, while not ideal, is sufficient. Claim counts are also used for pharmacy claims.

### **3.3.2.8 Financial data elements under pharmacy benefits**

Several primary financial variables are present in the UPlan medical claims data. The UPlan aggregated medical claims data presented only paid amount financial variables. The primary financial variables used in this study were paid financial variables aggregated at the HCPCS and CPT code level by month and year, and by place of service. The paid financial variables include member, employer and secondary payer cost share. Member cost share data elements include copay, coinsurance and deductible. Employer cost share elements include paid amount, and secondary payer cost share coordination of benefit (COB). The total paid is the sum of all of the paid financial variables, including

member paid, employer paid and secondary payer paid. To obtain total paid amount paid.

Financial variables were added together in the following equation:

$$\text{Total Paid Amount} = \text{Copay} + \text{Coinsurance} + \text{COB} + \text{Deductible} + \text{Plan Paid}$$

### **3.4 Data quality, data linking, and data enchantments**

The data provided for this study was aggregated clean paid claims data, which is the data UPlan used to make business decisions. The data provided for pharmacy and medical claims data were assessed for completeness and quality. Each provided data variable was evaluated to ensure that data was complete and appropriate for that specified variable. For example, did the data values provided for financial, utilization and date variables make sense? When outliers were identified, the data source was consulted for clarification and context.

#### **3.4.1 Data quality**

Data quality checks are a critical part of using claims data to evaluate trends. Each variable in this study needs a level of precautionary controls to ensure appropriate operation of the variable from the data source. Appendix 1 and Appendix 2 describe some of the data elements. Ensuring the quality of data source is critical for a retrospective claims analysis. Key steps to ensure quality of data include checking for relevance and reliability/validity of the data source. To ensure relevance, each data attribute is described. Steps were taken to ensure reliability and validity of the data, including data quality checks. The data for this study was originally collected for administrative purposes rather than research purposes. It was collected for claims processing and payment. Quality checks are important with administrative databases and were

performed to prevent unreliability of data that may occur due to changes in reporting/coding over time.

It is important to note that depending on the type of claim data used, the process to check the quality of data varies. For example, if the data provided for this study was claim-level data, and not aggregated data, then the process would include not only data quality check, but also data cleaning processes. This is because claims level data contains not only paid claims, but also other types of claim records, including claim inquiries, claim reversals, claim duplication and claim denials. All of these additional claim records within claims data must be cleaned and resolved prior to assessment of claims data.

The cleaning process for pharmacy claims data includes identification of invalid or duplicated claim records, listed below. If evaluating claims level pharmacy claims data shows invalid or duplicated claim records they have to be identified and removed. Below is a list of conceptual reasons for prescription claims records invalidation and/or duplication.

1. *Inquiries*: Claim records that are price or coverage inquiries by the pharmacy, but not filled prescriptions, remove each claim record and no paid claim exists.
2. *Reversals*: There are claim records that were run as a claim, but reversed. The initial claim and the reversal claim would need to be removed. A reversal claim is a claim that has a duplicate claim with an opposite financial charge and paid amounts, and thus the sum of a claim and its reversal claim has to be zero.
3. *Duplicated claims*: A duplicated claim is one that has identical claim elements, including the same prescription number and the same service date as well as:
  - Member Unique ID

- Member Gender
- Member Age
- Provider ID
- Pharmacy ID (or Zip Code)
- NDC (for a specific Rx it is possible that different NDC numbers may be used; however the NDC number was included, so there is one claim number per NDC)

4. Claim denials: When a claim is submitted for a prescription, but in the adjudication process is found to be: (1) not covered, (2) lacking prior authorization, (3) refilled too early, or (4) subject to other utilization or management controls that result in denial of the claim, the claim record will be considered invalid for inclusion in the clean claim data set. These claims may be present in the data as:

- Zero quantity, Zero payment financial fields
- Negative quantity, Negative payment financial fields

The claims-level data cleaning process for medical claims includes identification of invalid or duplicated claim records. Below is a list of conceptual reasons for prescription claims records invalidation and/or duplication.

1. Reversals: Claim records that are paid for and then reversed (2 records). Both claim records are removed. A reversal claim is a claim that has a duplicated claim with an opposite financial charge and paid amounts, and thus the sum of a reversal claim has to be zero.

2. Claims adjustments and late charges: Claims submitted for a late charge using the same claim number as a claim that was previously submitted and processed.

3. Duplicated claims (Same as double billing) A claim record may be submitted twice, either accidentally or fraudulently. When there are two claims for the same prescription event and no other plausible explanation can be found, the last filed claim record will be assumed to be the correct record and the earlier of the claim records will be considered invalid.

4. Claim denials: When a claim is submitted for a prescription, but in the adjudication process is found to be: (1) not covered, (2) lacking prior authorization, (3) refilled too early, or (4) subject to other utilization or management controls that result in denial of the claim, the claim record will be considered invalid for inclusion in the clean claim data set.

5. Zero or negative charges: Out-of-balance claims result from a claim with a negative or zero charge amount. Thus, claims with a negative or zero charge must be evaluated to ensure that the claim is not out-of-balance. An out-of-balance claim occurs when you have a positive paid amount, but you have a negative or zero charge.

#### **3.4.1.1 Pharmacy claims data quality**

The clean aggregated paid pharmacy claims data provided for this study was reviewed and evaluated for data quality. A key focus was on the completeness of data for important variables, such as National Drug Code (NDC) number, amount paid (total, plan, member, and COB), number of units, number of days and number of clean paid claims over time. Variables were examined for the presence of valid codes for categorical variables, and/or the range and distribution of responses for continuous variables. Once this initial assessment is complete, the pharmacy aggregated claims data was linked to a

drug information database (i.e., Medi-Span Rx Pro+) to provide enhancement of the claims data with other drug product variables and data.

#### **3.4.1.2 Medical claims data quality**

The clean aggregated paid medical claims data provided for this study was reviewed and evaluated for data quality. All medical claims data fields were examined to determine if they represent claims for drug products administered as a medical benefit. The primary method to identify drug claims in the medical claim data set was HCPCS codes. The most common HCPCS codes for drugs are known as "J codes". However, there are other codes that also represent drug products, such as A, B, C, Q, P, S, CPT, and other codes. A key focus was on the completeness of data for important variables such as HCPCS codes, amount paid (total, plan, member, and COB), and number of clean paid claims over time. Once this initial assessment was complete, the medical aggregated claims data was linked to a drug information database (i.e., Medi-Span NDC-HCPCS Crosswalk, Medi-Span Rx Pro+) to provide enhancement of the claims data with other drug product variables and data.

#### **3.4.2 Data enhancement**

The aggregate paid pharmacy and medical claims data were enhanced by adding other classification variables from a drug information database, Medi-Span Price Rx Pro, as well as calculated relational utilization and financial variables.

Relational quantitative measures were analyzed and calculated, examined and evaluated. As used here, the term "relational" variable means a new measure calculated using two different primary measures, such as the aggregate amount paid on claim

divided by the aggregate number of claims to yield the relational variable of amount paid per claim. Relational quantitative measures used is the dollar amount paid per claim (including total, plan, member, COB, paid amounts). As noted above, the dollar amounts paid may be reported as total amounts, or the amounts may be broken down to plan paid amount and patient paid out-of-pocket amount. Each of these relational variables were calculated and assessed for data quality purposes. Outliers for these relational variable values were evaluated underlying data integrity issues in the primary variables.

Medi-Span Price Rx provides information on pharmaceutical drug products, chemicals, over-the-counter (OTC) products, medical devices, supplies and related times. Medi-Span Price Rx Pro database assigns each NDC to a specific Generic Product Identifier (GPI). The GPI defines pharmaceutically equivalent drug products that are identical in terms of:

- Active ingredients(s)
- Route of administration
- Dosage form
- Strength or concentration
- Therapeutic use

Medi-Span Price Rx Pro database provides an indicator for drug application type from the Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluation (also known as Electronic Orange Book). Drug application type indicators include New Drug Application (NDA), Abbreviated New Drug Application (ANDA) and Biologic License Application (BLA). Medi-Span Price Rx Pro provides an indicator for what name is linked with each NDC trademarked name (T), branded generic name (B) or generic name (G). In addition it provides Multi-Source Codes, which identify drug products as either single or multiple source original drug

products or a generic copy of the standard drug product. Some of the key data elements provided by Medi-Span Price Rx Pro include:

- American Hospital Formulary Service Code: American Society of Health-System Pharmacists to use the American Hospital Formulary Service Therapeutic Classification Compilation (AHFSCC) Code.
- Brand name code
- CMS drug category code
- Daily dosage unit and duration values
- DEA class codes
- Dosage form
- Inactive date/inactive flag
- Labeler name/labeler code and labeler type code
- Limited distribution code
- Maintenance drug code
- NDC effective date
- Package description, package size, package size unit of measure, and package quantity
- Route of administration
- Rx-OTC Code
- Therapeutic Equivalence Evaluation Code

#### **3.4.2.1 Pharmacy claims data enhancement**

If there were any pharmacy claims with NDCs that do not match to the NDC numbers in the Medi-Span Price Rx Pro database, those claims were reviewed in an attempt to resolve any mismatches. After a reasonable attempt to resolve mismatches, the claims not matching were labeled as unknown and reported accordingly in analysis. Among the enhanced classification variables that are available in the Medi-Span database are the following:

1. Generic Product Identifier (GPI). A 14-digit hierarchical code attached to each NDC number and thus each claim in the pharmacy data set. The GPI code breaks drug products down to a unique set of interchangeable drug products regardless of manufacturer or package size. The code consists of seven subsets, each providing increasingly more specific information about a drug product. For example, the GPI code 58-20-00-60-10-01-05 is for the drug product known as Nortriptyline HCL cap 10 mg (an antidepressant) and can be further classified as follows:



S	Drug Range	Central Nervous System Drugs
58	Drug group	Antidepressants
58-20	Drug class	Tricyclic agents
58-20-00	Drug sub-class	
58-20-00-60	Drug name	Nortriptyline
58-20-00-60-10	Drug name extension	Nortriptyline Hydrochloride
58-20-00-60-10-01	Dosage form	Capsule
58-20-00-60-10-01-05	Strength	10 mg.

There are other systems for grouping drug products by therapeutic class, such as the IMS Uniform System of Classification (USC) code or the American Hospital Formulary Service (AHFS) code. For this project GPI level classification was used.

2. Therapeutic equivalence code. This is a code assigned by the U.S. Food & Drug Administration to indicate which generic drug products have been shown to have bio-equivalence to the reference listed brand name drug product and can thus be substituted by pharmacists when dispensing a prescription. The therapeutic equivalence code indicates which drug products can be "generically substituted" by the pharmacist.

3. Regulatory Status. Regulatory status indicates whether a drug product is available by prescription only (Rx) or over-the-counter (OTC). Even though the pharmacy data set is prescription claims, a certain number of the prescribed drugs are for drugs that are available OTC.

4. Patent & Exclusivity Status. This code indicates whether a drug product is under patent or has market exclusivity and whether it has market competitors. The categories under this code (variable) are:

- N Single source ( the Product is patented or has an active exclusivity)  
aka: Single source (SS) or Patented brand
- M Co-licensed single source (meaning licensed by patent/exclusivity holder)  
aka: Co-licensed single source (Co-SS), Co-licensed brand
- O Originator (meaning original NDA holder with generic competitor)  
aka: Innovator multiple source (IMS), Off-patent brand
- Y Generic (meaning off-patent and exclusivity and 1 or more other therapeutically equivalent drug products in the market) aka: Non-innovator multiple source (NMS) generic

5. Brand and generic code. This category is similar to the Patent and exclusivity code above, but this code simplifies the code to a dichotomous variable, with the options being either "B" (brand) or "G" (generic). The Brand code includes the SS, Co-SS, and IMS categories. The "Generic" code includes the NMS category.

6. Dosage Form. There are about 100 different dosage forms for drug products. For purposes of this project, these codes were collapsed into only a few broad categories, such as oral-solid, oral-liquid, injectable, topical, ophthalmic, and other.

7. Specialty code. There is no specialty code in Medi-Span or any other commercial database. This code was developed using other categorical criteria in the Medi-Span database (e.g., FDA approval type, that is, NDA or BLA) and was supplemented with other data, such as price per claim or prescription.

8. Date of market approval. Indicates the date a drug product was first approved by the FDA to be marketed in the United States.

9. FDA approval type. Indicates whether a drug product was approved by the FDA based upon submission of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biological License application (BLA). The NDA and ANDA drug products are typically traditional, small molecule drugs, while the BLA drug products usually are referred to as “biologicals”. Most biologicals are considered to be specialty drug products.
10. Other codes and categorical variable in the Medi-Span database were used, if needed, and as appropriate.

Once the NDC linkage between the pharmacy claims data and the Medi-Span Price Rx Pro database was made, the relevant Medi-Span variables were appended to the pharmacy claim record. These variables were used for grouping drug products into useful categories for analysis.

#### **3.4.2.2 Medical claims data enhancement**

Three levels of data enhancement were completed for drugs flowing through the medical benefit. First, the UPlan medical claims data was linked to Medi-Span’s HCPCS-NDC Crosswalk data set. Second, the UPlan data linked with Medi-Span’s HCPCS-NDC Crosswalk data set was then linked to Medi-Span Price Rx Pro. Finally, a HCPCS codes classification into drug and drug-related groups was created by an expert process using one physician and one pharmacist.

UPlan medical claims data was linked with Medi-Span’s HCPCS-NDC Crosswalk data set using HCPCS codes. Medi-Span’s HCPCS-NDC Crosswalk data set was used to provide detailed drug information for drugs paid for under medical benefits present in the medical claims. The HCPCS was developed by the federal government’s Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services, CMS) to standardize the coding system used to process Medicare claims. Healthcare Common Procedure Coding System (HCPCS) are used to bill for

supplies, materials, injections, various services and procedures. The Medi-Span HCPCS database contains a linking file of NDC to HCPCS codes along with HCPCS code description. Only those Level II National HCPCS codes representing products that are also present in the Medi-Span Drug files are included in the Medi-Span HCPCS-NDC files. Level II HPCPCS codes that are related to drugs, but not associated with a specific product and thus not linked with an NDC, included J3490 (Unclassified drugs), J3590 (Unclassified biologics), J9999 (Not otherwise classified, antineoplastic drugs) and C9399 (Unclassified drugs or biologics [Medicare hospital outpatient setting]).

The Medi-Span HCPCS-NDC Crosswalk database was then linked with Medi-Span Price Rx Pro using NDCs. Medi-Span Price Rx Pro contained a therapeutic classification hierarchy known as the Generic Product Identifier (GPI). Once the data was linked at the NDC level, the HCPCS database was then organized at the GPI level, as each HCPCS may be linked with multiple NDCs. In addition, each HCPCS may also be linked with multiple GPI 14s. In order to have a one-to-one connection between HCPCS and GPI, it was determined that the highest level of GPI to be in reference database was GPI6. The reference database then had GPI 06, GPI 04, GPI 02, GPI 00. Examples of GPI 06, GPI 04 and GPI 02 are provided below:

S	Drug Range	Central Nervous System Drugs
58	Drug group	Antidepressants
58-20	Drug class	Tricyclic agents
58-20-00	Drug sub-class	

This allowed for each HCPCS code to be linked with one GPI. Many HCPCS that don't identify a specific drug product were linked with the unknown GPI Group. Expert evaluations of HCPCS codes that were linked with NDCs, but were not appropriately

linked with a GPI class, were manually evaluated and manually assigned to an appropriate GPI Group. An iterative development approach was used to develop a final reference database crosswalk file, including HCPCS codes, NDC codes, therapeutic classification using Medi-Span's GPI (level 6) and the specialty drug classification described in section 3.5.

The UPlan data enhanced by the above steps was then evaluated manually by two experts (one physician and one pharmacist) to create classification codes as drug or drug-related codes for each HCPCS. The physician and pharmacist expert reviewers utilized available sources, including the Center for Medicare and Medicaid Services (CMS) public use HCPCS files, Medi-Span HCPCS Codes Database, Release (9/2015) Medi-Span Price Rx Pro® Release (9/2015), and Micromedex to assist in the classification process. Drugs and drug related code HCPCS codes were identified and classified and grouped accordingly. Each HCPCS code was classified into the following codes:

D	Drugs	HCPCS codes that represent drug products
DA	Drug and Drug Administration	HCPCS codes that represent both a drug and its administration together
A	Drug Administration	HCPCS codes that represent drug administration and drug administration supplies
DD	Diagnostic Drugs	HCPCS codes that represent drugs used for diagnostics
I	Immunization and Immunization Administration	HCPCS codes that represent drugs for immunization and immunization administration
ESRD	End Stage Renal Disease	HCPCS codes for drug-related HCPCS codes used ESRD
DM	Drug monitoring	HCPCS codes representing drug monitoring
MTM	Drug Therapy Management	HCPCS codes representing MTM services
DME	Durable Medical Equipment	HCPCS codes that represent claims for DME
NDME	Non-Durable Medical Equipment	HCPCS codes that represent NDME
WC	Wound Care	HCPCS codes that represent wound care products
OST	Ostomy Care Products	HCPCS codes that represent Ostomy care products

At first glance the HCPCS codes represented in some of the above classification groups may not make sense being a part of drug and drug-related codes.

However, these codes are included: 1) if they were a part of the Medi-Span’s HCPCS-NDC Crosswalk data set, and 2) if determined experts (one physician and one pharmacist) to fit into one of the above groups.

### 3.4.2.3 Combining pharmacy and medical claims data

A summary data set combining both pharmacy and medical claims data was created. This data set aligned and combined similar data elements from pharmacy and medical claims data. The combining of the two data sets was helpful in answering several of the research objectives outlined in this study regarding specialty drugs. Table 3.13 contains the data elements contained in the pharmacy and medical claims data.

**Table 3.13 Data Elements for Combined Pharmacy and Medical Claims Summary Data**

<b>Data Element Type</b>	<b>Combined 2006 to 2014 Pharmacy and Medical Data Elements</b>	<b>Data Element Description</b>
Record identifier	Type of Claim	Indicates if the line is a HCPCS code or an NDC code
Place of service identifier	Place of Service Code	Place of service codes are two digit codes used on professional claims and facility claims to specify the entity where service(s) were rendered under medical benefit. A letter (R, M, S, RM) indicates the pharmacy type where the drug was dispensed to the user under pharmacy benefit.
Place of service identifier	Place of Service	Provides the name for the place of service code where service was rendered under medical benefit, and provides the pharmacy type name (retail, mail, specialty, mail at retail) where the drug was dispensed under pharmacy benefit
Product identifier	NDC/HCPCS	This field contains the NDC or HCPCS or CPT code
Product identifier	Drug Name	Provides the description (name) for the NDC and HCPCS or CPT code used

Date	Year	Year of claim
Date	Month	Month of claim
Utilization	Unique Claim Count	The number of unique claims submitted and paid by the UPlan under medical benefit
Financial	Plan Paid	The amount paid by payer (e.g employer like UPlan) for a claim
Financial	Coinsurance Amount	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a stated percentage of medical and pharmacy expenses after the deductible amount, if any, was paid
Financial	Deductible Amount	A fixed dollar amount during the benefit period - usually a year - that an insured person pays before the insurer starts to make payments for covered medical and pharmacy services. Plans may have both per individual and family deductibles.
Financial	Coordination of Benefits Amount	For members with secondary insurance plan, COB represents the amount paid by the secondary plan
Financial	Copayment Amount	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a fixed dollar amount when a medical and pharmacy service is received. The insurer is responsible for the rest of the reimbursement
Financial	Total Paid (including COB)	The amount paid by plan and member including all member (e.g employer like UPlan) for a claim
Product identifier	SP Classification	Specialty classification code developed by experts
Product identifier	Drug Classification	HCPCS code classification codes developed by experts (Only for HCPCS)
Product identifier	GPI0	Highest level therapeutic classification
Product identifier	GPI0 Name	Therapeutic classification name
Product identifier	GPI02	Drug group code
Product identifier	GPI02 Name	Drug group code name

### **3.5 Operationalization of specialty drug definition**

Specialty drug classifications were developed by experts in the pharmaceutical market, and clinical expert reviews were completed by four pharmacists and a physician. Specialty drug classification of drugs and drug-related products flowing under the medical benefit were completed at the Health Care Procedural Coding System (HCPCS) code level. Specialty drug classification for drugs flowing under the pharmacy benefit was completed at the Generic Product Identifier (GPI) level. Manual review and validation was completed to ensure specialty drug classification at the drug name level was identical between drugs flowing under pharmacy and medical benefit. The expert review panel identified several characteristics associated with specialty drug classification. The drug class, dosage form, product handling, product administration, product administration site of care, clinical indication, orphan drug status, and need for clinical monitoring were characteristics identified to be associated with individual drugs having specialty status. Several specific drug types were also associated with specialty status, including radiopharmaceuticals and antidote drugs. Cost was considered in determining specialty status, in particular high cost per unit or per course of therapy drugs. However, high cost alone was not sufficient to determine that a drug product should be assigned to a specialty status.

#### **3.5.1 Specialty drug operationalization under Pharmacy claims**

1. Identify the universe of GPI codes considered to be drugs and drug-related codes for study. This identification was completed using Medi-Span's GPI dataset, which included crosswalk of GPI to NDCs.

2. Drug or drug-related products were classified at the GPI level to identify drugs and drug-related products and assign their status as a specialty drug or specialty drug-related product by expert reviewers. Each reviewer completed an independent review of the drugs and scored each drug as “specialty” or “non-specialty”. After each reviewer had assessed the drug, the reviewers met as a group to reach a consensus on the specialty status of each product at the GPI code level. This process was repeated a second time on a different date for data validation purposes.

3. This list of GPIs with specialty classification information was then linked to UPlan pharmacy claims data at the NDC level.

### **3.5.2 Specialty drug operationalization under Medical claims**

1. Identify the universe of HCPCS codes considered to be drugs and drug-related codes for study. This identification was initially completed for a study conducted for the Minnesota Department of Health using the Minnesota All Payers Claims Database (MN-APCD). A list of HCPCS codes identified in the MN APCD database was cross-walked to Medi-Span’s HCPCS-NDC crosswalk database, which was then linked to the Medi-Span PriceRx Pro database, which included NDC and GPI level data.

2. The HCPCS list linked to GPI were used to define specialty drugs. Drug or drug-related products were defined at the HCPCS level to identify drugs and drug-related products and assigned their status as a specialty drug or specialty drug-related product by expert reviewers. Each reviewer completed an independent review of the drugs and scored each drug as “specialty” or “non-specialty”. After each reviewer had assessed the



drugs and drug-related products, the reviewers met as a group to reach a consensus on the specialty status of each product at the HCPCS code level.

3. This list of HCPCS codes with GPI and specialty classification information was then linked to the UPlan data set at the HCPCS level.

### **3.6 Statistical analysis process for each study aim and research question**

The research design for this study is a retrospective descriptive analysis of administrative pharmacy and medical claims data. This study evaluates several variables, including those that may have a slight variation between pharmacy and medical claims. For pharmacy claims, expenditure is the dependent variable. Independent variables include utilization identified as the number of claims and drug characteristics. For medical claims, expenditure is the dependent variable. Independent variables include utilization identified as the number of claims, drug characteristics, and site of service.

### **3.6.1 Aim 1**

Aim 1 contained research questions 1a and 1b. Each of the research questions presented in Aim 1 are descriptive analysis.

### **3.6.2 Aim 2**

Aim 2 contained research questions 2a to 2e. Each of the research questions presented in Aim 2 are descriptive analysis.

### **3.6.3 Aim 3**

Aim 3 contained research questions 3a and 3b. Each of the research questions presented in Aim 3 are descriptive analysis.

### **3.6.4 Aim 4**

Aim 4 contained research questions 4a to 4c. Each of the research questions presented in Aim 4 are descriptive analysis.

## **3.7 Study Limitations**

A limitation of the overall study is that it was done at the aggregated level rather than at the claim level. Thus, the study is limited to aggregated trends rather than being able to drill down to the individual claim and member level trends over time. The key

assessments employers can benefit from at the claim level and not at the aggregate level include, but are not limited to:

- Claim level variation in utilization and expenditures by
  - Site of service or channel of distribution
  - Provider
  - NDC
- Appropriateness of claims in utilization and expenditure by
  - Site of service or channel of distribution
  - Provider

The ability to identify variations among sites of service or distribution channel, provider, and NDC are critical to helping employers identify management opportunities.

### **3.7.1 Study limitations under pharmacy benefits**

The use of aggregated pharmacy claims data limits the ability to do detailed analysis at the claim level. For example, when it comes to pharmacy claims, both traditional and specialty claims, an employer may be interested in knowing the cost variations for the same NDC and quantity between different distribution channels and specific pharmacies. Likewise, if the claims level data was available an assessment could be made of provider trends and variations. Such as: Are the providers writing for specialty prescription drugs qualified to do so? In addition, evaluating claim line data allows an employer to identify reimbursement differences within the GPI group. All of these provide an opportunity for an employer to deploy different specialty management

strategies. However, given the aggregated nature of this study, this level of assessment and strategy development is not possible.

### **3.7.2 Study limitation under medical benefits**

A major limitation of medical drug claims data is that it does not include direct links in the reimbursement data between the HCPCS and the associated drug used by NDC, drug quantity dispensed/administered, and units of measure, creating a major secondary data use problem. In addition, when new drug products come to market, they receive NDC codes immediately. However, it may take six months to a year for them to be assigned a HCPCS code. In those cases, several HCPCS programs use the “not otherwise specified”, “not otherwise classified”, or “other” subclasses. While providing a coded component for reimbursement, these subclasses fails to provide specific insight on the actual drugs utilized. In attempting to find a solution to the low granularity of the HCPCS and help manage secondary data use, all HCPCS codes were reviewed and linked in a crosswalk file to NDC codes. However, many of the HCPCS did not have a corresponding NDC for use, in part due to the inclusive nature of the HCPCS coding selection process, which included drug HCPCS codes related to drug administration. Outside these “non-drug” elements, which would be expected to have low propensity to match to NDCs, the ambiguity of the HCPCS code system was a bigger problem. Basically, every drug product in the market has an NDC code which could be linked, but since NDC data was not present at the point of claim creation, the inherent HCPCS

ambiguity prevented these drugs from being readily identified and linkable retrospectively to other drug information sources, even after extensive expert review.

To address this major limitation in practice, starting in 2014, the UPlan, along with other employers in the state of Minnesota, started asking for the inclusion of NDC codes as a requirement for billing and reimbursement for drugs flowing through the medical benefit. Starting in 2017 the health plan managing the UPlan's medical benefit started requiring and collecting NDC codes for drugs flowing through the medical benefit. This change in employer demand from the medical claims processor echoed the importance of NDC codes on the medical side of the benefit. While the UPlan has made progress, there are many employers in the market place who don't use NDC codes for drugs on the medical side of the benefit because their health plans are not requiring them as part of the billing process. Until they do, their ability to fully understand drug trends on the medical side of the benefit will be limited.

## CHAPTER 4: RESULTS

### 4 Introduction

This chapter consists of five sections. The first section outlines general trends observed. The second section outlines results for study Aim one and associated research questions. The third section outlines results for study Aim two and associated research questions. The fourth section outlines results for study Aim three and associated research questions. The fifth section outlines results for study Aim four and associated research questions.

#### 4.1 General trend

Total drug and drug-related expenditures grew by 76.5 percent (\$28,536,013.47 million), from \$37,313,004.20 to \$65,849,017.67 million from 2006 to 2014 respectively, as seen in Figure 4.1.

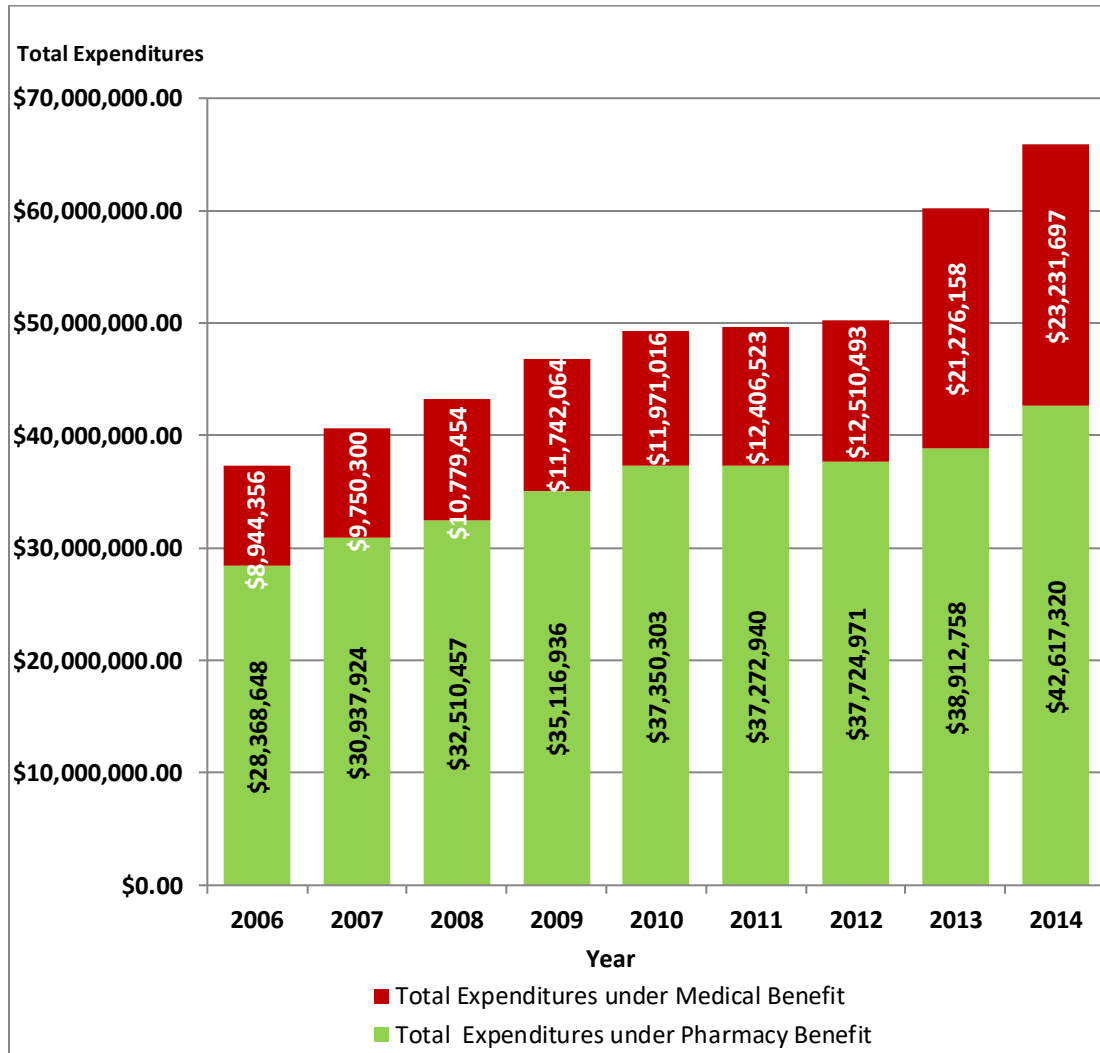
##### 4.1.1 Overall trends

Drug and drug-related expenditures under pharmacy benefit were greater than drug and drug-related expenditures under medical benefit.

The largest expenditures were observed in 2014 for both pharmacy and medical benefit at \$42,617,320.44 and \$23,231,697.23 million, respectively. Drug and drug-related expenditures under both pharmacy and medical benefits had some fluctuation over 2006 to 2014, although there was a general trend of expenditure increases as seen in monthly data in Figure 4.2. There was an exceptional and substantial drop in December 2012 for drugs and drug-related expenditures under the medical benefit, with

total drug and drug-related expenditures of \$261,546.00, a \$900,491.00 drop from November 2012. It is not clear why this drop occurred in December 2012.

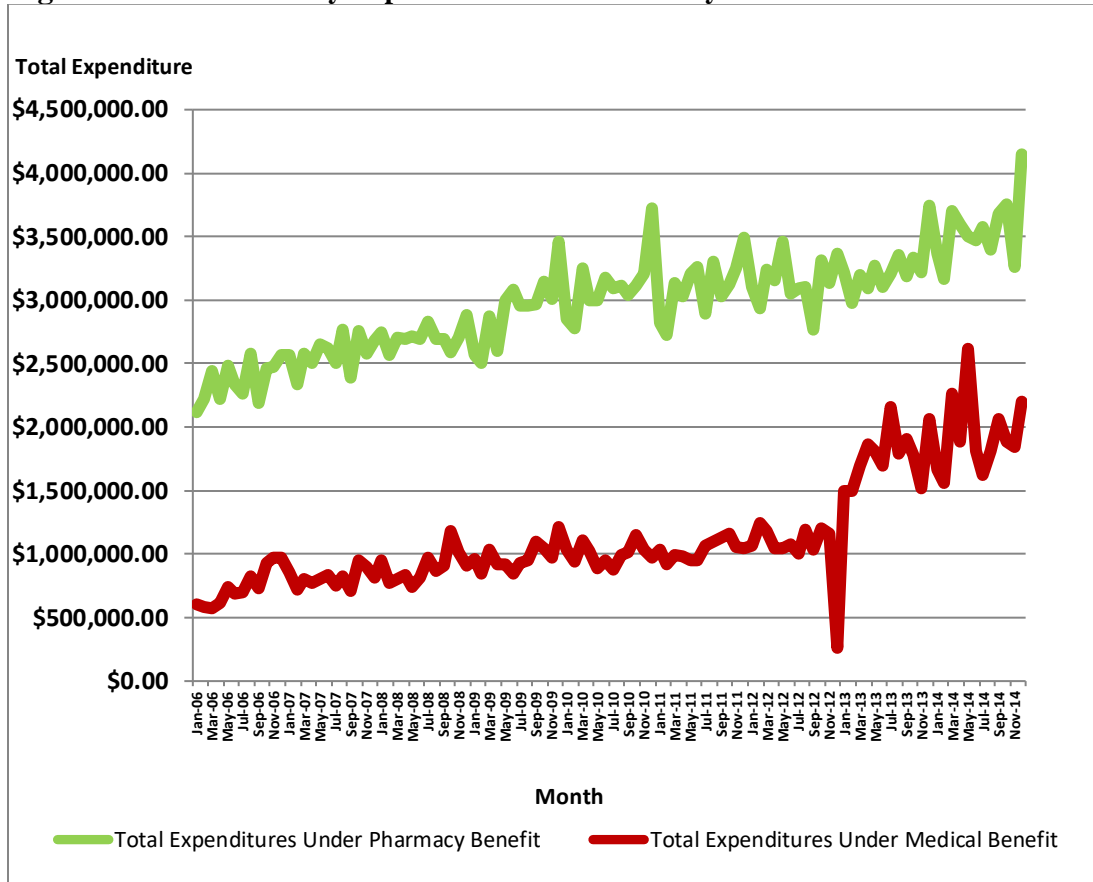
**Figure 4.1: Total Annual Expenditures under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.



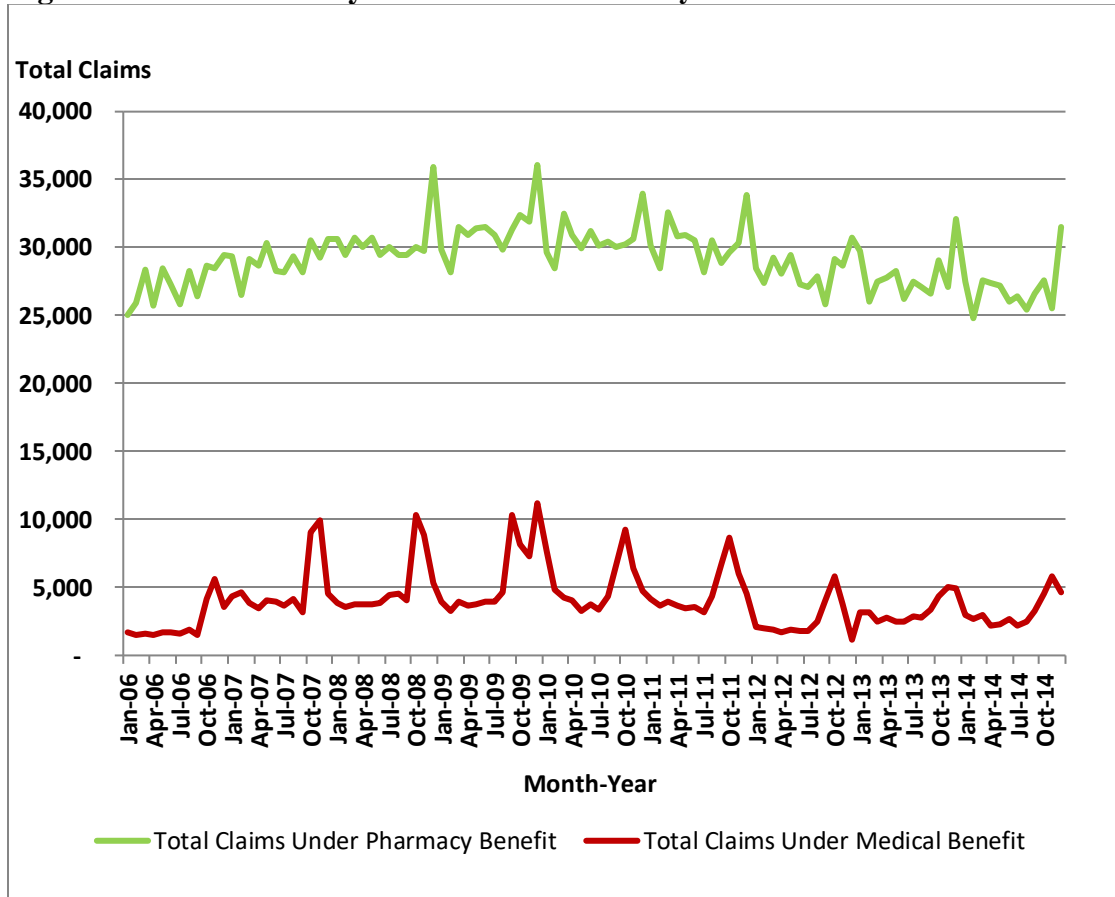
**Figure 4.2: Total Monthly Expenditure under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

This significant drop in expenditures in December 2012 was also noted as a drop in claims, which fell 2,608, from 3,761 to 1,153 respectively, as seen in Figure 4.3. Total drug and drug-related claims and expenditures went back up in January 2013 to 3,122 and \$1,492,976.00, respectively.

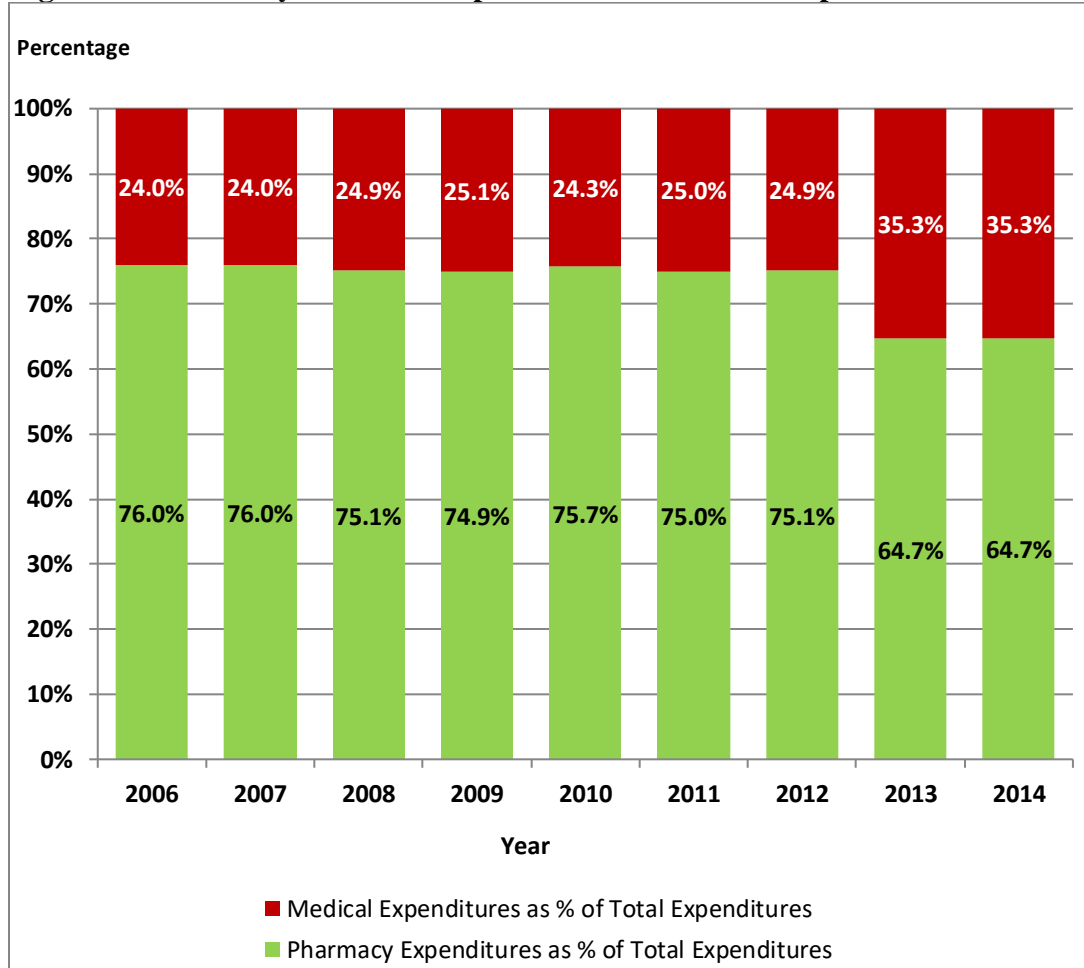
**Figure 4.3: Total Monthly Claims under Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

The percentage of total drug and drug-related expenditures accounted for by the pharmacy benefit generally went down from 2006 to 2014 with an overall drop from 76 percent to 65 percent, respectively. Conversely, the percent of total drug and drug-related expenditures accounted for by the medical benefit grew from 2006 to 2014, from 24 percent to 35 percent as noted in Figure 4.4. The largest percentage of total expenditures accounted for under the medical benefit was seen in 2013 and 2014, at 35 percent, while the largest percent of total drug and drug-related expenditures accounted for under the pharmacy benefit was observed in 2006, 2007 and 2010 at 76 percent. Overall, drug and drug-related claims under the pharmacy benefit accounted for greater than 65 percent of total drug and drug-related expenditures from 2006 to 2014.

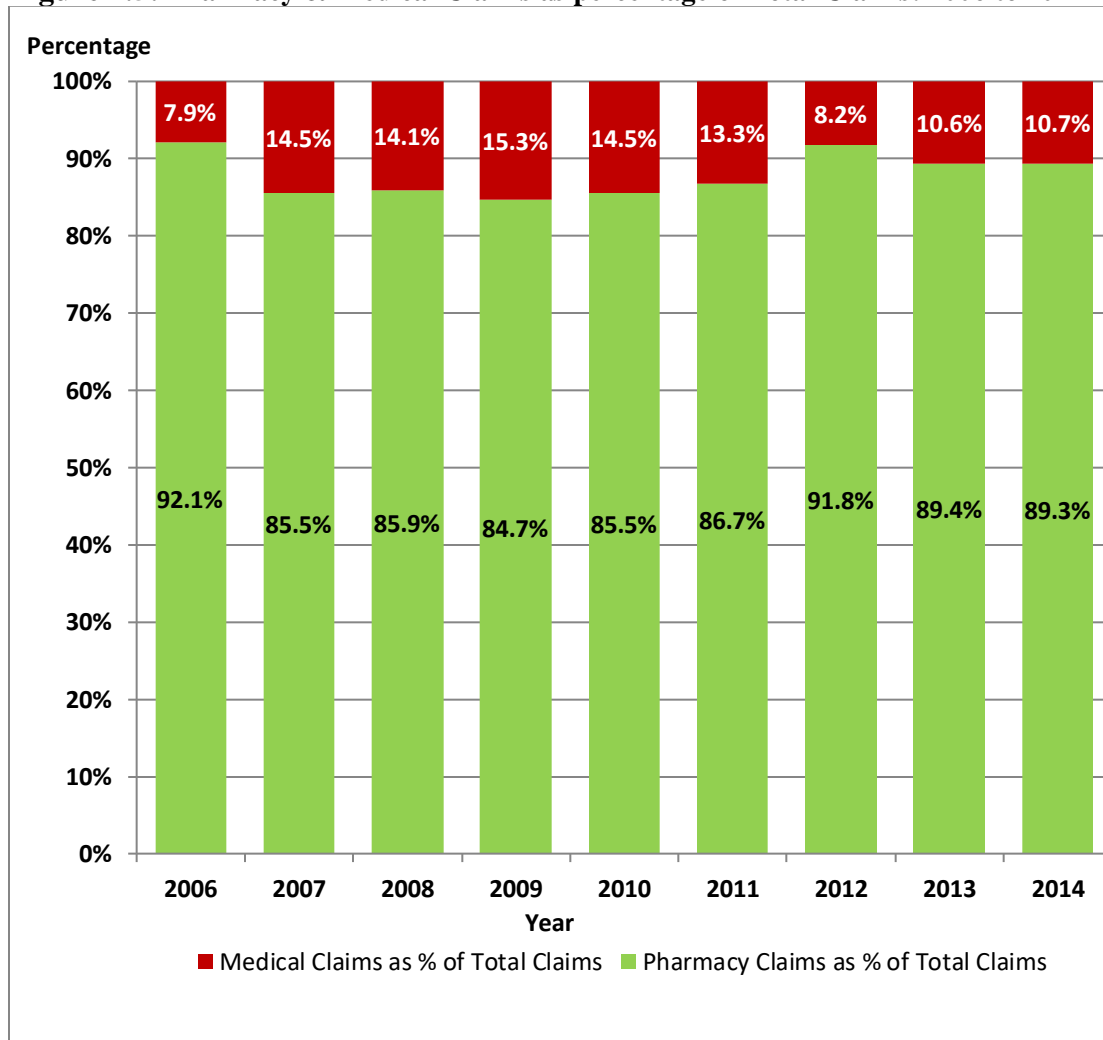
**Figure 4.4: Pharmacy & Medical Expenditures as % of Total Expenditures: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

Figure 4.5 shows that the pharmacy claims accounted for 85 percent to 92 percent of total drug and drug-related claims across the pharmacy and medical benefits from 2006 to 2014. During the same period, medical claims accounted for 8 percent to 15 percent of total drug and drug-related claims across the pharmacy and medical benefits from 2006 to 2014.

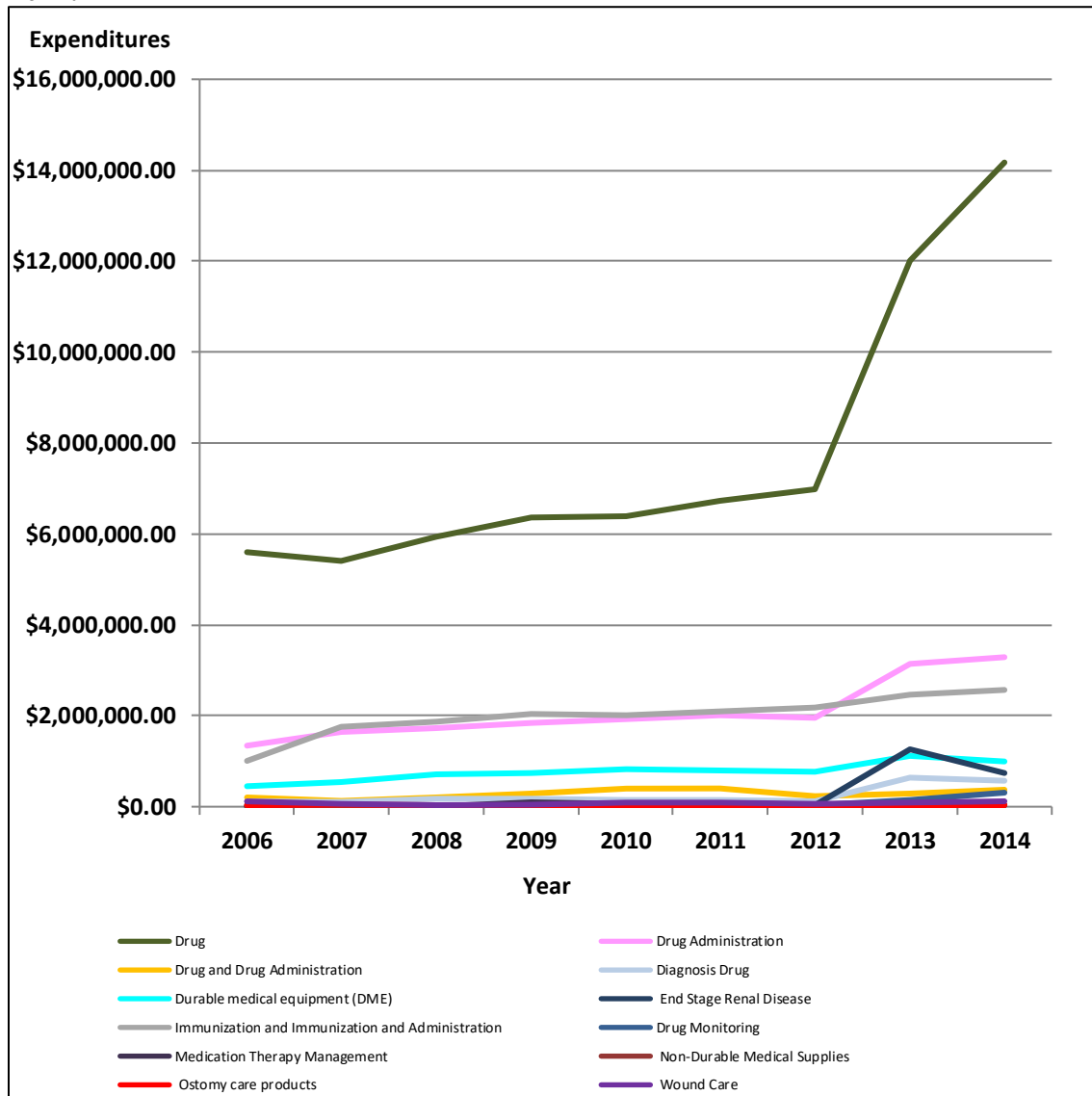
**Figure 4.5: Pharmacy & Medical Claims as percentage of Total Claims: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

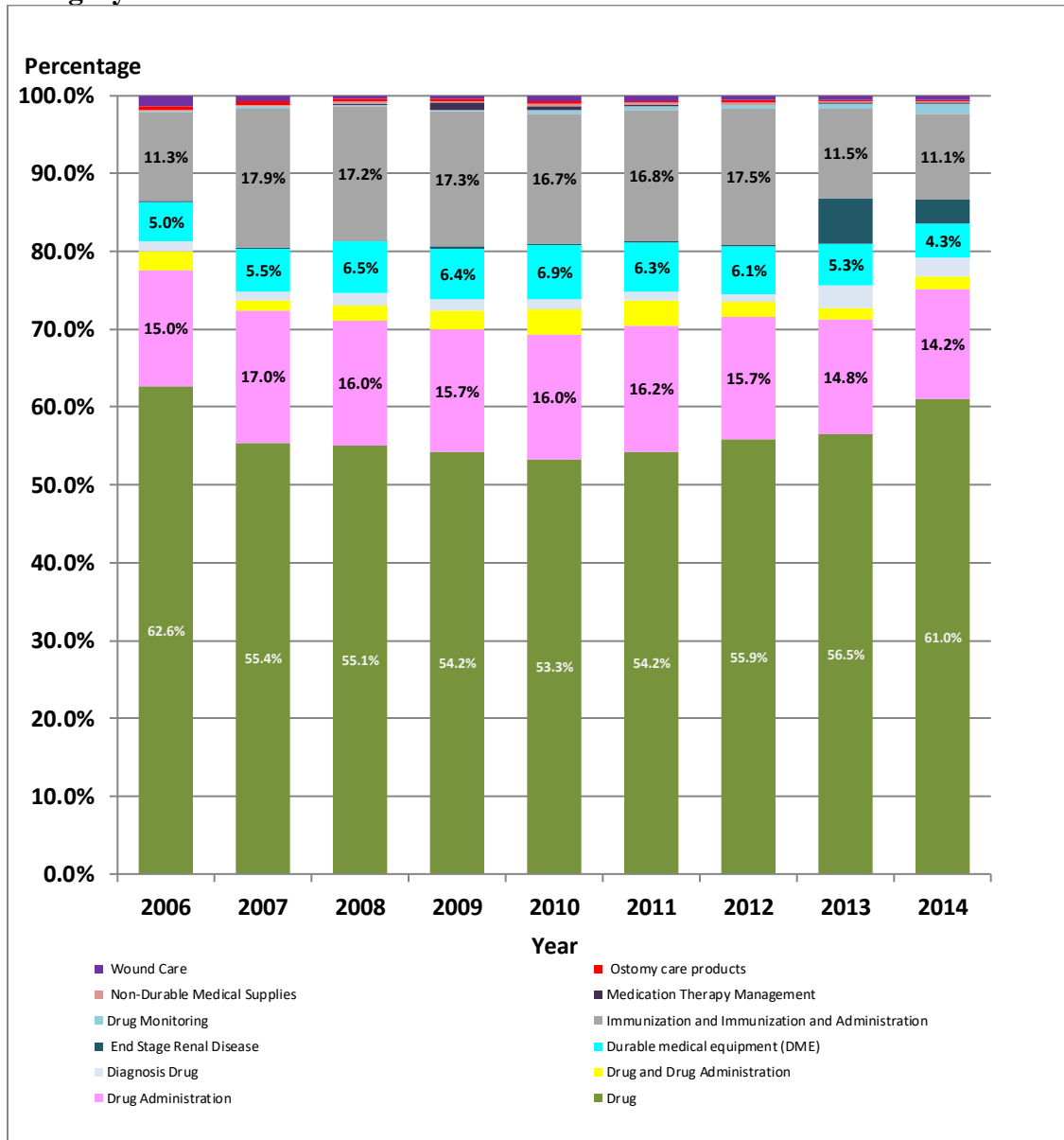
Total drug and drug-related claims under the pharmacy and medical benefits are broken down into various types of claims, as shown in Figure 4.6 and Figure 4.9. For total drug and drug-related expenditures under the medical benefit, the key drivers are drugs, drug administration, immunization and immunization administration, and durable medical equipment (DME), as observed in Figure 4.7. Together these four categories represented 88 percent to 96 percent of total drug and drug-related expenditures under the medical benefit over the period of 2006 to 2014. From 2006 to 2014 drugs accounted for a range of 53 percent to 63 percent of total drug and drug-related expenditures under the medical benefit. The other three key drivers of expenditures under the medical benefit over the course of the study period ranged from 14 percent to 16 percent for drug administration, 11 percent to 18 percent for immunization and immunization administration, and 4 percent to 7 percent for DME. Drug and drug-related expenditures for End Stage Renal Disease under the medical benefit were less than 1 percent from 2006 to 2012. In 2013, there was a jump in expenditure for End Stage Renal Disease, going from less than 1 percent to 6 percent in 2013, and going down to 3 percent in 2014. Each of the drug and drug-related categories listed in Figure 4.6 and Figure 4.7 are discussed in Chapter 3 section 3.3.2.2.

**Figure 4.6: Total Expenditures under the Medical Benefit By Category 2006 to 2014.\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

**Figure 4.7: Percentage of Total Expenditures under the Medical Benefit by Category: 2006 to 2014. \***

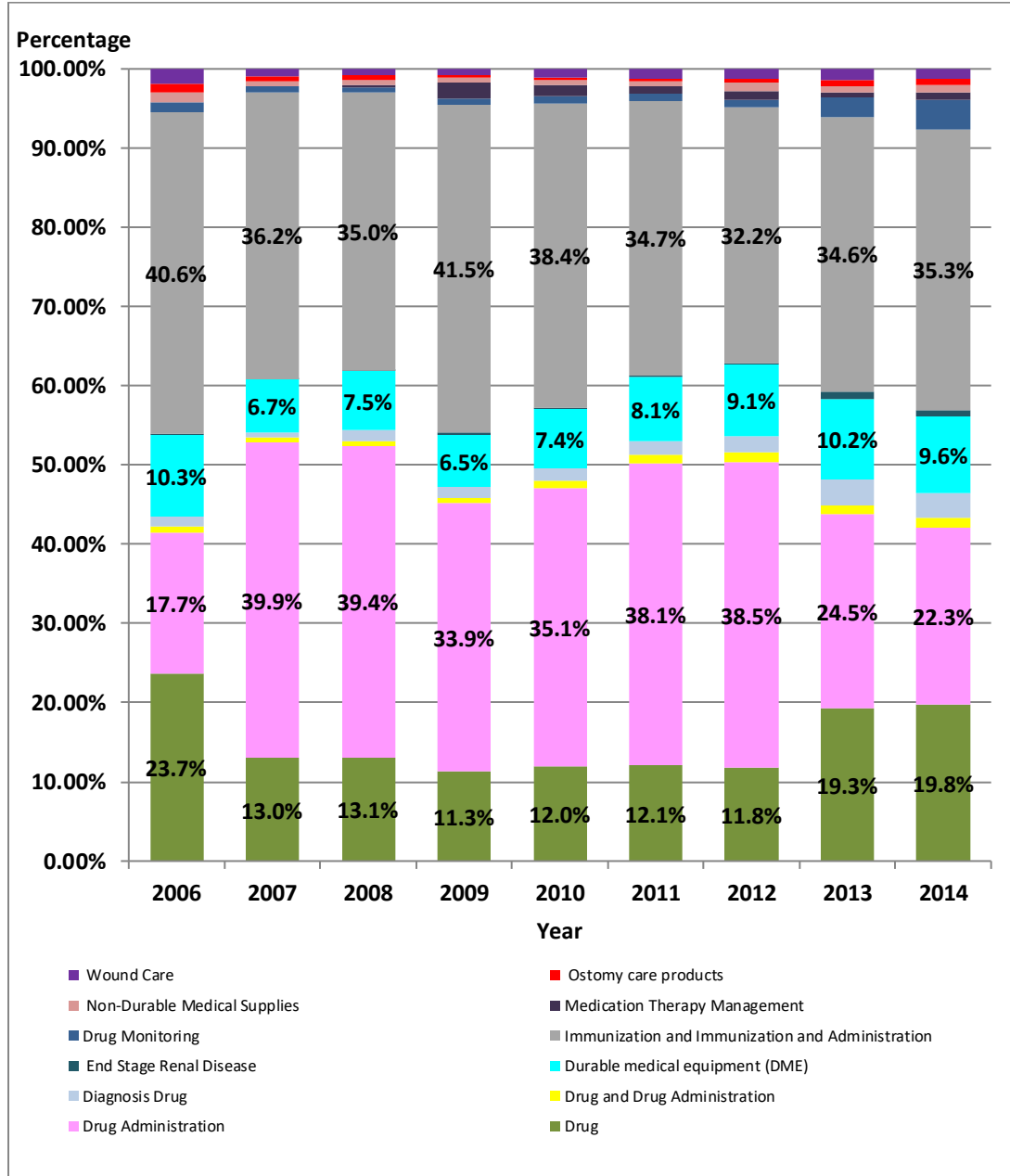


\*Total expenditures include total drug and drug-related expenditures under the medical benefit.



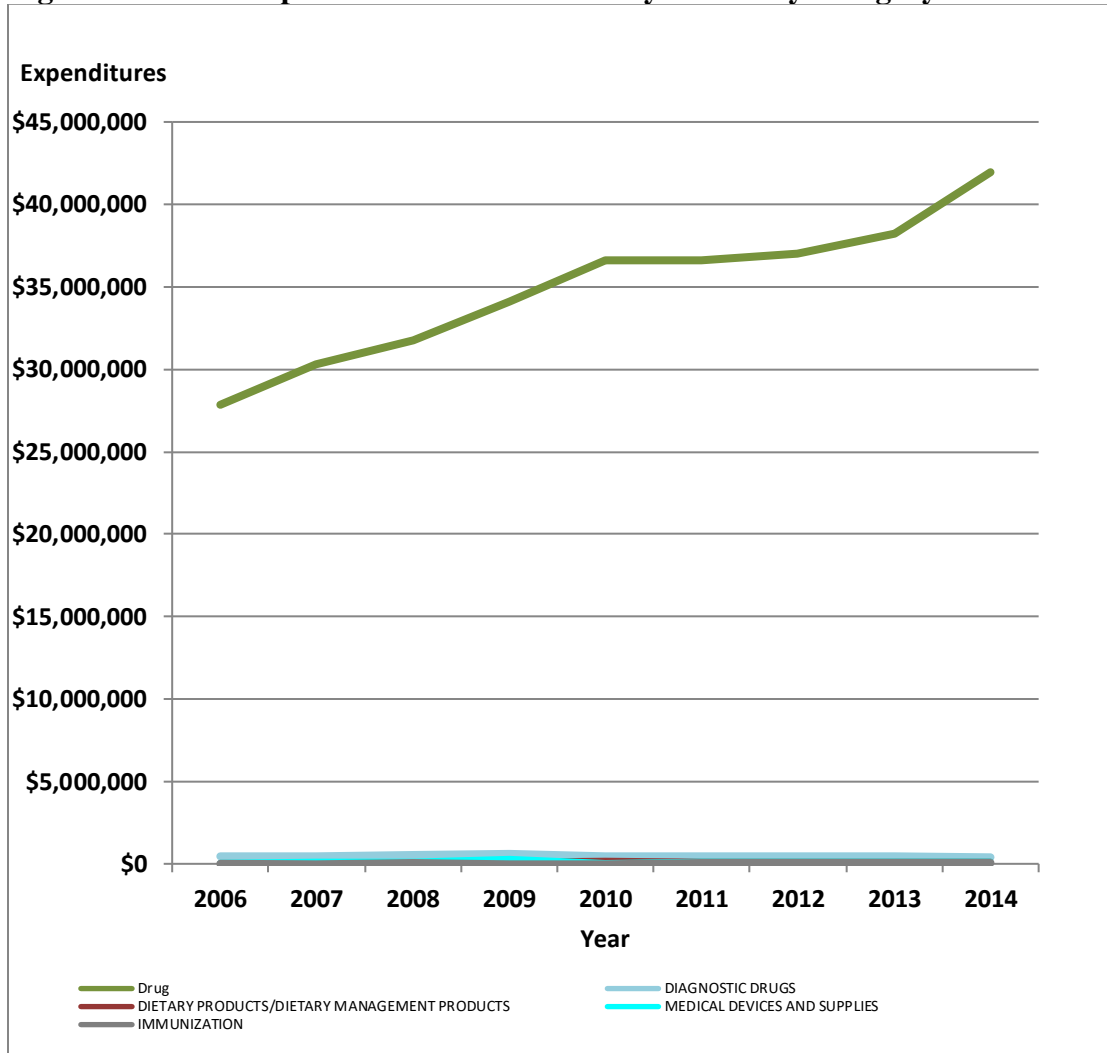
Medical benefit claims were evaluated by breakdown into the same categories, as previously used for total expenditures (see Figure 4.8), including drugs, drug administration, immunization and immunization administration, DME, and other categories. However, while drugs were the biggest drivers of total medical drug and drug-related expenditures, for claims data immunization and immunization administration ranged from 32 percent to 42 percent, and drug administration ranged from 17 percent to 40 percent of total medical claims over the course of 2006 to 2014 making these categories the top drivers of total medical drug and drug-related claims. Drug claims accounted for between 11 percent to 24 percent of total drug and drug-related claims under the medical benefit over the course of the study period.

**Figure 4.8: Percentage of Total Claims under the Medical Benefit by Category: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

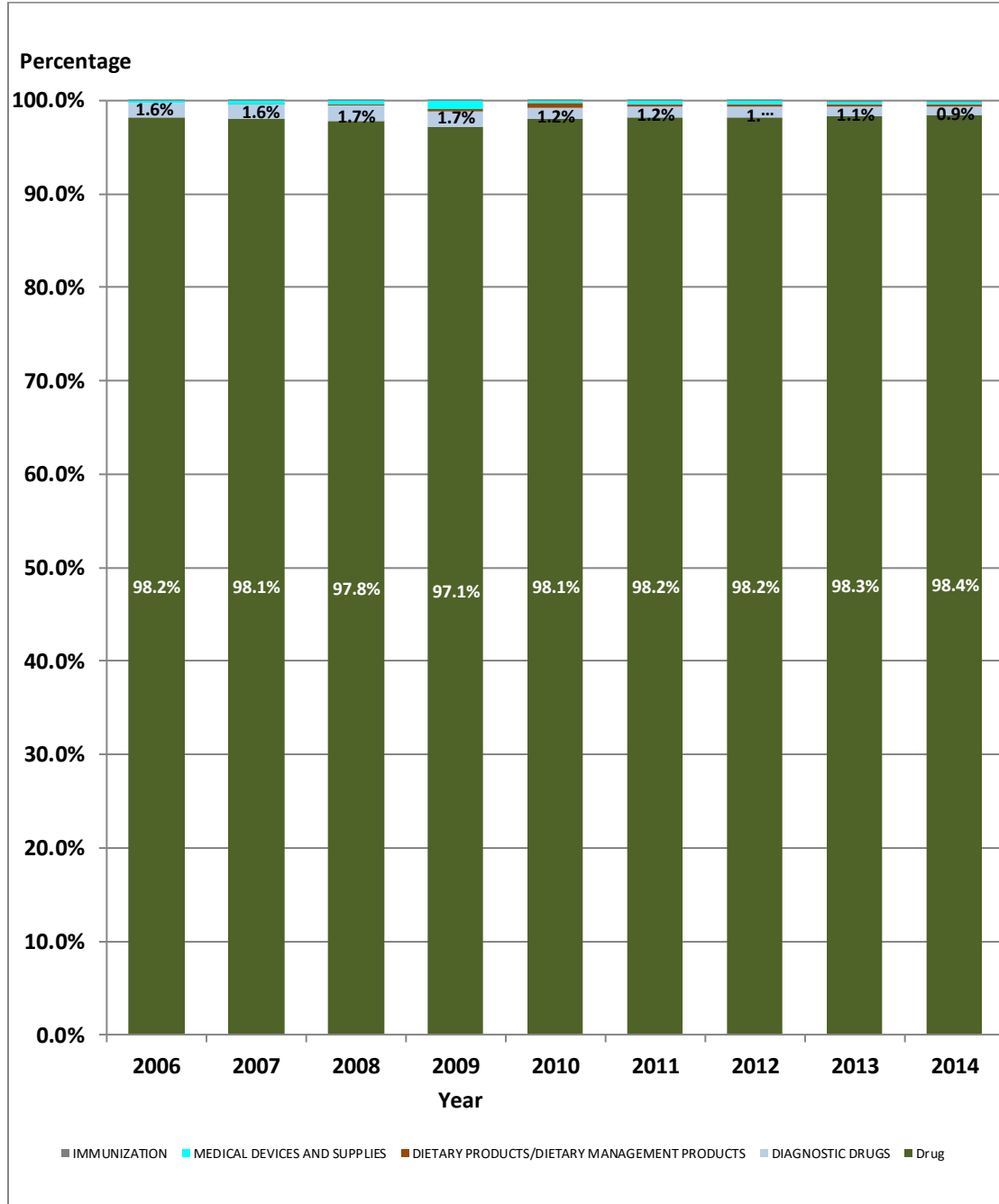
**Figure 4.9: Total Expenditures under Pharmacy Benefit by Category: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy benefit.

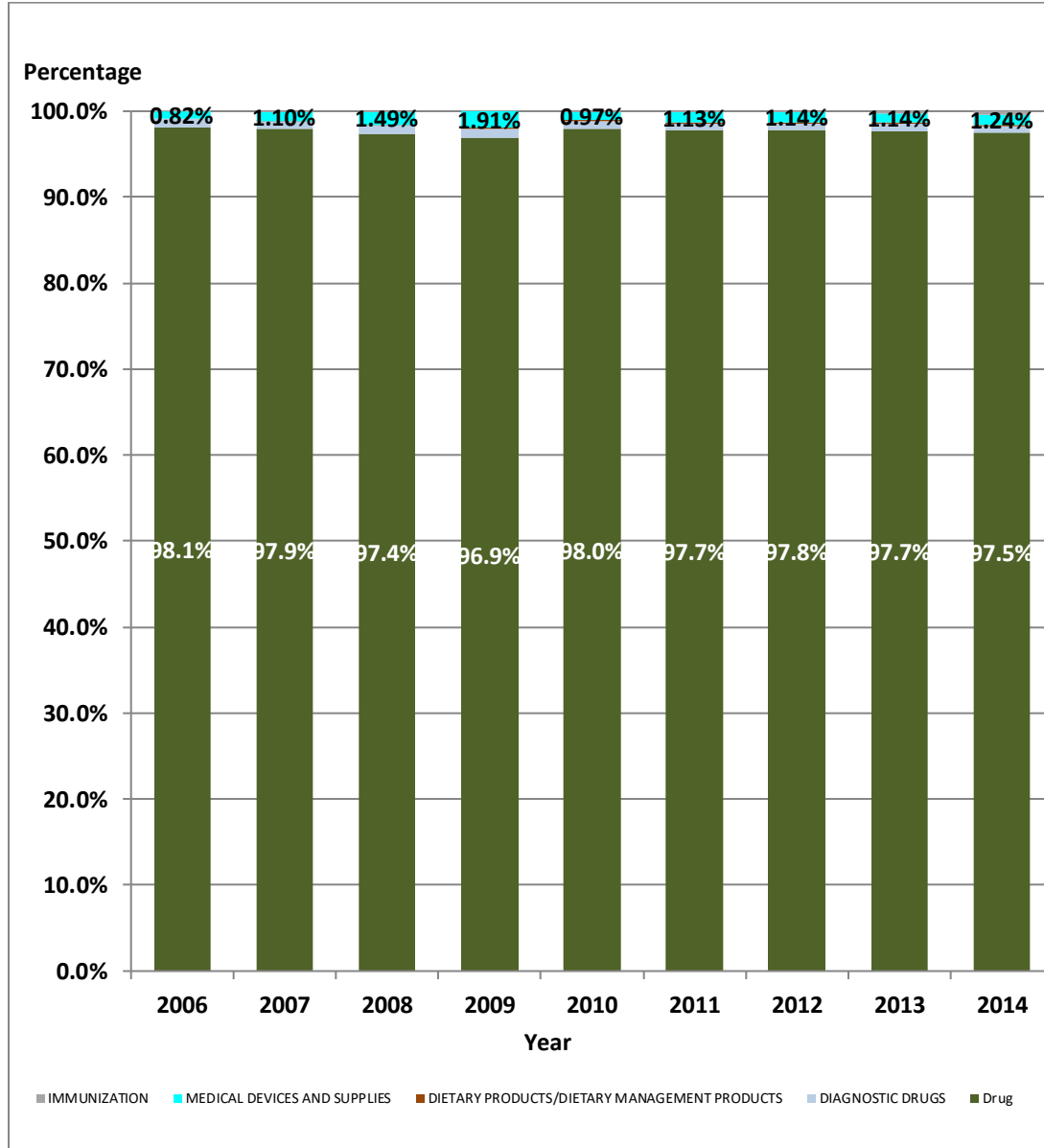
For total drug and drug-related expenditures under the pharmacy benefit, the key driver was drugs, as observed in Figure 4.9. Drugs represented 97 percent to 98 percent of total drug and drug-related expenditures under the pharmacy benefit over the period of 2006 to 2014. From 2006 to 2014, other categories accounted for a range of 1.56 percent to 2.85 percent of total drug and drug-related expenditures under the pharmacy benefit. These other categories included diagnostic drugs, dietary products and dietary management, medical devices and supplies, and immunization products, as noted in Figure 4.10. Figure 4.11 shows that drugs accounted for 97 percent to 98 percent of total drug and drug-related claims under the pharmacy benefit.

**Figure 4.10: Percentage of Total Expenditures for Pharmacy Benefit by Category: 2006 to 2014.\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy benefit.

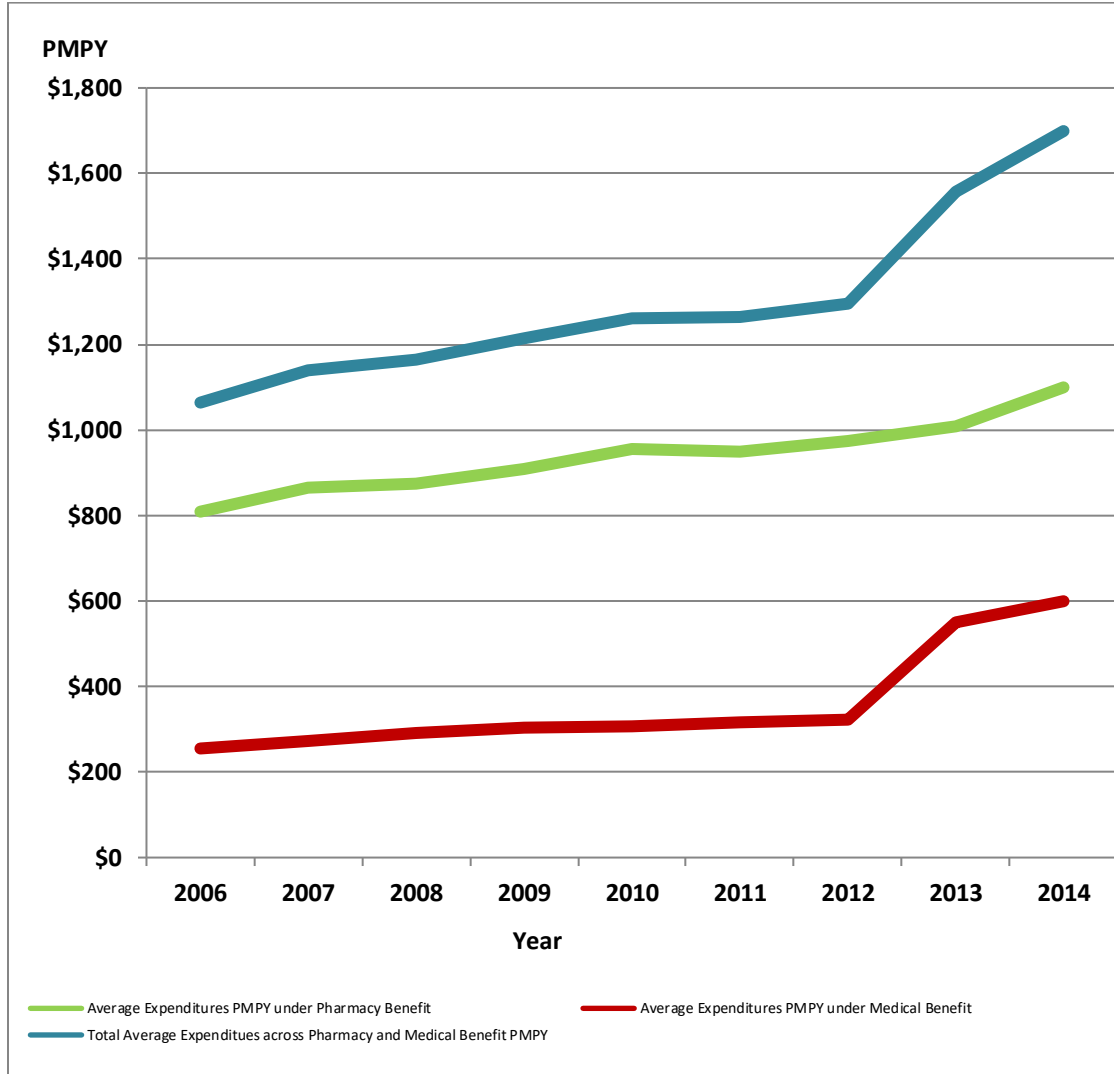
**Figure 4.11: Percentage of Total Claims under the Pharmacy Benefit by Category: 2006 to 2014.\***



\*Total claims include total drug and drug-related claims under pharmacy benefit.

Figure 4.12 and Table 4.1 demonstrate the PMPY (per member per year) expenditure for drugs and drug-related claims under pharmacy and medical benefits from 2006 to 2014. From 2006 to 2014, the PMPY for drugs and drug-related claims flowing through the pharmacy benefit grew from \$809.01 to \$1,099.69, a 36 percent growth. For drugs flowing through the medical benefit a PMPY growth of 135 percent was noted from 2006 to 2014, from \$255.07 to \$599.47. The overall PMPY for drugs across the pharmacy and medical benefits grew from \$1,064.08 to \$1,699.15, a 60 percent growth.

**Figure 4.12: PMPY Expenditures under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.



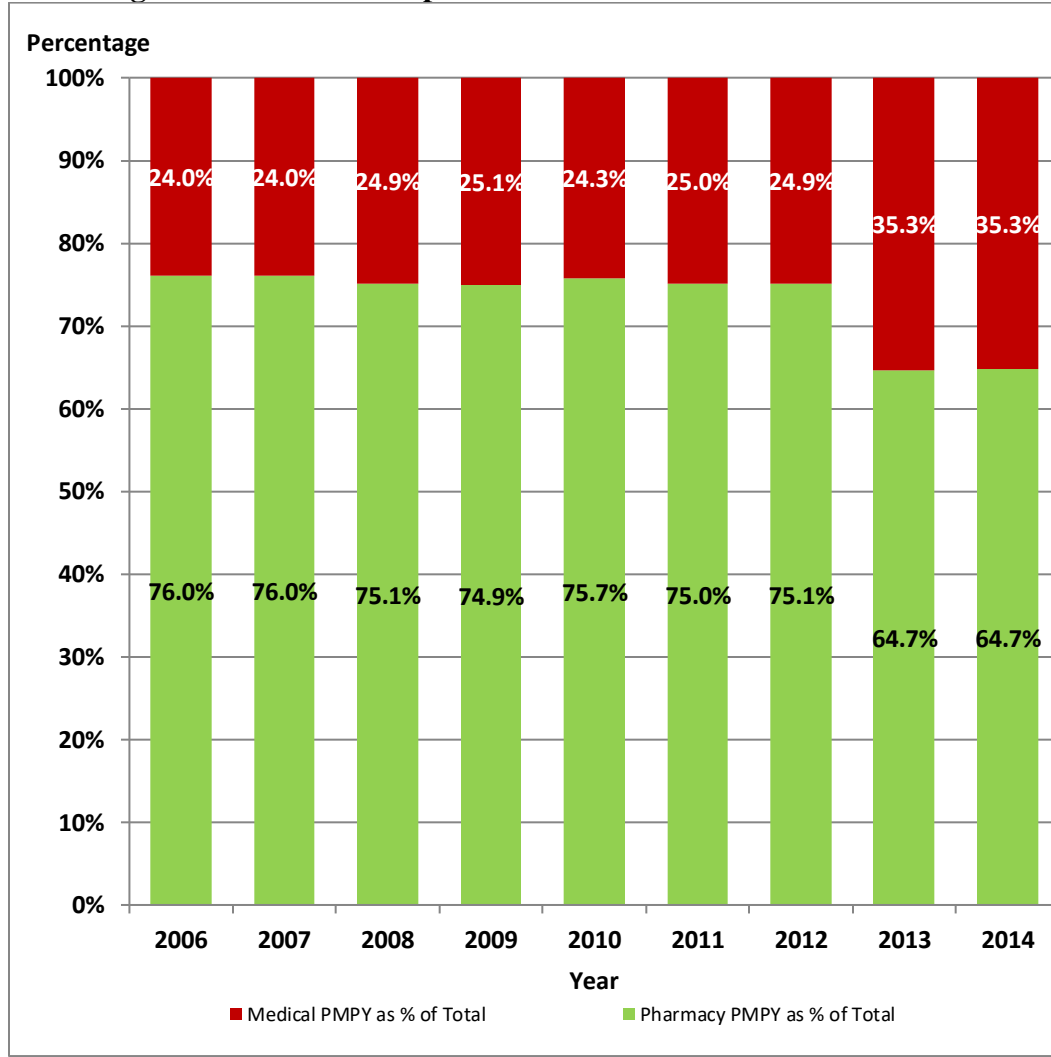
**Table 4.1: PMPY Expenditures under Pharmacy & Medical Benefits: 2006 to 2014\***

Year	Total Pharmacy Drug and Drug-related Expenditures PMPY	Total Medical Drug and Drug-related Expenditures PMPY	Total Drug and Drug-related Expenditures PMPY
2006	\$809.01	\$255.07	\$1,064.08
2007	\$865.35	\$272.72	\$1,138.07
2008	\$874.95	\$290.11	\$1,165.05
2009	\$910.33	\$304.39	\$1,214.72
2010	\$956.08	\$306.43	\$1,262.51
2011	\$949.00	\$315.88	\$1,264.88
2012	\$973.60	\$322.87	\$1,296.47
2013	\$1,007.27	\$550.74	\$1,558.01
2014	\$1,099.69	\$599.47	\$1,699.15

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

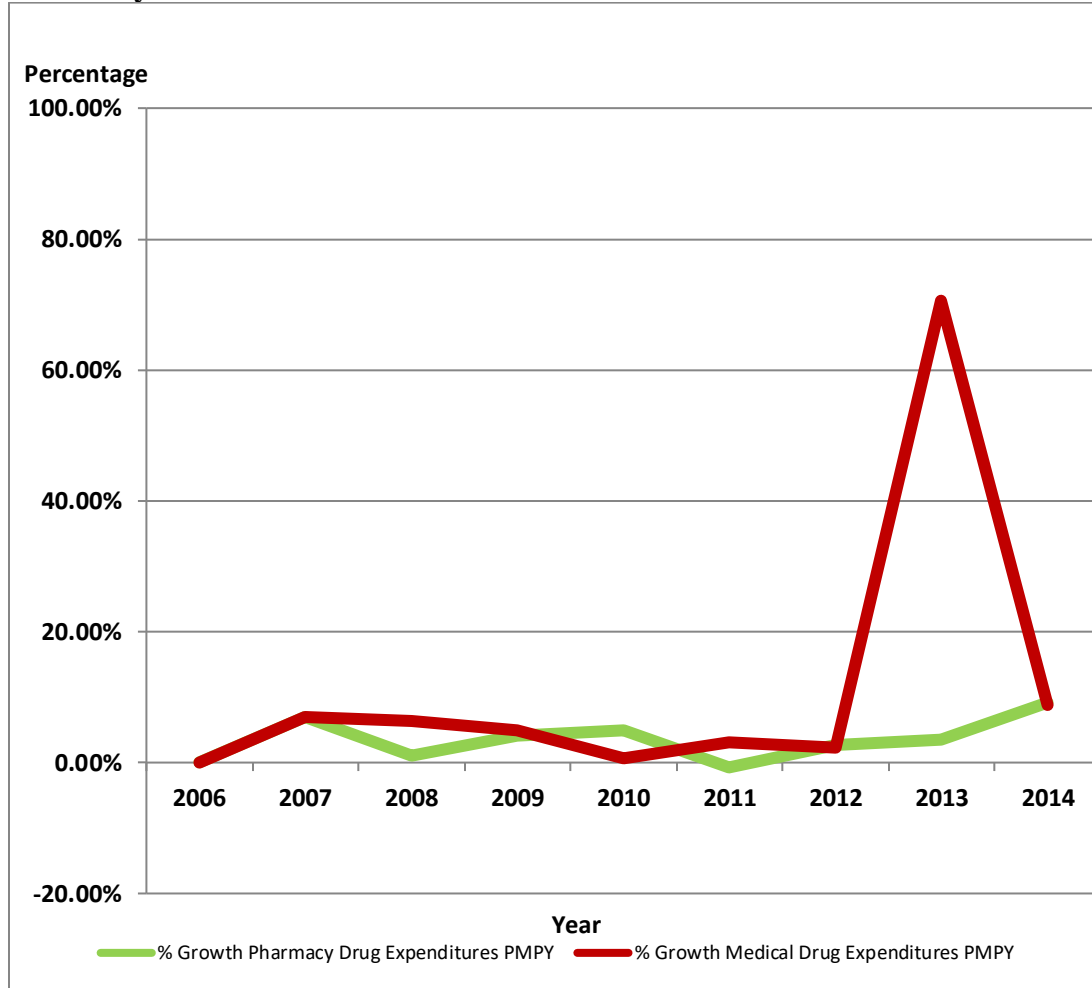
In general, the PMPY for drugs and drug-related expenditures under the pharmacy benefit was greater than the PMPY for drugs under the medical benefit. Pharmacy PMPY as a percentage of total PMPY ranged from 65 percent to 76 percent from 2006 to 2014, while it ranged from 24 percent to 35 percent for medical PMPY. The PMPY under the medical benefit is growing as a share of the total from 2006 to 2014, while the share is going down under pharmacy benefit for the same period.

**Figure 4.13: PMPY Expenditures under Pharmacy & Medical Benefits as Percentage of Total PMPY Expenditures: 2006 to 2014**



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.14: Percentage Growth Year to Year in PMPY Expenditure under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

As seen with total expenditures, Figure 4.14 shows a significant increase in the growth rate for medical drug PMPY from 2012 to 2013, and in 2014 the growth rate returns to the previous trend line. Factors regarding this growth and decline of medical drug PMPY will with be discussed in chapter five.

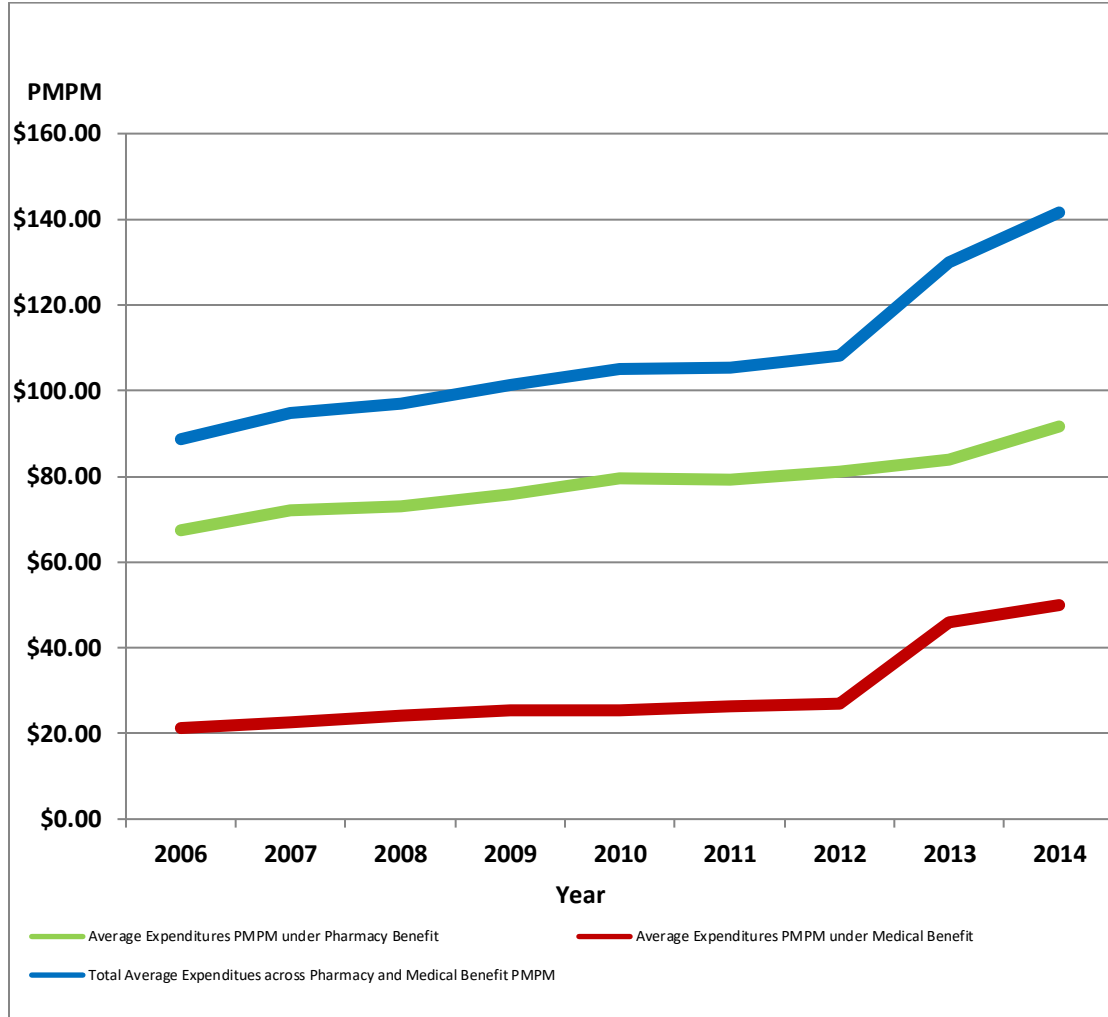
**Table 4.2: Percentage Growth Year to Year in PMPY Expenditure for Drugs under Pharmacy & Medical Benefit: 2006 to 2014**

Year	% Growth Pharmacy Drug and Drug-related Expenditures PMPY	% Growth Medical Drug and Drug-related Expenditures PMPY	% Growth Pharmacy & Medical Drug Expenditures PMPY
2006			
2007	6.96%	6.92%	6.95%
2008	1.11%	6.38%	2.37%
2009	4.04%	4.92%	4.26%
2010	5.03%	0.67%	3.93%
2011	-0.74%	3.08%	0.19%
2012	2.59%	2.21%	2.50%
2013	3.46%	70.58%	20.17%
2014	9.18%	8.85%	9.06%

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

In 2013, there was a notable annual growth in the PMPY expenditure under the medical benefit at 70.58 percent from 2012. For pharmacy benefit, the highest growth was noted from 2013 to 2014. For overall drug expenditures, the highest growth was noted from 2007 to 2008, at 6.96 percent, as noted in Table 4.2.

**Figure 4.15: PMPM Expenditures under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

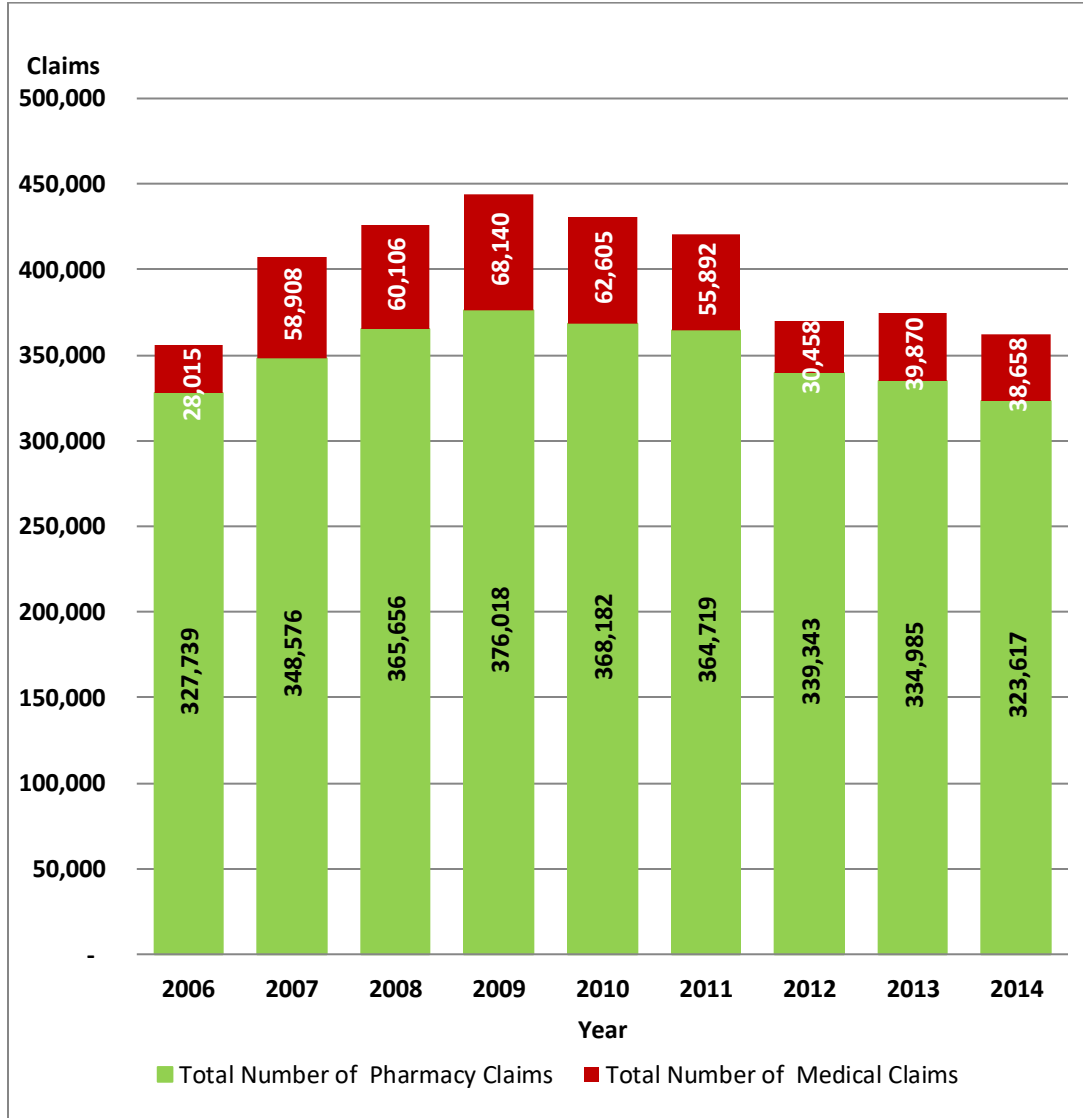
Figure 4.15 and Table 4.3 show the PMPM (per member per month) expenditures for drugs and drug-related claims flowing through both the pharmacy and medical benefits. The PMPM for drugs and drug-related expenditures under the pharmacy benefit ranged from \$67.42 to \$91.64 from 2006 to 2014, with a difference of 36 percent. For drugs under the medical benefit, the PMPM showed a higher growth at \$21.26 to \$49.96, a difference of 135 percent. The PMPM for total drug expenditures ranged from \$88.67 to \$141.60 a difference of 60 percent.

**Table 4.3: PMPM Expenditures under Pharmacy & Medical Benefits:  
2006 to 2014\***

<b>Year</b>	<b>Total Pharmacy Drug and Drug-related Expenditures PMPM</b>	<b>Total Medical Drug and Drug Expenditures PMPM</b>	<b>Total Drug and Drug-related Expenditures PMPM</b>
2006	\$67.42	\$21.26	\$88.67
2007	\$72.11	\$22.73	\$94.84
2008	\$72.91	\$24.18	\$97.09
2009	\$75.86	\$25.37	\$101.23
2010	\$79.67	\$25.54	\$105.21
2011	\$79.08	\$26.32	\$105.41
2012	\$81.13	\$26.91	\$108.04
2013	\$83.94	\$45.89	\$129.83
2014	\$91.64	\$49.96	\$141.60

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.16: Total Number of Claims under Pharmacy & Medical Benefits: 2006 to 2014\***

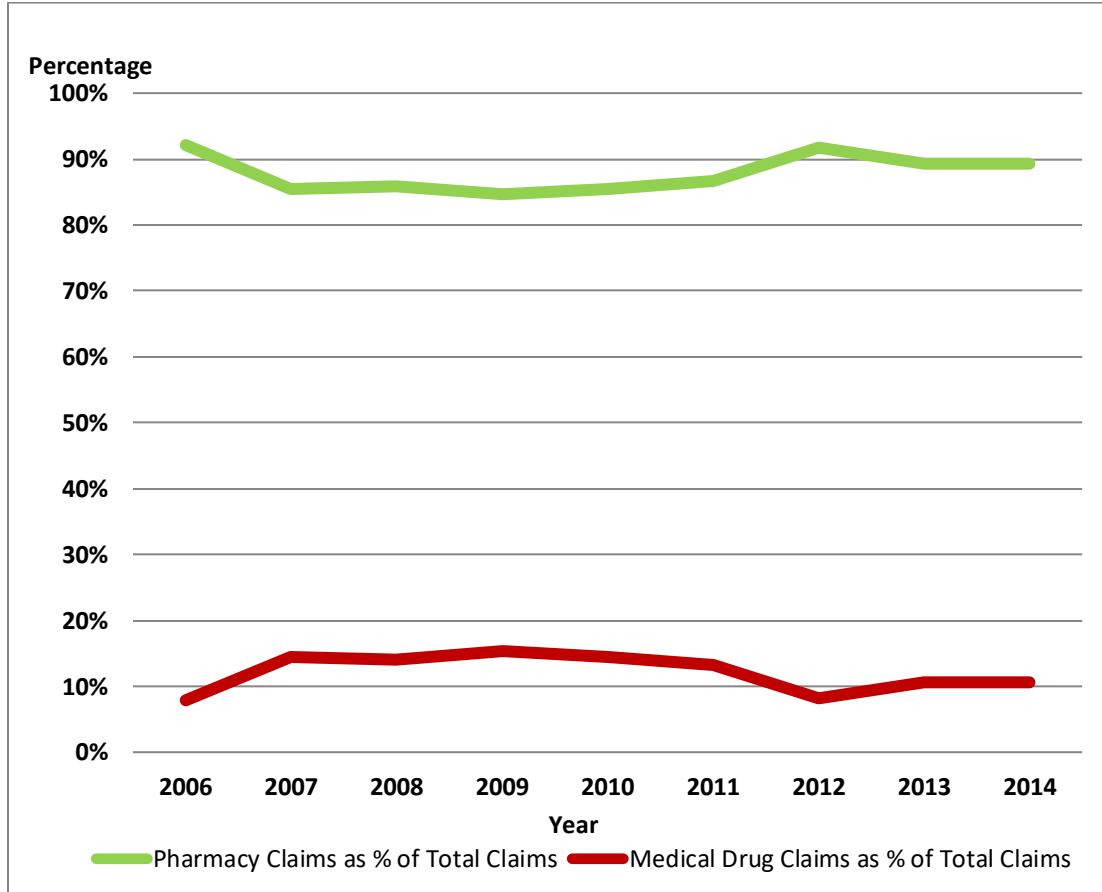


\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

The total number of drug and drug-related claims grew from 355,754 to 362,275 from 2006 to 2014. The number of drug and drug-related claims under the pharmacy benefit fluctuated from 2006 to 2014, with the largest number of claims seen in 2009, at 376,018. Total drug and drug-related claims under the medical benefit grew from 28,015 to 38,658 from 2006 to 2014. The largest number of drug claims under the medical benefit were observed in 2009 at 68,140. The numbers of drug and drug-related claims under the pharmacy benefit were greater than the number of drug claims under the medical benefit during the study period of 2006 to 2014. Drug and drug-related claims under the pharmacy benefit accounted for 85 percent or greater of the total drug claims throughout the study period from 2006 to 2014, as seen in Figure 4.17.



**Figure 4.17: Percentage of Pharmacy & Medical Claims as Percentage of Total Claims: 2006 to 2014\***

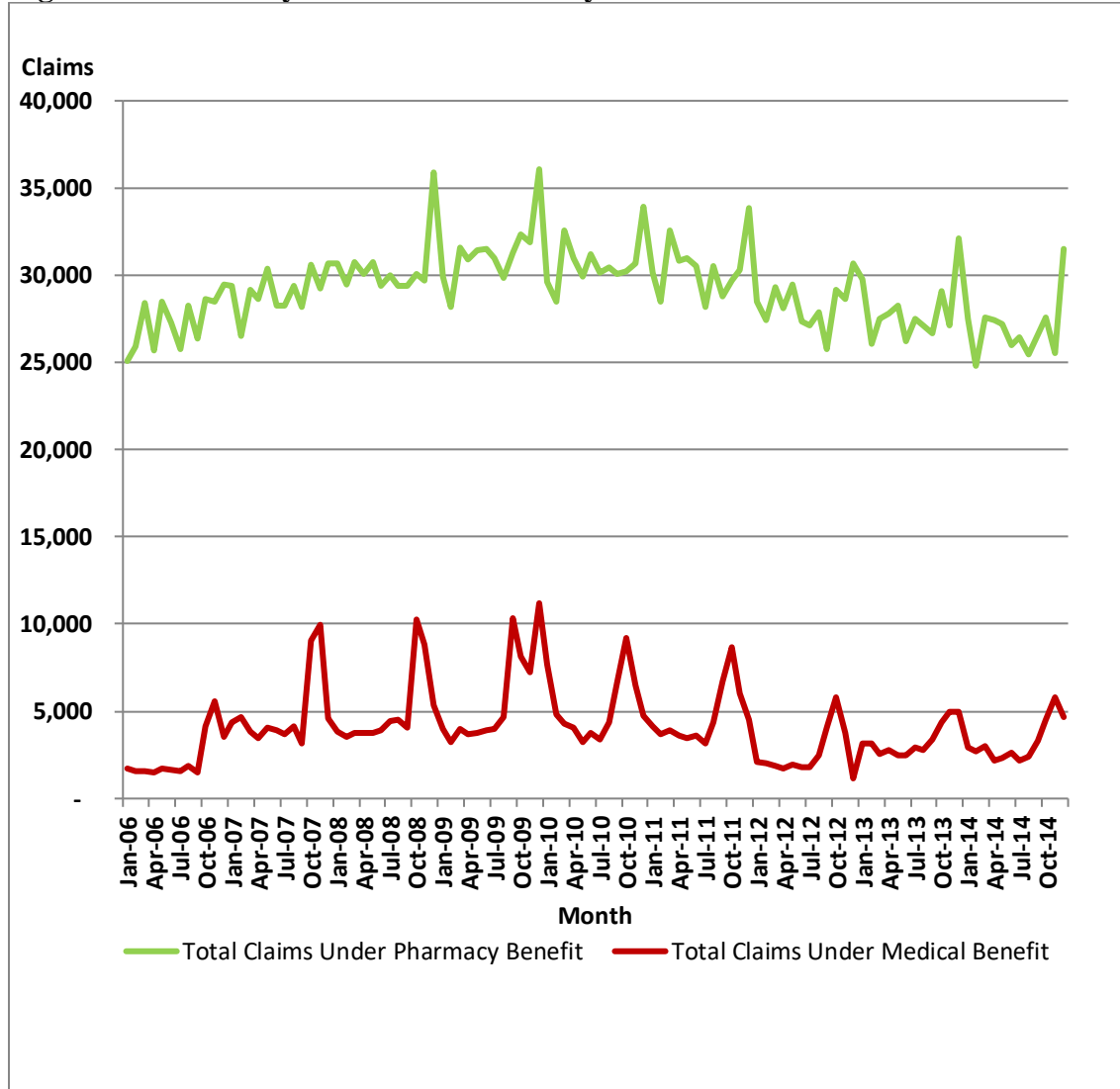


\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

The percent of total drug and drug-related claims accounted for by the pharmacy benefit went down from 2006 to 2014, from 92 percent to 89 percent. The percentage of total drug claims accounted for by the medical benefit grew from 8 percent to 11 percent from 2006 to 2014. The largest percentage of total claims accounted for by the pharmacy benefit was noted in 2006 and 2012 at 92 percent and under the medical benefit in 2009 and 2010 at 15 percent.

The average expenditure per claim under the pharmacy benefit demonstrated a slow but steady growth from 2006 to 2014, as noted in Figure 4.19 per month and Figure 4.20 per year. Expenditures per claim under the medical benefit demonstrated a clear fluctuation throughout 2006 to 2014. During fall to early winter the average expenditure per claim went down across the study period from 2006 to 2014. Further investigation of claims under the medical benefit shows the impact seasonal immunizations have on average expenditure per claim, as noted in Figure 4.22 and Figure 4.23. There is a distinct increase in the number of immunization claims, as seen in the next graph, with the number of claims under the pharmacy and medical benefits.

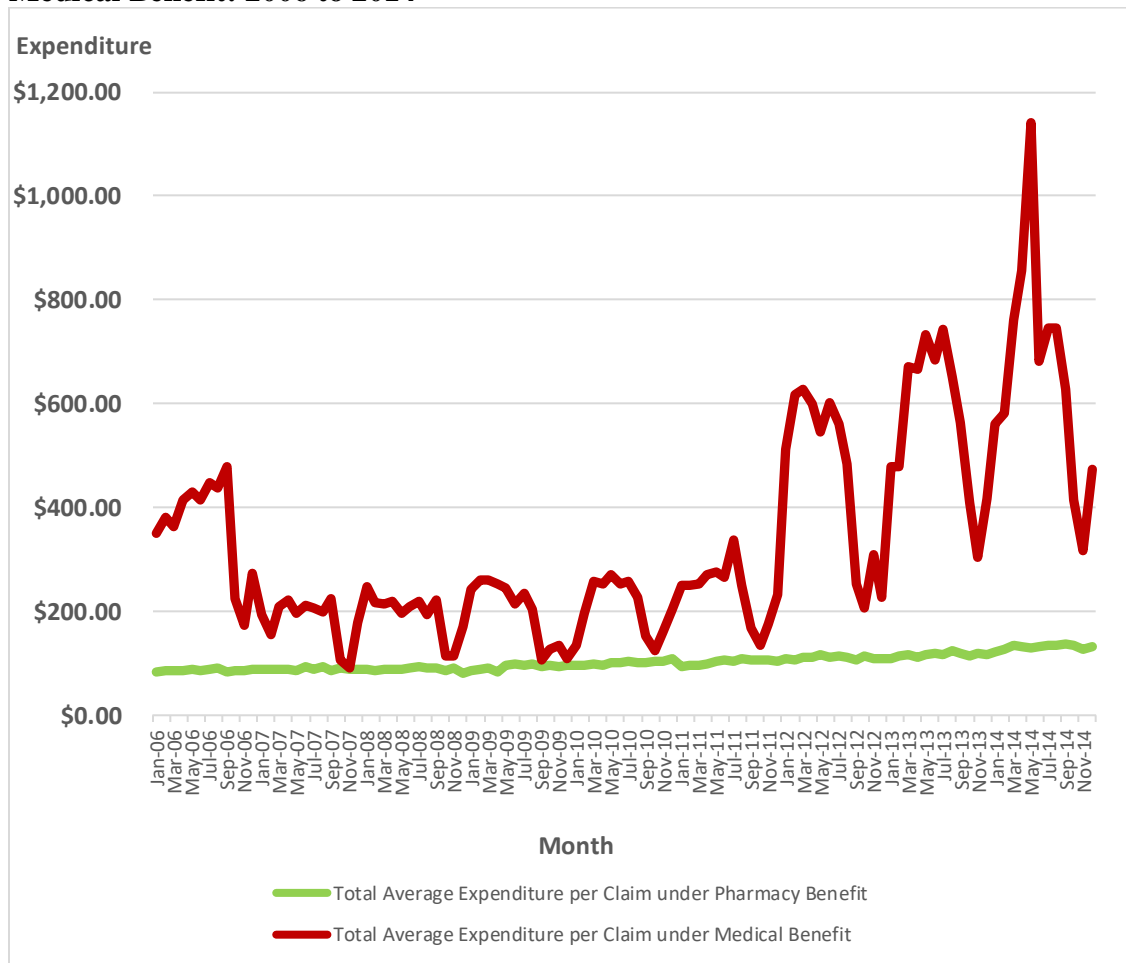
**Figure 4.18: Monthly Number of Pharmacy & Medical Claims: 2006 to 2014**



\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

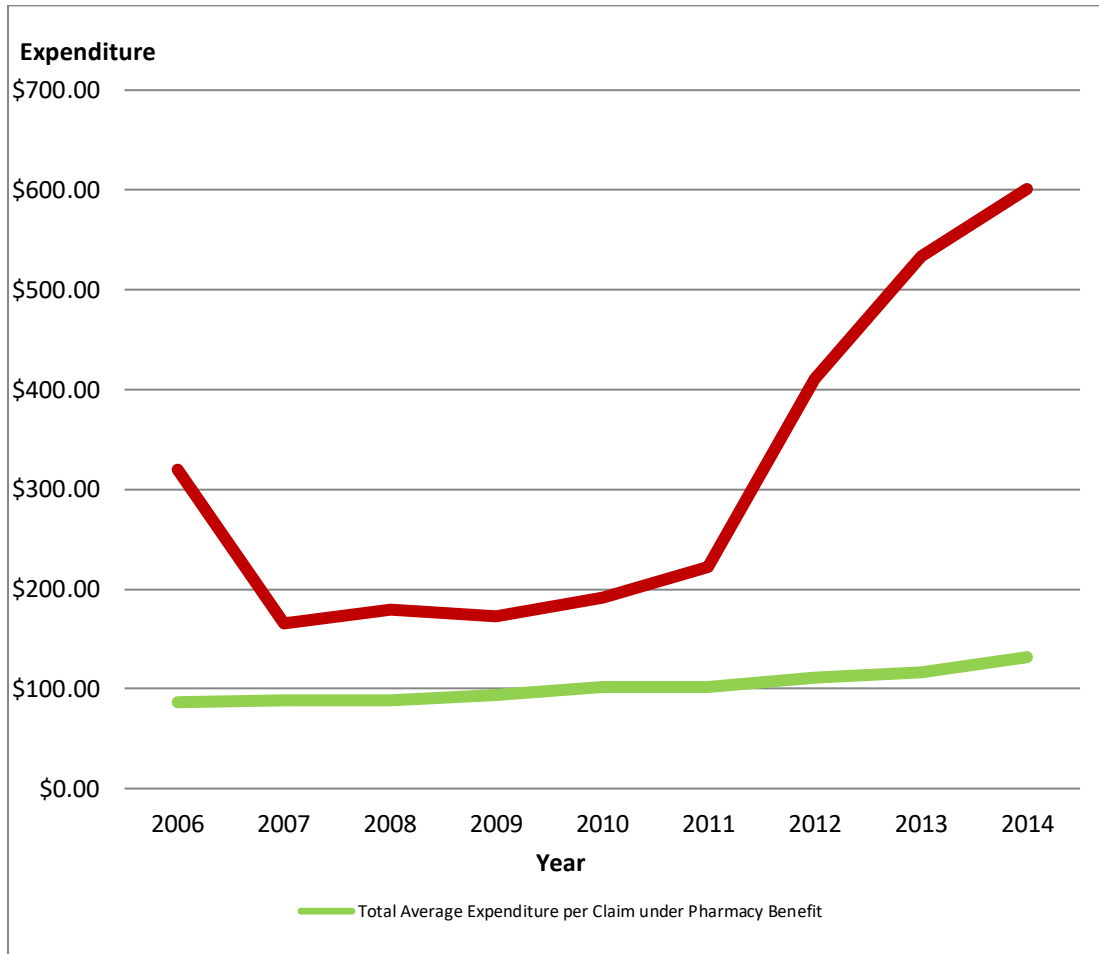
Figure 4.18 demonstrates an increase in the number of medical claims during the fall and early winter. This increase in the number of medical claims is observed for the entire study period from 2006 to 2014. Thus, the increase of lower cost claims during fall and early winter results in a lower expenditure per claim as noted for the period from 2006 to 2014 and observed in Figure 4.19.

**Figure 4.19: Monthly Total Average Expenditure per Claim under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

**Figure 4.20: Annual Average Expenditure per Pharmacy & Medical Claim: 2006 to 2014\***

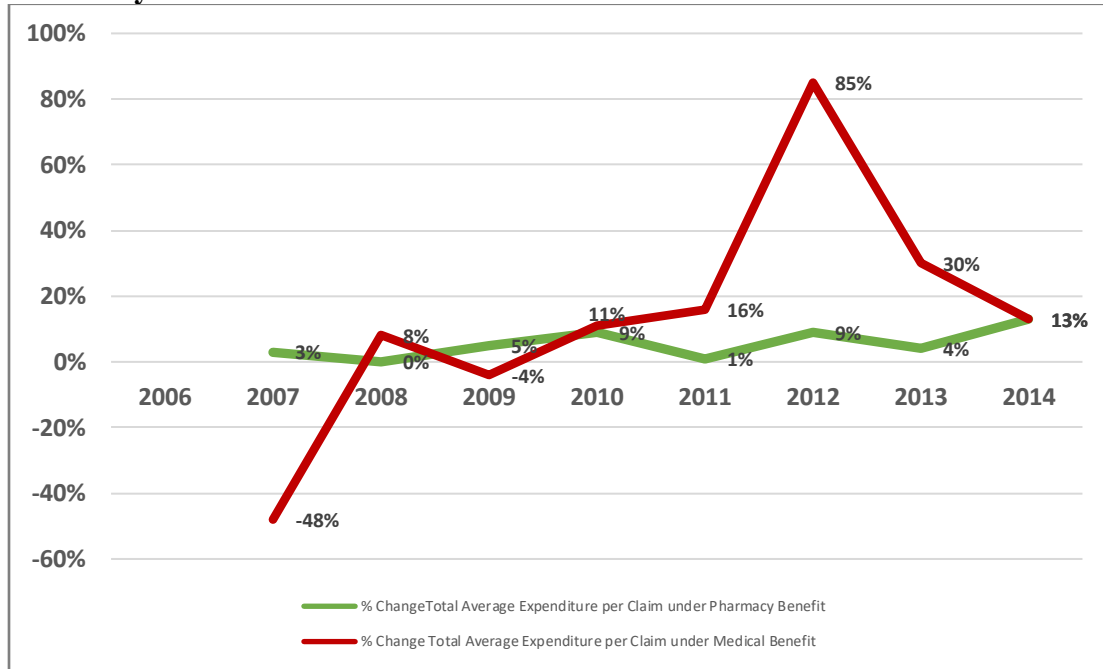


\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

Figure 4.20 shows an average cost per claim by year for drug and drug-related claims under the pharmacy and medical benefits. The annual average cost per claim under the pharmacy benefit shows steady growth, growing from \$86.56 to \$131.69 in 2006 to 2014. The annual average cost per claim under the medical benefit appears to have a U shape. The annual average cost per claim under the medical benefit was \$319.27 in 2006. It went down and ranged from \$165 to \$221.97 from 2007 to 2011. However, there was an 85 percent jump from 2011 to 2012, going from a \$221.97 to \$410.75 annual average cost per claim. The growth in the annual average cost per claim continued to go up 30 percent

from 2012 to 2013 and 13 percent from 2013 to 2014, with an overall growth of 171 percent from 2011 to 2014.

**Figure 4.21: Percentage Change in per Claim Expenditures Year to Year under Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

The percent change in expenditures per claim under pharmacy benefit show slow and steady growth over time. The percent change in per claim expenditures under the medical benefit fluctuated from 2006 to 2014, as seen in Figure 4.21.

From 2006 to 2014 per claim expenditures for the medical benefit were slightly greater than for pharmacy benefit claims in most years.

**Figure 4.22: Immunization & Immunization Administration Claims under Medical Benefit by Month: 2004 to 2014**

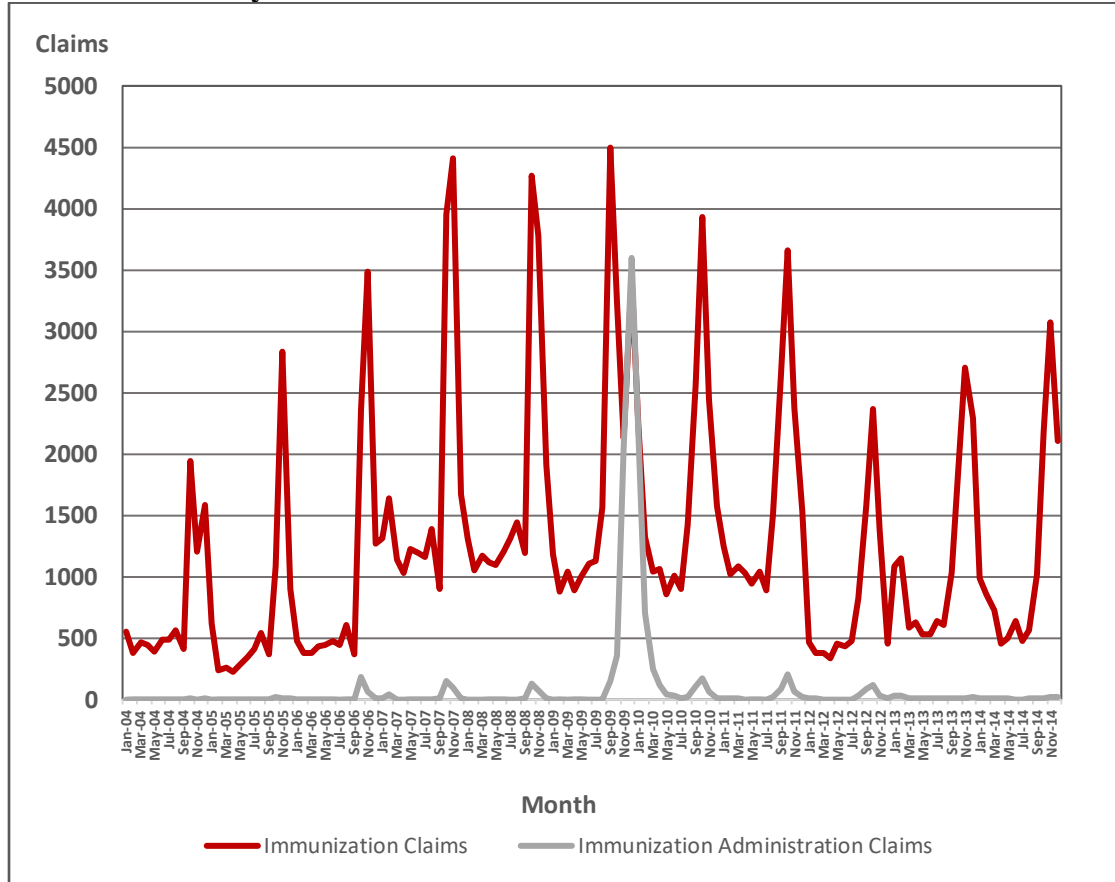
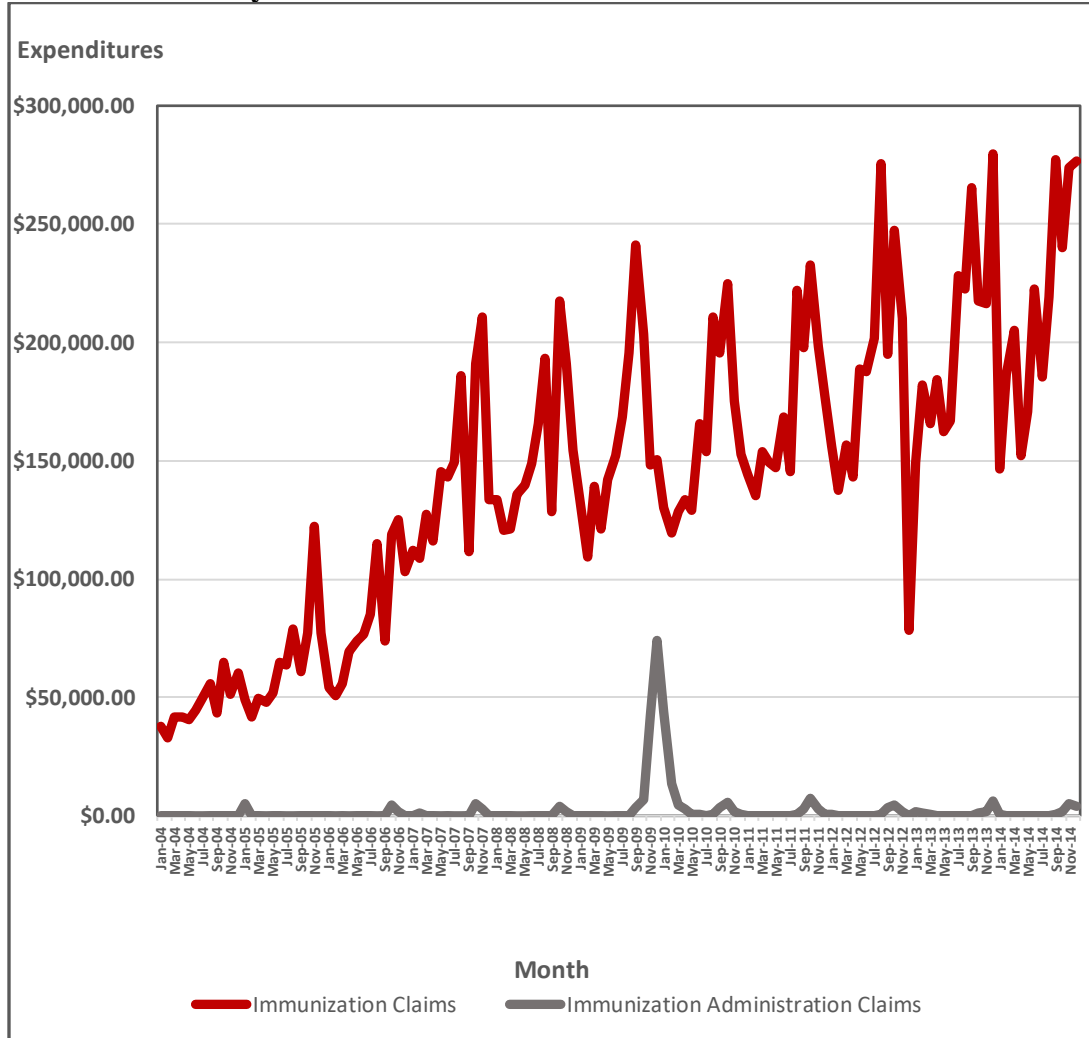


Figure 4.22 shows the seasonal fluctuation in number of claims for immunization. The number of claims clearly had a spike up during the fall of each year, but came back down during the winter, spring, and summer. This fluctuation can be explained primarily by the seasonal use of flu immunizations. Figure 4.23 shows the average cost per an immunization claim under the medical benefit following a similar trend, however expenditures appear to be going up overtime, while total number of claims remains relatively consistent over time.

**Figure 4.23: Immunization & Immunization Administration Expenditures under Medical Benefit by Month: 2004 to 2014**

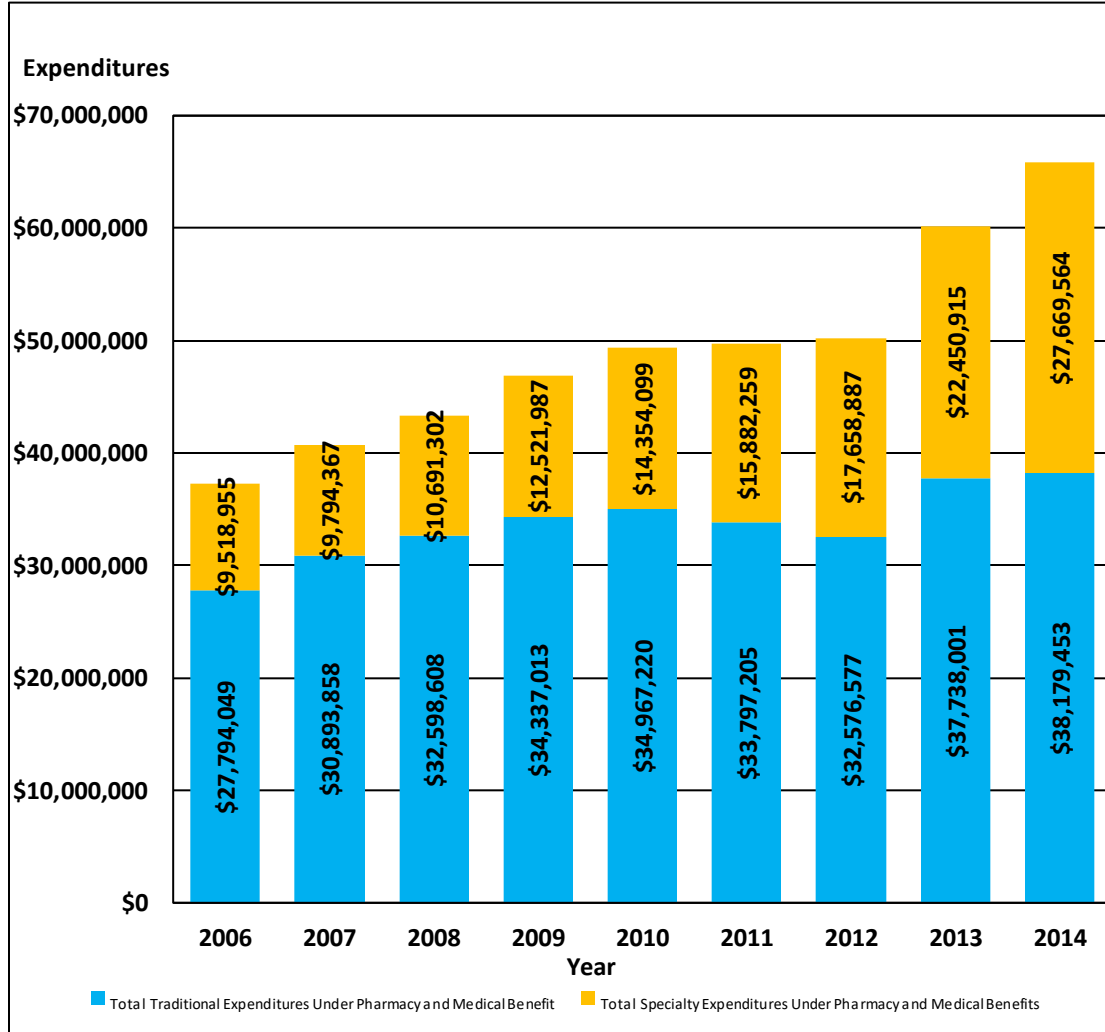




#### **4.1.2 General trends for specialty vs. traditional drugs**

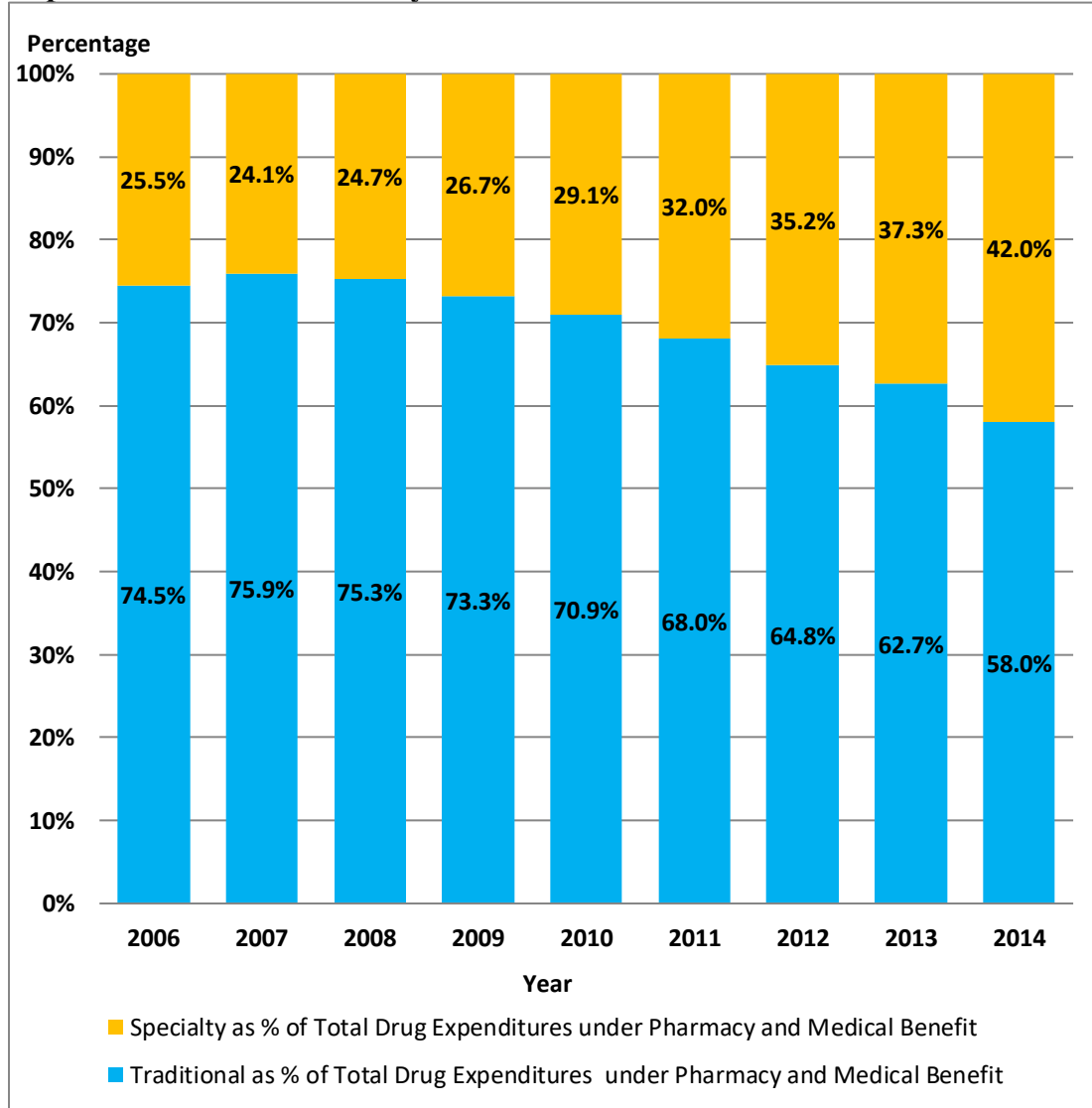
Expenditures for traditional drugs accounted for a greater portion of the total drug expenditures than did specialty drugs from 2006 to 2014. Specialty drug and specialty drug-related expenditures grew from 2006 to 2014 from \$9.5 to \$27.6 million, and traditional drug and traditional drug-related expenditures grew from \$27.7 to \$38.1 million respectively. As seen in Figure 4.24, the growth in specialty drug and specialty drug-related expenditures was notably greater than was observed for traditional drugs from 2006 to 2014, at 191 percent from \$9.5 million to \$27.6 million for specialty and 37 percent growth from \$27.7 million to \$38.1 million for traditional.

**Figure 4.24: Total Specialty & Traditional Expenditures across Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.25: Specialty vs. Traditional Expenditures as Percentage of Total Expenditures under Pharmacy & Medical Benefits: 2006 to 2014\***

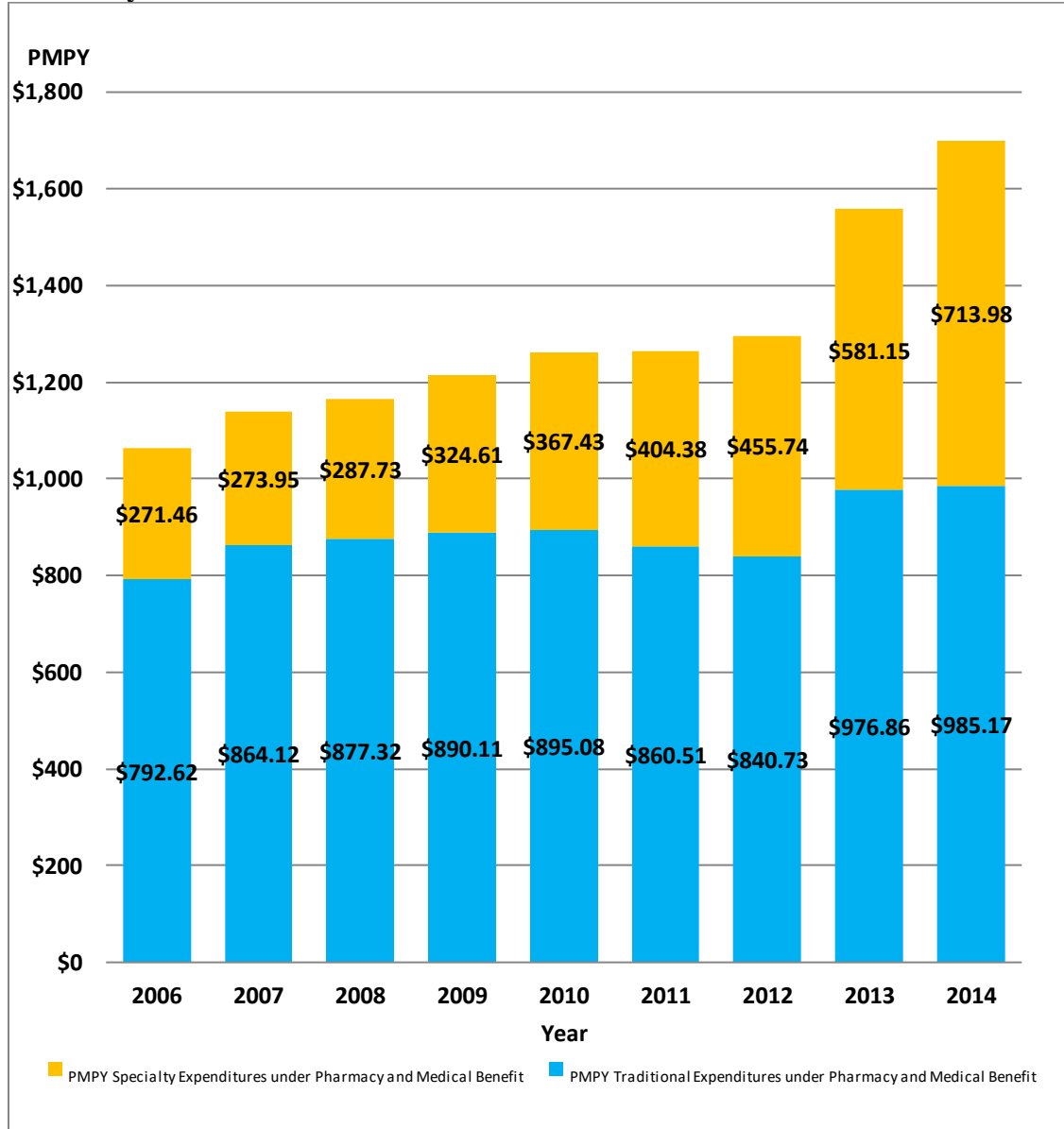


\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

From 2006 to 2014, traditional drug and drug-related expenditures accounted for 58 percent and greater of total drug and drug-related expenditures, as observed in Figure 4.25. However, specialty drug and drug-related expenditures accounted for between 24 percent to 42 percent of total drug and drug-related expenditures over the study period.

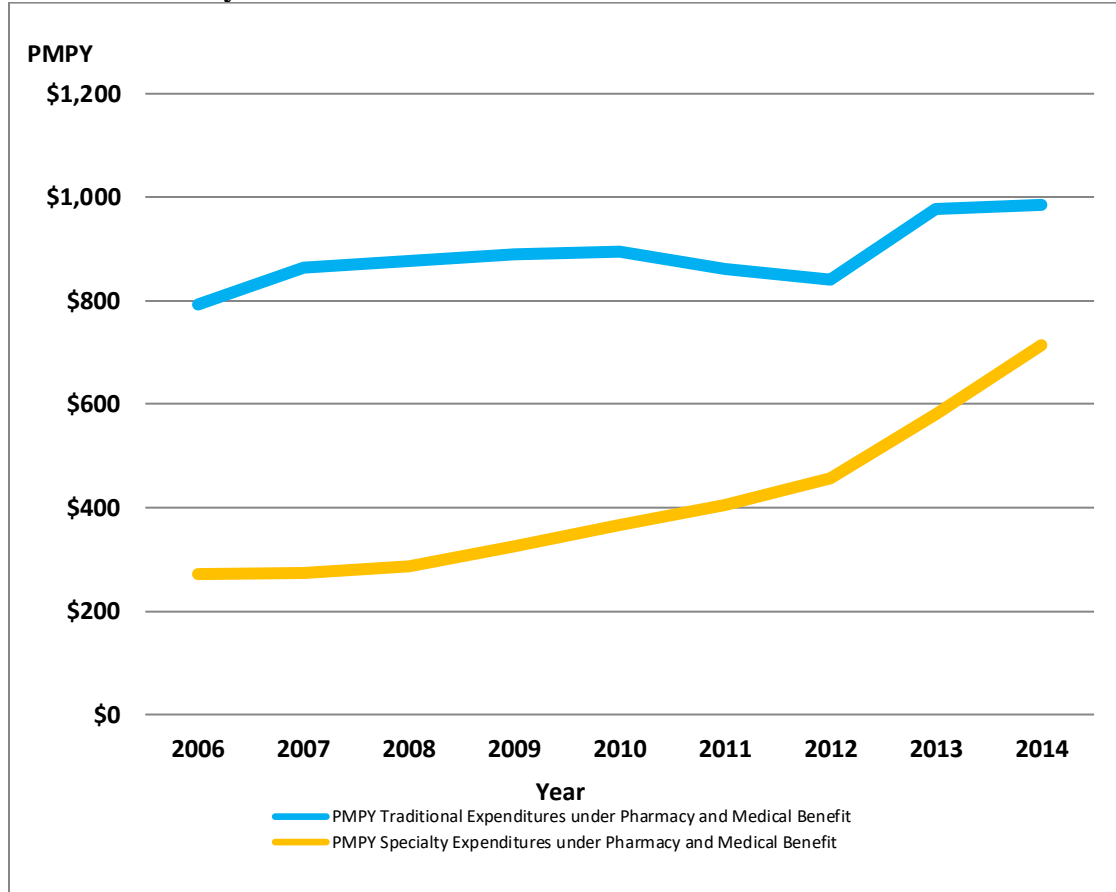
The percent of total drug and drug-related expenditures accounted for by specialty drug and specialty drug-related expenditures grew from 26 percent to 42 percent. The percent of total drug and traditional drug-related expenditures represented by traditional drug and drug-related expenditures went down from 74 percent to 58 percent, a 17 percent decline from 2006 to 2014. The percentage of total drug and drug-related expenditures represented by specialty drug and drug-related expenditures went up from 26 percent to 42 percent from 2006 to 2014, an increase of 65 percent.

**Figure 4.26: PMPY Expenditures for Specialty & Traditional Expenditures across Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.27: PMPY Expenditures for Specialty & Traditional Drug Expenditures under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

A greater growth is observed for specialty PMPY as compared to traditional PMPY from 2006 to 2014, at 163 percent vs. 24 percent. The specialty drug and drug-related PMPY grew from \$271.46 to \$713.98 from 2006 to 2014; while the traditional drug and drug-related PMPY grew from \$798.62 to \$985.17.

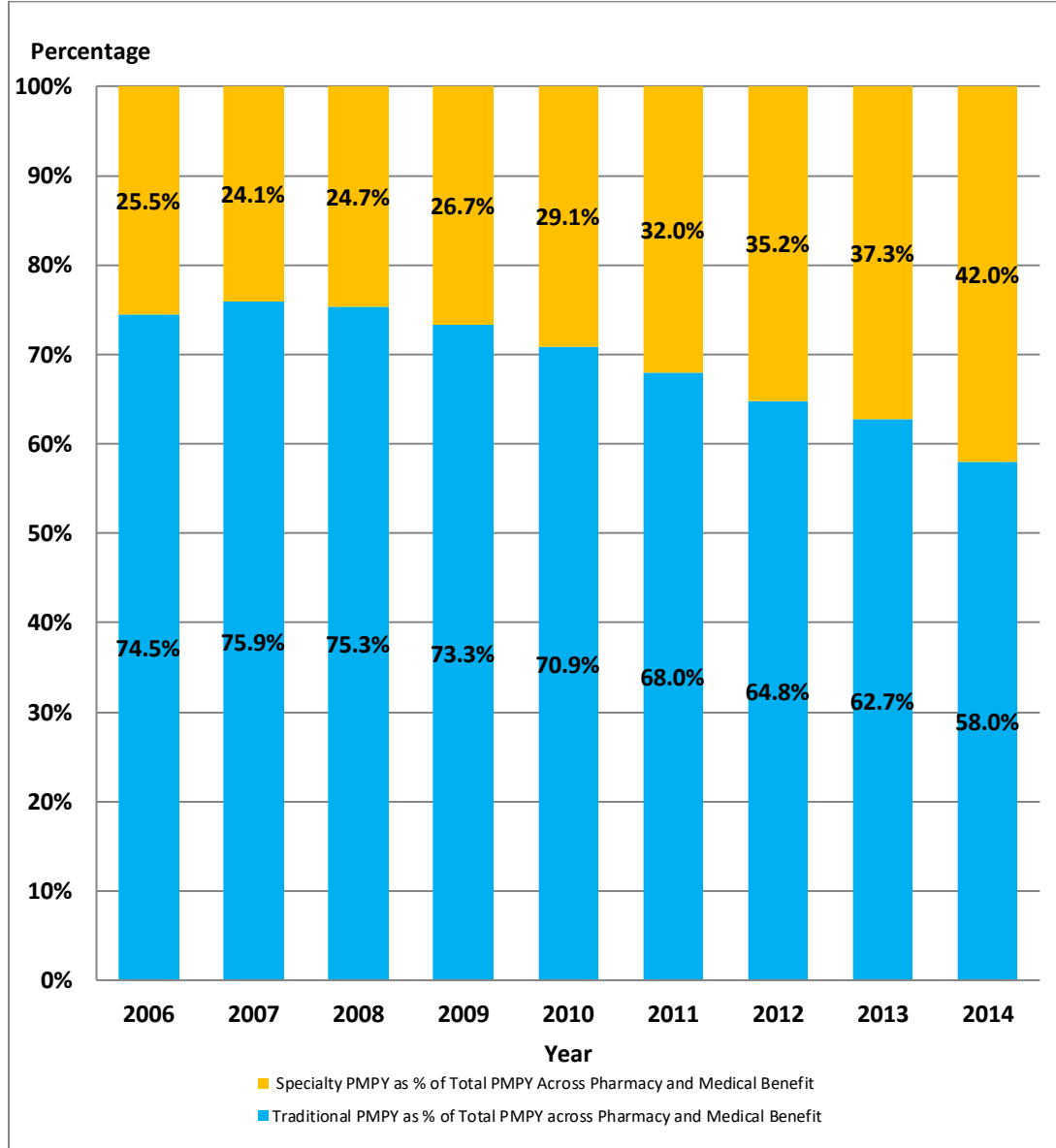
**Table 4.4: PMPY Expenditures for Specialty & Traditional Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014\***

Year	PMPY Traditional Expenditures under Pharmacy and Medical Benefits	PMPY Expenditures Pharmacy and Medical Benefits	Specialty under Medical
2006	\$792.62	\$271.46	
2007	\$864.12	\$273.95	
2008	\$877.32	\$287.73	
2009	\$890.11	\$324.61	
2010	\$895.08	\$367.43	
2011	\$860.51	\$404.38	
2012	\$840.73	\$455.74	
2013	\$976.86	\$581.15	
2014	\$985.17	\$713.98	

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

A similar trend for total drug and drug-related expenditures, including the PMPY for both traditional and specialty, is shown in Figure 4.25 and Figure 4.28. The percentage of total PMPY accounted for by specialty drug and drug-related expenditures grew over the period 2006 to 2014 from 26 percent to 42 percent. The percentage PMPY accounted for by traditional drug and drug-related expenditures went down over the period 2006 to 2014, from 74 percent to 58 per cent.

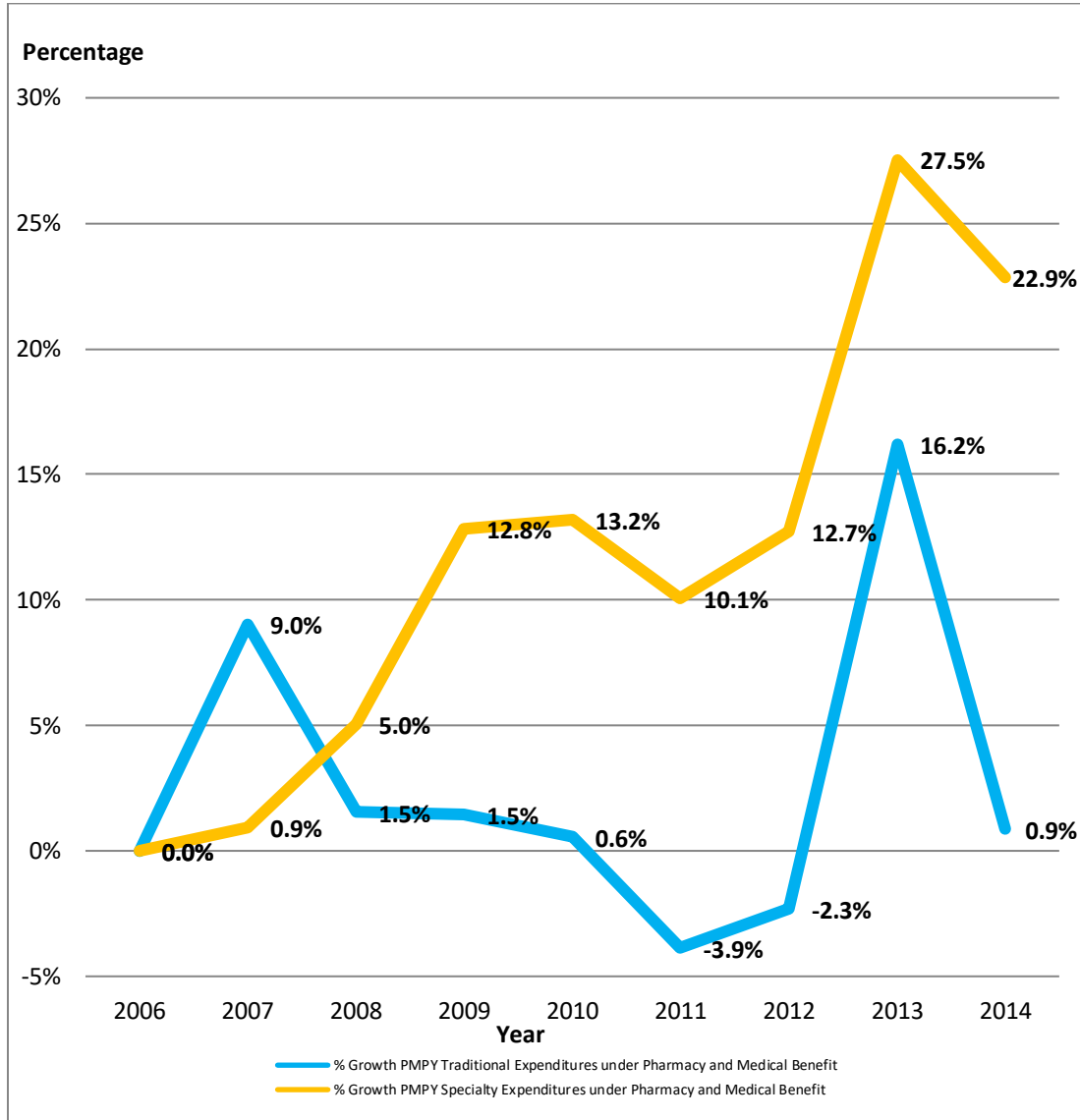
**Figure 4.28: PMPY Expenditures for Specialty & Traditional Expenditures as a Percentage of Total PMPY Expenditures across Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.



**Figure 4.29: Percentage Growth PMPY Expenditures Year to Year for Specialty & Traditional Drugs & Drug-Related Claims across Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

The year-to-year growth in PMPY fluctuated for both specialty and traditional drug and drug-related expenditures as seen in Figure 4.29 and Table 4.5. The greatest growth was observed for both traditional and specialty drugs from 2012 to 2013 at 16 percent and 28 percent, respectively.

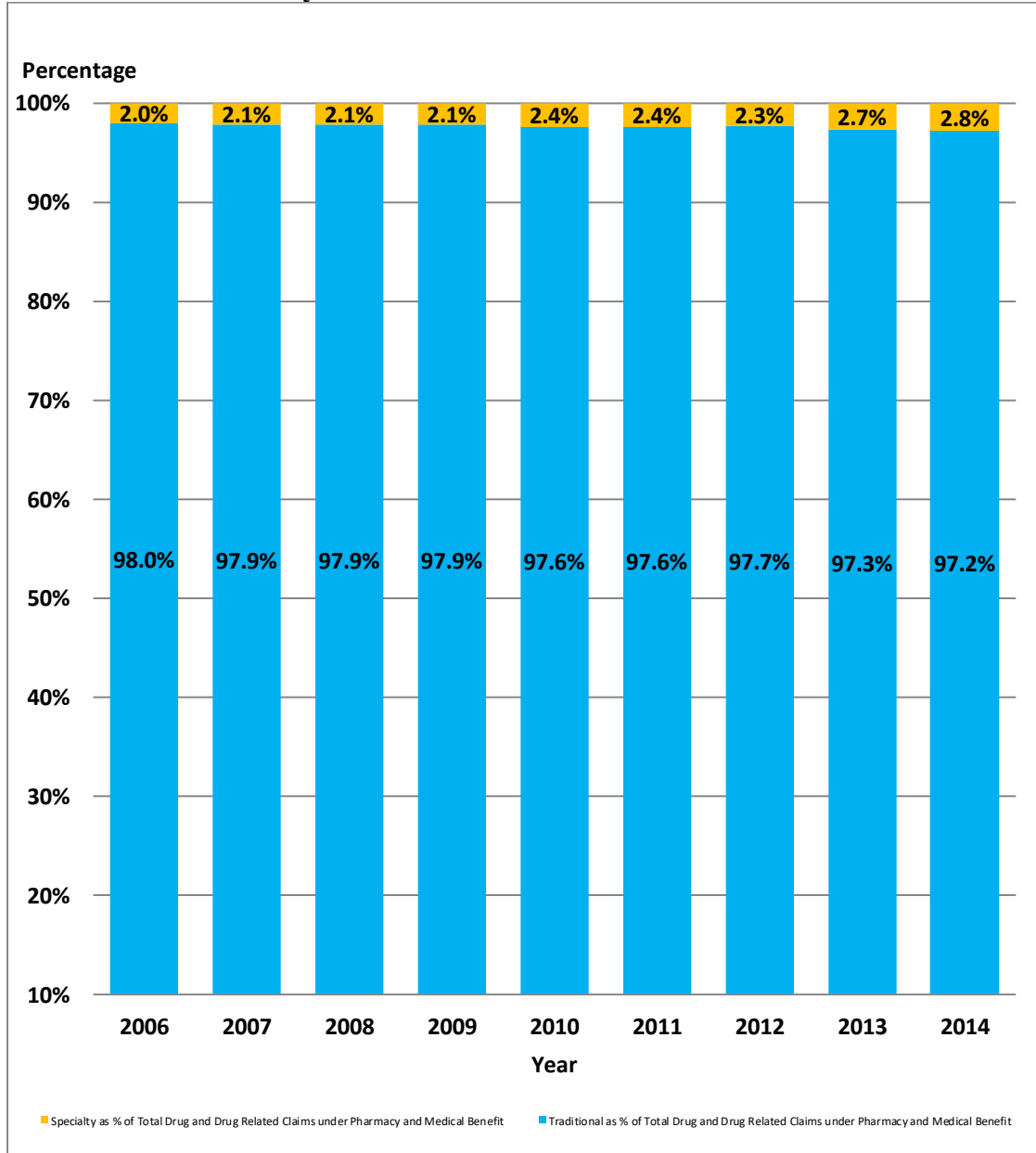
**Table 4.5: Percent Growth PMPY Expenditures Year to Year for Specialty & Traditional Expenditures across Pharmacy & Medical Benefits: 2006 to 2014\***

Year	% Growth PMPY Traditional Expenditures under Pharmacy and Medical Benefit	% Growth PMPY Specialty Expenditures under Pharmacy and Medical Benefit
2006		
2007	0.00%	0.00%
2008	9.02%	0.92%
2009	1.53%	5.03%
2010	1.46%	12.81%
2011	0.56%	13.19%
2012	-3.86%	10.05%
2013	-2.30%	12.70%
2014	16.19%	27.52%

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

Figure 4.30 outlines over the time how the percent of total drug and drug-related claims accounted for by specialty remained low and constant, between 2 percent to 3 percent from 2006 to 2014. The percentage of total drug and drug-related claims accounted for by traditional remained high and constant over time, ranging from 98 percent to 97 percent from 2006 to 2014.

**Figure 4.30: Specialty vs. Traditional Drug Claims as Percentage of Total Drug Claims under Pharmacy & Medical Benefits: 2006 to 2014\***

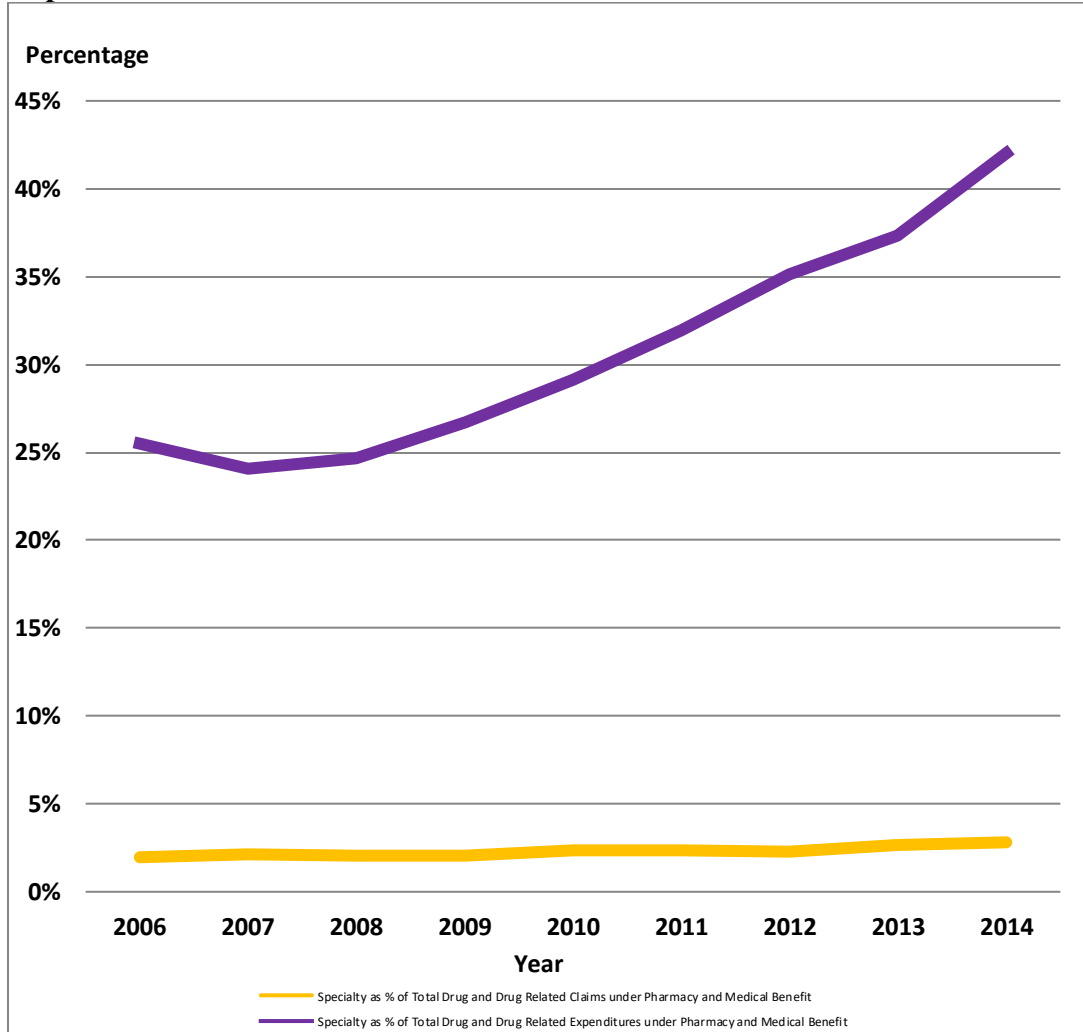


\*Total claims include total drug and drug-related claims under pharmacy and medical benefits.

However, over time, specialty drug and drug-related claims accounted for a growing percent of total drug and drug-related claims, and the number of specialty claims ranged between 6,996 to 10,203 per year over the study period. In 2006 specialty drug

and drug-related expenditures accounted for 26 percent of total drug and drug-related claims, but account for 2 percent of total drug and drug-related claims.

**Figure 4.31: Specialty Expenditures & Utilization as a Percentage of Total Expenditures & Utilization: 2006 to 2014\***



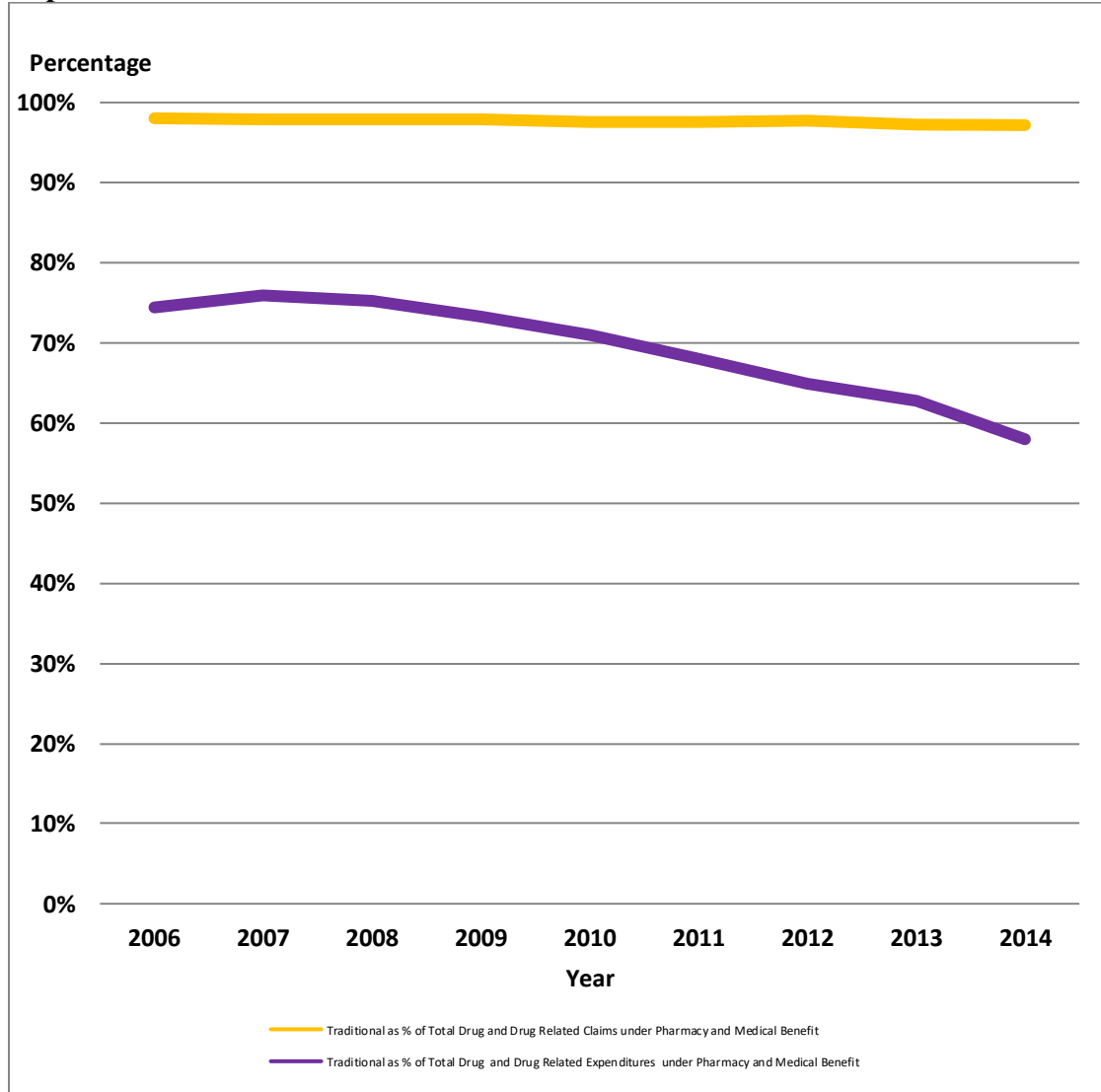
\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

Specialty drug and drug-related utilization as a percent of total drug and drug-related utilization stayed steady from 2006 to 2014, increasing from 2 percent to 2.8 percent, respectively.

In 2014 specialty drug and drug-related expenditures represented 42 percent of total drug expenditures, but only represented 2.8 percent of total drug and drug-related claims. This finding is in line with industry trends noted in the background section of this study. While specialty drug and drug-related claims account for a small portion of total

drug and drug-related claims, they represent greater than 40 percent of total drug and drug-related expenditures. This highlights the importance of why employers and various stakeholders need to understand what is contributing to the growth of specialty expenditures in their population to more effectively manage these drugs and drug-related expenditures.

**Figure 4.32: Traditional Expenditures & Utilization as a Percentage of Total Expenditure & Utilization: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

In contrast to expenditures for specialty drugs, Figure 4.25 shows expenditures for traditional drugs as a percent of total drug expenditures decreased from 74 percent to 58 percent from 2006 to 2014.

## **4.2 Aim one results**

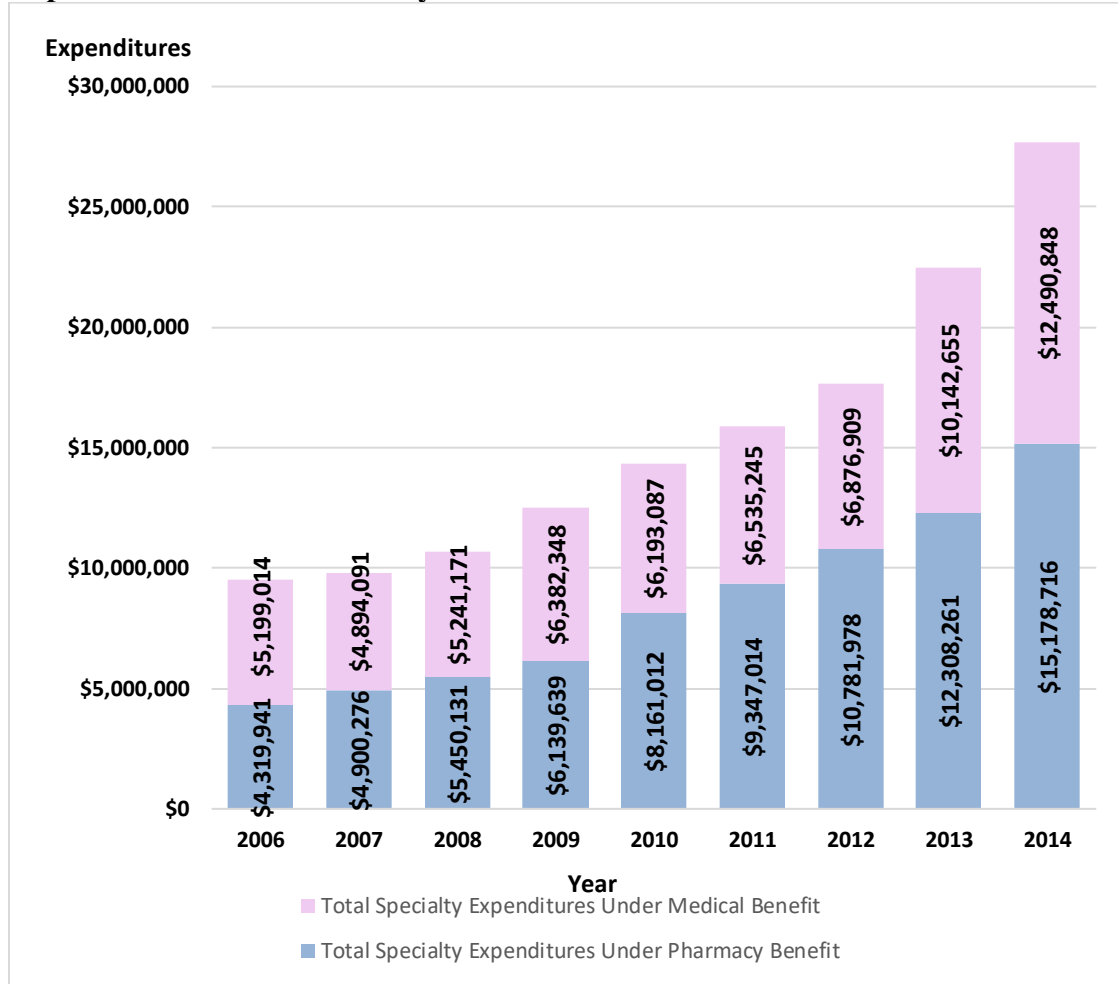
Describe specialty drug and drug-related product trends including expenditures and utilization under the pharmacy and medical benefits from 2006 to 2014 for the University of Minnesota UPlan.

### **4.2.1 Question 1a**

What is the total utilization and expenditures of specialty drugs and drug-related products under the pharmacy benefit and medical benefit from 2006 to 2014?



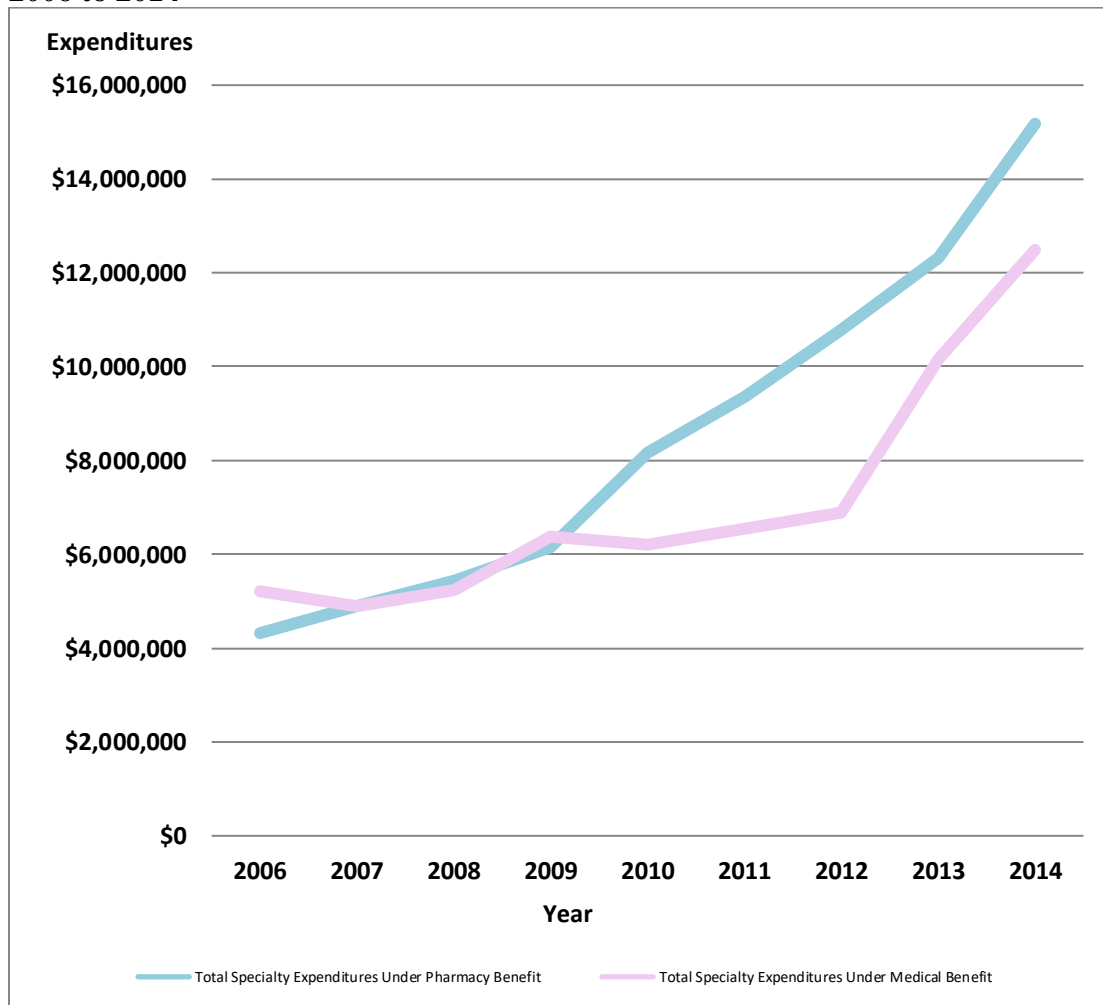
**Figure 4.33: Total Expenditures on Specialty Drugs and Drug-Related Expenditures across Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

A clear growth in total specialty expenditures was observed from 2006 to 2014, with a total growth of \$18.1 million, as seen in Figure 4.33. Drug and drug-related expenditures for specialty across pharmacy and medical benefits grew from \$9.5 million to \$27.6 million from 2006 to 2014, respectively.

**Figure 4.34: Total Specialty Expenditures under Pharmacy & Medical Benefit: 2006 to 2014\***

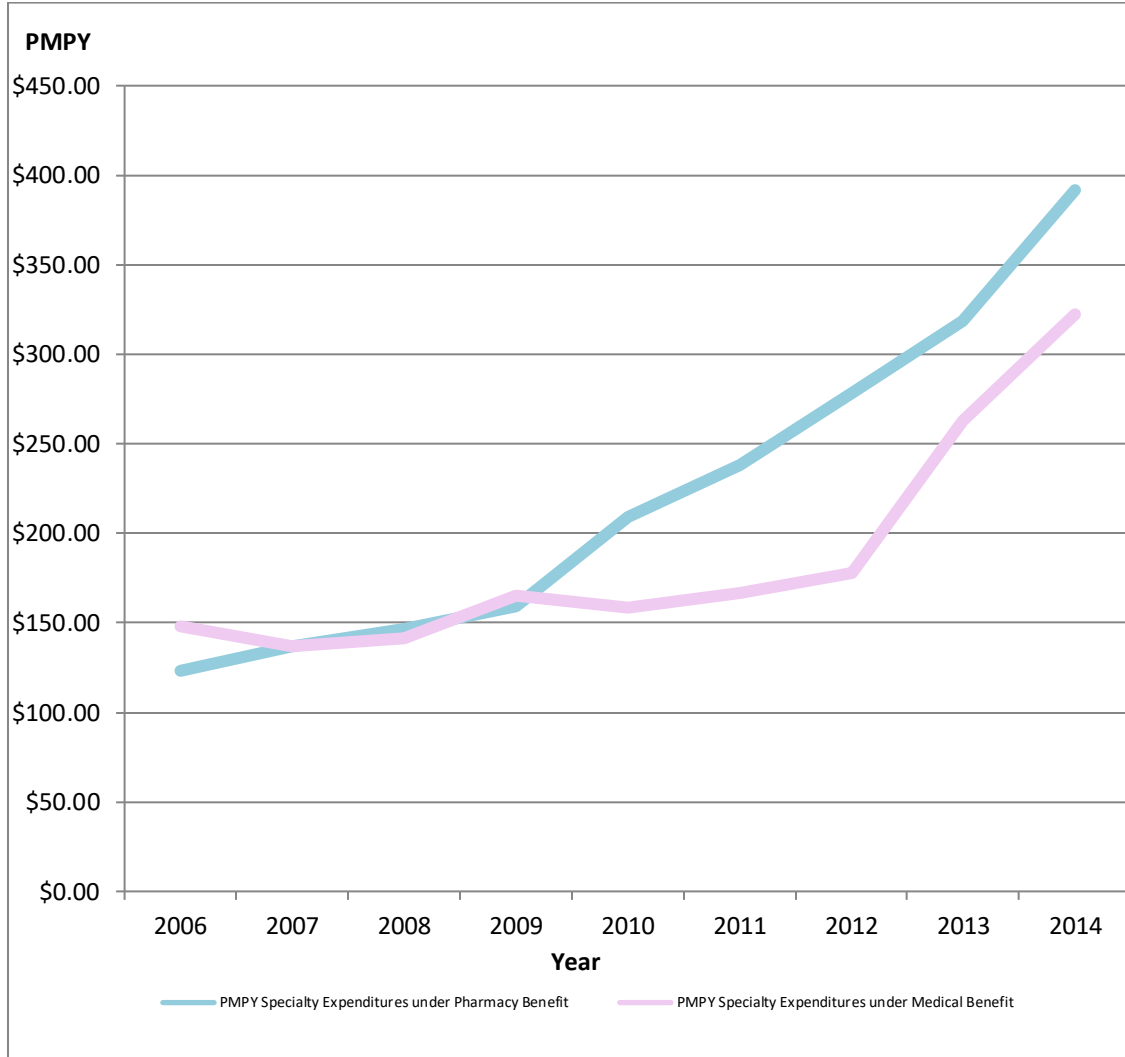


\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

Figure 4.34 shows that the specialty expenditures grew more from 2006 to 2014 under the pharmacy benefit than specialty expenditures under the medical benefit, at \$10.8 million vs. \$7.2 million. Specialty expenditures under the medical benefit grew from \$5.1million to \$12.4 million, while specialty expenditures under the pharmacy benefit grew from \$4.3 million to \$15.1 million. In 2006 and 2009 specialty expenditures were slightly greater under the medical benefit than those under the pharmacy benefit. However, from 2010 to 2014 specialty drug and drug-related expenditures were notably greater under the pharmacy benefit than they were under the medical benefit.

The PMPY expenditure for specialty drugs under the pharmacy benefit had a greater growth from 2006 to 2014 than under the medical benefit, at 348 percent vs. 268 percent. In 2006 and 2014 specialty drugs under the pharmacy benefit had a PMPY of \$93.60 and \$419.29. Under the medical benefit, specialty drugs had a PMPY that ranged from \$92.85 to \$342.08 from 2006 to 2014.

**Figure 4.35: PMPY Expenditure for Specialty Drugs under Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

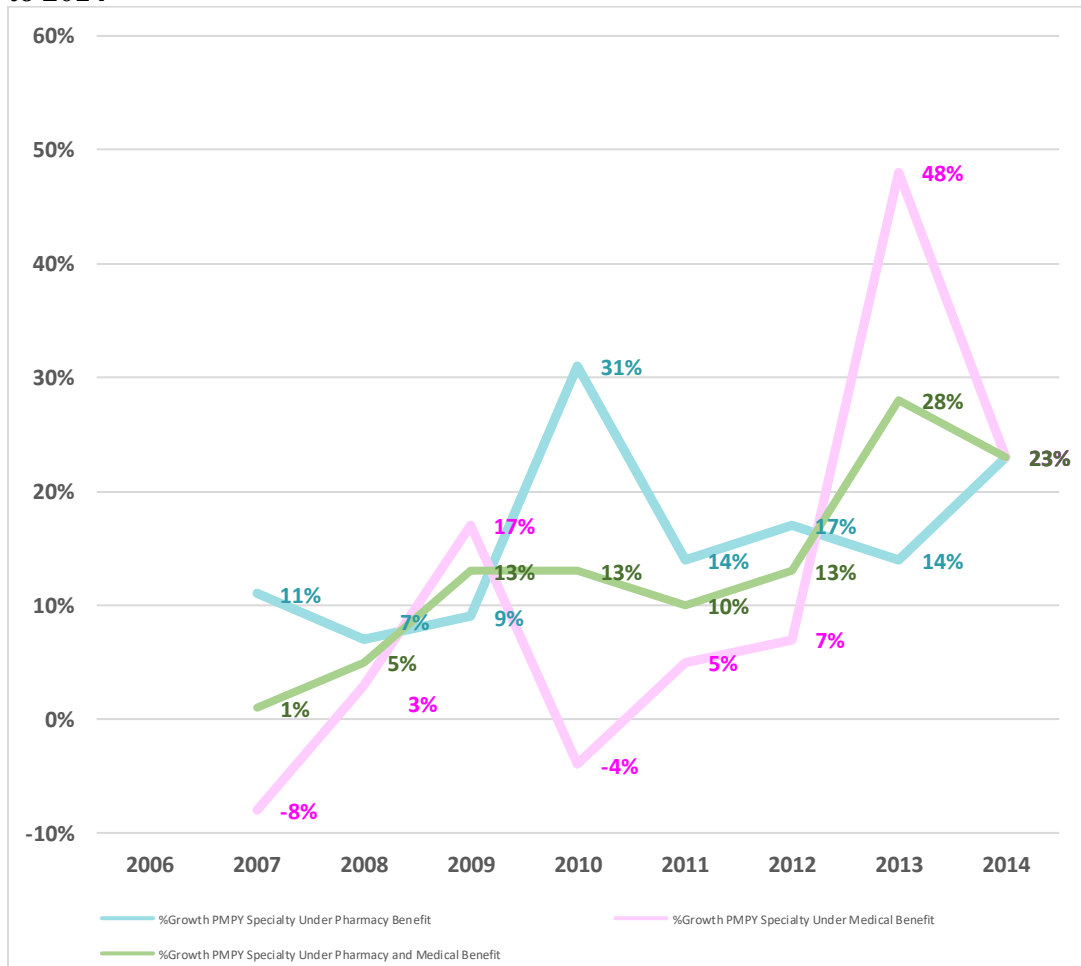
Except for 2006 and 2009 PMPY for specialty drug and drug-related expenditures was greater under the pharmacy benefit than under medical benefit, as seen in Figure 4.35 and Table 4.6. Overall, PMPY for specialty drugs across pharmacy and medical benefits grew 163 percent, from \$271.6 to \$713.98 from 2006 to 2014.

**Table 4.6: PMPY Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014\***

Year	Grand Total PMPY Under Specialty Pharmacy	Grand Total PMPY Medical Specialty	Grand Total PMPY Medical and Pharmacy Specialty
2006	\$123.19	\$148.26	\$271.46
2007	\$137.06	\$136.92	\$273.95
2008	\$146.68	\$141.06	\$287.73
2009	\$159.16	\$165.46	\$324.61
2010	\$208.90	\$158.53	\$367.43
2011	\$237.98	\$166.39	\$404.38
2012	\$278.26	\$177.48	\$455.74
2013	\$318.60	\$262.55	\$581.15
2014	\$391.67	\$322.31	\$713.98

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.36: Percentage Growth in PMPY Expenditure Year to Year for Specialty Drugs and Drug-Related Expenditures under Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

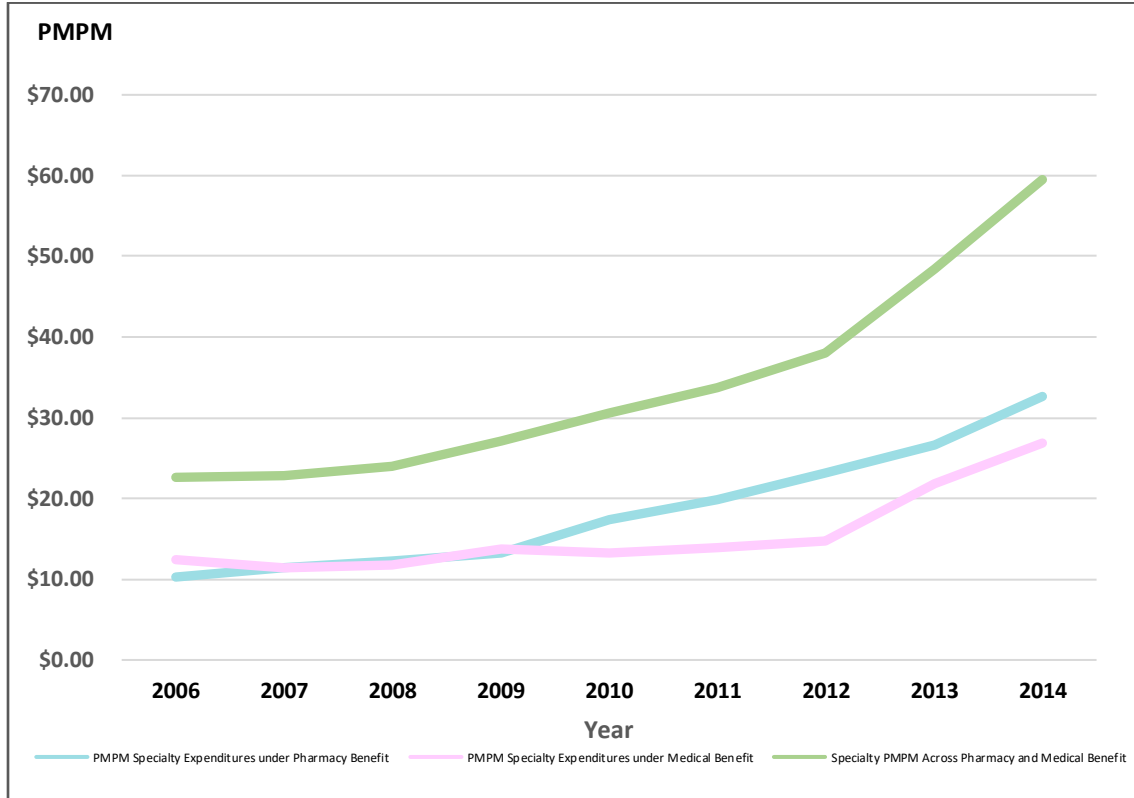
The year-to-year growth in PMPY fluctuated for specialty drug and drug-related expenditures flowing through both pharmacy and medical benefits, as seen in Figure 4.36 and Table 4.7.

**Table 4.7: Percentage Growth in PMPY Specialty Expenditure Year to Year Pharmacy & Medical Benefits: 2006 to 2014\***

<b>Year</b>	<b>% Growth PMPY Under Specialty Pharmacy</b>	<b>% Growth PMPY Medical Specialty</b>	<b>% Growth PMPY Pharmacy and Medical Specialty</b>
2006			
2007	11%	-8%	1%
2008	7%	3%	5%
2009	9%	17%	13%
2010	31%	-4%	13%
2011	14%	5%	10%
2012	17%	7%	13%
2013	14%	48%	28%
2014	23%	23%	23%

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.37: PMPM Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

The drug and drug-related specialty PMPM expenditure flowing through the pharmacy benefit grew from 2006 to 2014 by \$22.37, from \$10.27 to \$32.64. For drug expenditures flowing through the medical benefit, PMPM grew by \$14.50 from \$12.36 to \$26.86 from 2006 to 2014. The overall drug and drug-related specialty PMPM across pharmacy and medical benefits grew from \$22.62 to \$59.50 a difference of \$36.88 from 2006 to 2014.

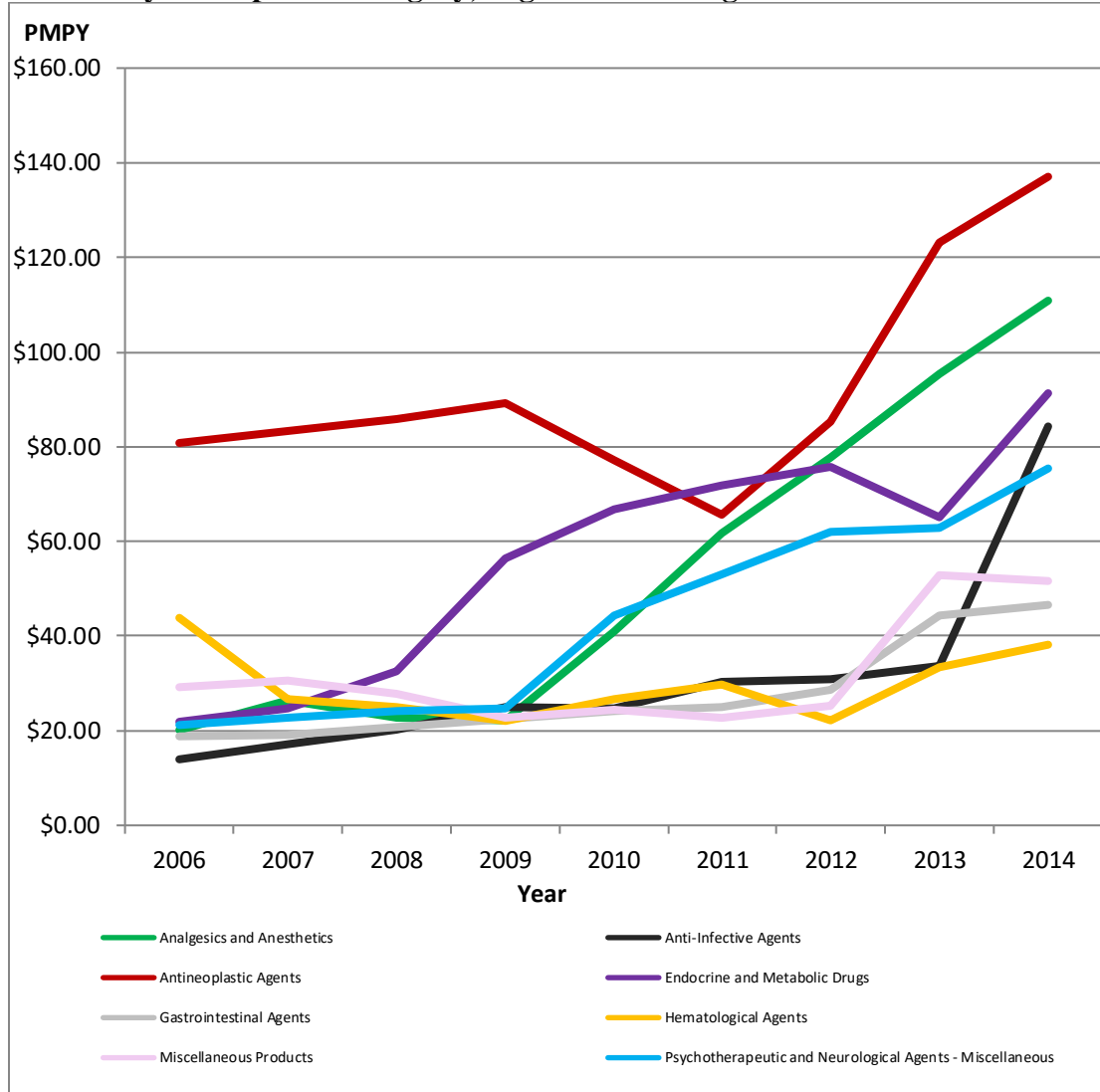
**Table 4.8: PMPM Expenditure for Specialty under Pharmacy & Medical Benefits: 2006 to 2014\***

<b>Year</b>	<b>PMPM Specialty under Pharmacy</b>	<b>PMPM Specialty under Medical</b>	<b>PMPM Specialty under Pharmacy &amp; Medical</b>
2006	\$10.27	\$12.36	\$22.62
2007	\$11.42	\$11.41	\$22.83
2008	\$12.22	\$11.76	\$23.98
2009	\$13.26	\$13.79	\$27.05
2010	\$17.41	\$13.21	\$30.62
2011	\$19.83	\$13.87	\$33.70
2012	\$23.19	\$14.79	\$37.98
2013	\$26.55	\$21.88	\$48.43
2014	\$32.64	\$26.86	\$59.50

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

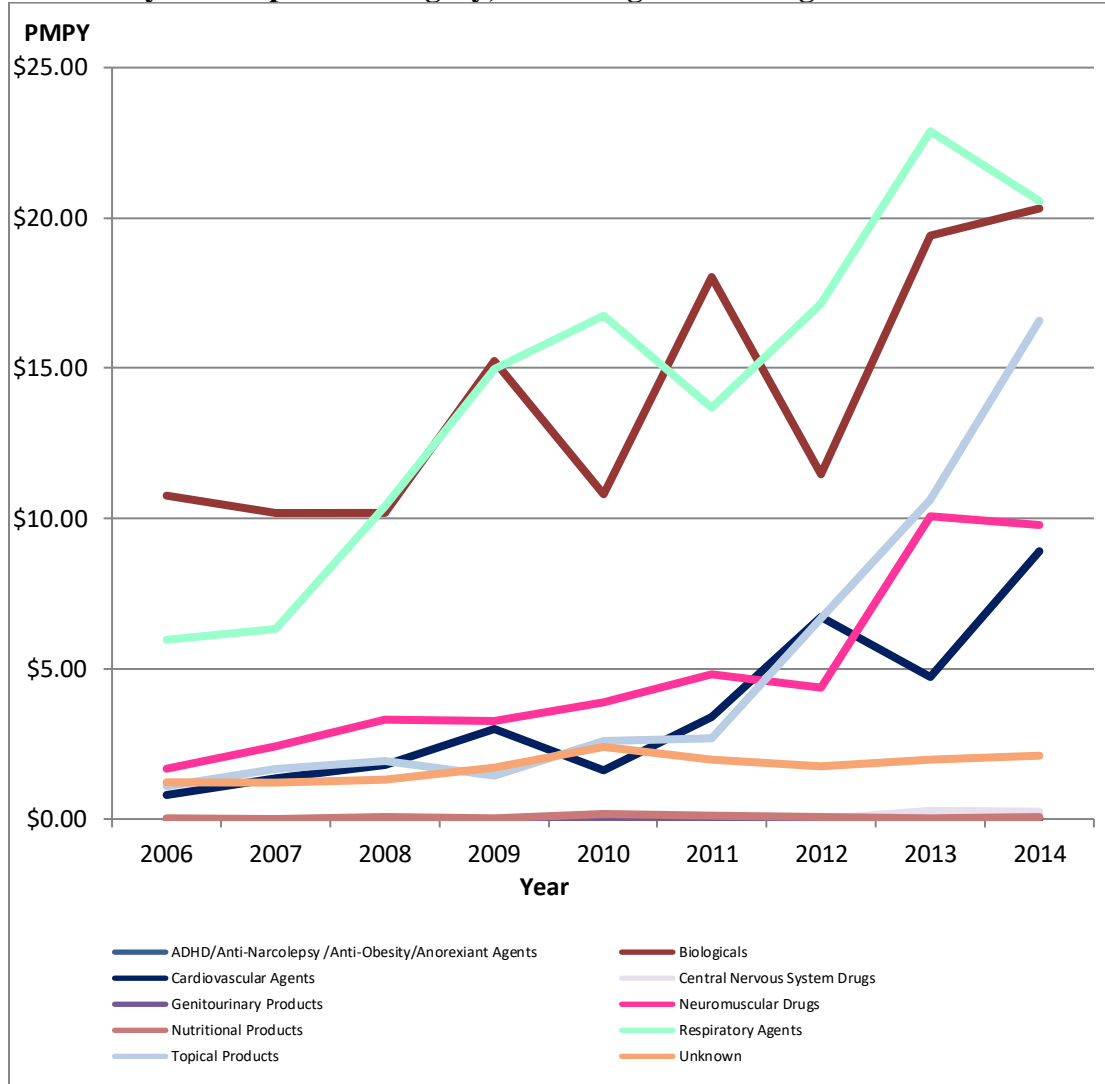


**Figure 4.38A: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Higher Cost Categories: 2006 to 2014\***



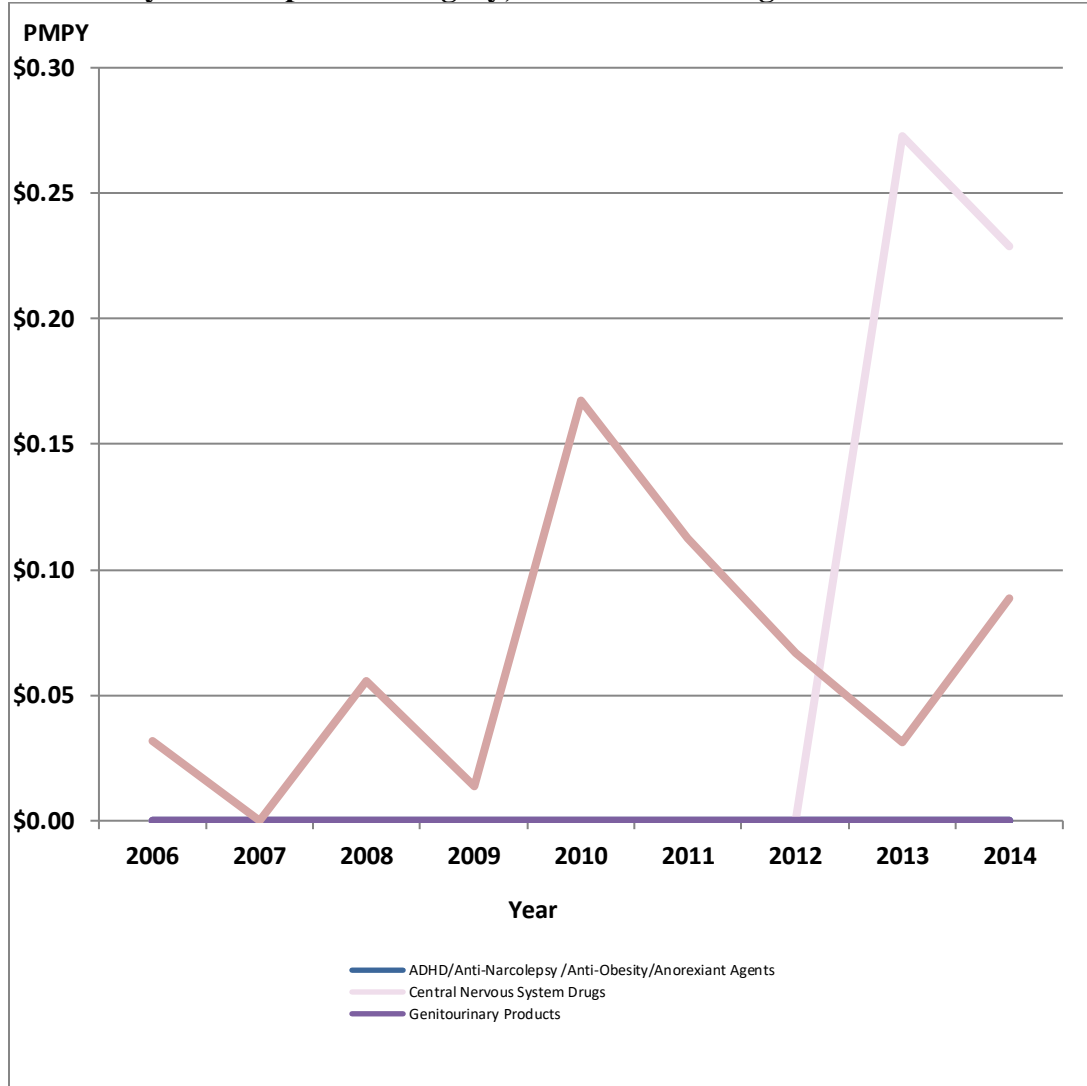
\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.38B: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Mid-Range Cost Categories: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.38C: PMPY Expenditure for Specialty across Pharmacy & Medical Benefits by Therapeutic Category, Lowest Cost Categories: 2004 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

The therapeutic category with the largest PMPY expenditure in 2006 and 2014 was antineoplastic agents at \$80.86 and \$137.05, Figure 4.38A. The 2011 PMPY for endocrine and metabolic agents was greater than that of antineoplastic agents. In 2006, the top two therapeutic categories for overall PMPY for specialty drugs across pharmacy and medical benefits were antineoplastic agents and hematological agents. In 2014 the top two therapeutic categories for overall PMPY for specialty drugs across pharmacy and medical benefits were antineoplastic agents and analgesics and anesthetics. Two of the highest PMPY expenditure drugs, Enbrel and Humira, were for autoimmune diseases and are included in the analgesics and anesthetics category.

**Table 4.9: PMPY for Specialty Expenditures across Pharmacy & Medical Benefits by Therapeutic Category: 2006 to 2014\***

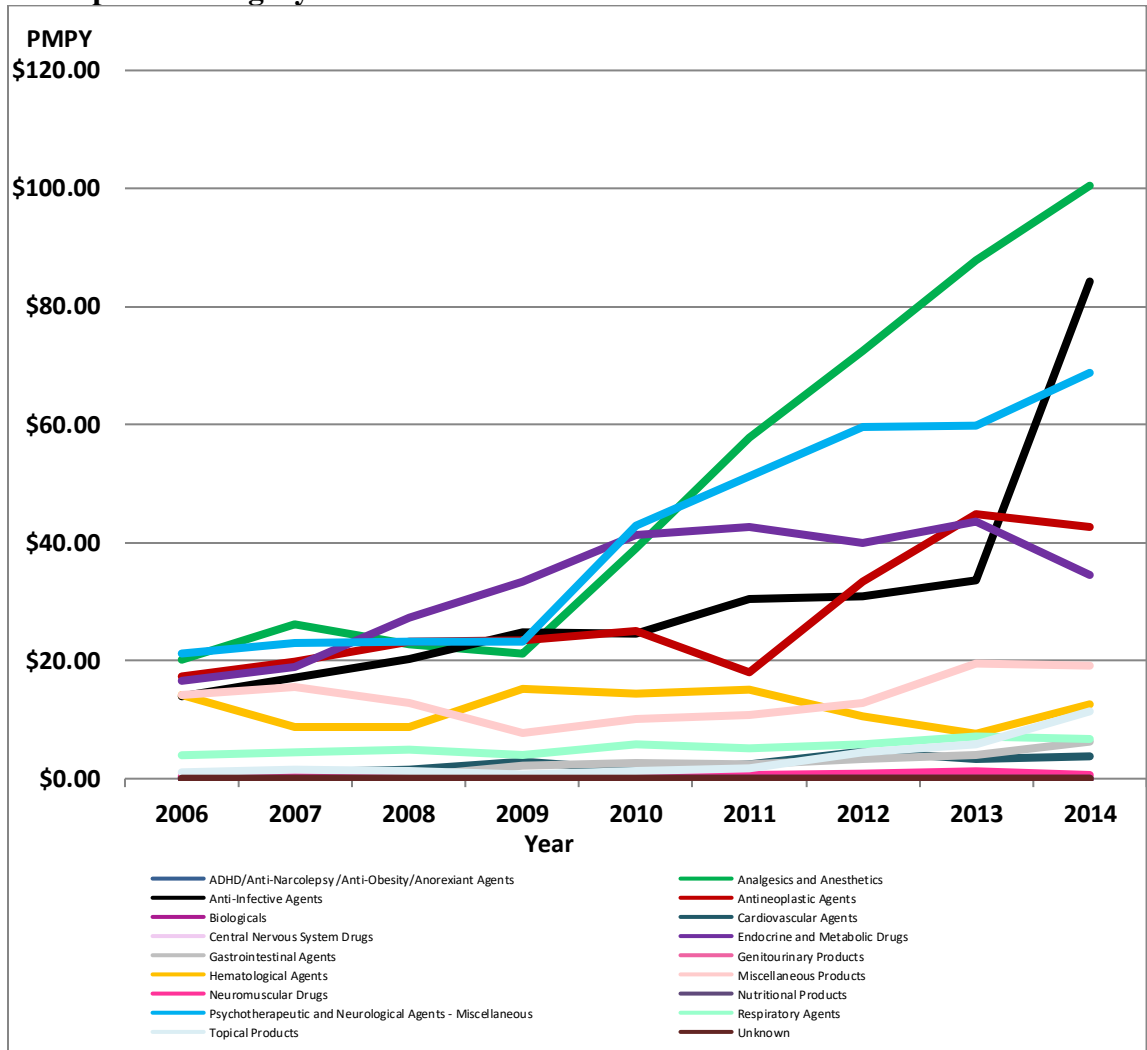
Therapeutic Categories	2006	2007	2008	2009	2010	2011	2012	2013	2014
Antineoplastic Agents	\$80.86	\$83.19	\$85.72	\$89.26	\$77.08	\$65.63	\$85.25	\$123.03	\$137.05
Hematological Agents	\$43.85	\$26.68	\$25.03	\$22.06	\$26.73	\$29.62	\$22.25	\$33.50	\$38.27
Miscellaneous Products	\$29.19	\$30.70	\$27.76	\$22.74	\$24.30	\$22.72	\$25.21	\$52.86	\$51.61
Endocrine and Metabolic Drugs	\$21.89	\$24.79	\$32.45	\$56.53	\$66.76	\$71.79	\$75.61	\$65.22	\$91.31
Psychotherapeutic and Neurological Agents - Miscellaneous	\$21.20	\$22.88	\$24.25	\$24.73	\$44.48	\$52.95	\$61.95	\$62.93	\$75.41
Analgesics and Anesthetics	\$20.16	\$26.29	\$22.65	\$22.25	\$41.08	\$61.63	\$77.81	\$95.52	\$110.87
Gastrointestinal Agents	\$18.81	\$19.12	\$20.72	\$22.44	\$24.15	\$25.00	\$28.64	\$44.43	\$46.58
Anti-Infective Agents	\$13.95	\$17.14	\$20.18	\$24.99	\$24.65	\$30.34	\$30.82	\$33.66	\$84.29
Biologicals	\$10.78	\$10.20	\$10.18	\$15.24	\$10.79	\$18.05	\$11.45	\$19.39	\$20.31
Respiratory Agents	\$5.96	\$6.31	\$10.38	\$14.97	\$16.74	\$13.69	\$17.16	\$22.88	\$20.57
Neuromuscular Drugs	\$1.67	\$2.43	\$3.31	\$3.27	\$3.89	\$4.80	\$4.36	\$10.07	\$9.77
Unknown	\$1.21	\$1.21	\$1.32	\$1.70	\$2.40	\$1.97	\$1.75	\$1.99	\$2.12
Topical Products	\$1.09	\$1.66	\$1.93	\$1.44	\$2.58	\$2.68	\$6.66	\$10.62	\$75.41
Cardiovascular Agents	\$0.80	\$1.34	\$1.78	\$2.99	\$1.63	\$3.38	\$6.74	\$4.74	\$8.91
Nutritional Products	\$0.03	\$0.00	\$0.06	\$0.01	\$0.17	\$0.11	\$0.07	\$0.03	\$0.09

ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Central Nervous System Drugs	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.27	\$0.23
Genitourinary Products	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

Figure 4.39 and Table 4.10 demonstrate that in 2006 the top three therapeutic categories with the highest PMPY under the pharmacy benefit were analgesics and anesthetics, psychotherapeutic and neurological agents, and antineoplastic agents. In 2014, the top three therapeutic categories were analgesics and anesthetics, anti-infective agents, and psychotherapeutic and neurological agents. From 2006 to 2014 the PMPY for analgesics and anesthetics agents under the pharmacy benefit grew by 398 percent, antineoplastic agents by 147 percent and psychotherapeutic and neurological agents by 224 percent. The miscellaneous category includes the highest expenditure product Revlimid. Revlimid has three FDA approved indications, including myelodysplastic syndrome, mantle cell lymphoma and multiple myeloma.

**Figure 4.39: PMPY Expenditure for Specialty under the Pharmacy Benefit by Therapeutic Category: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy benefit.

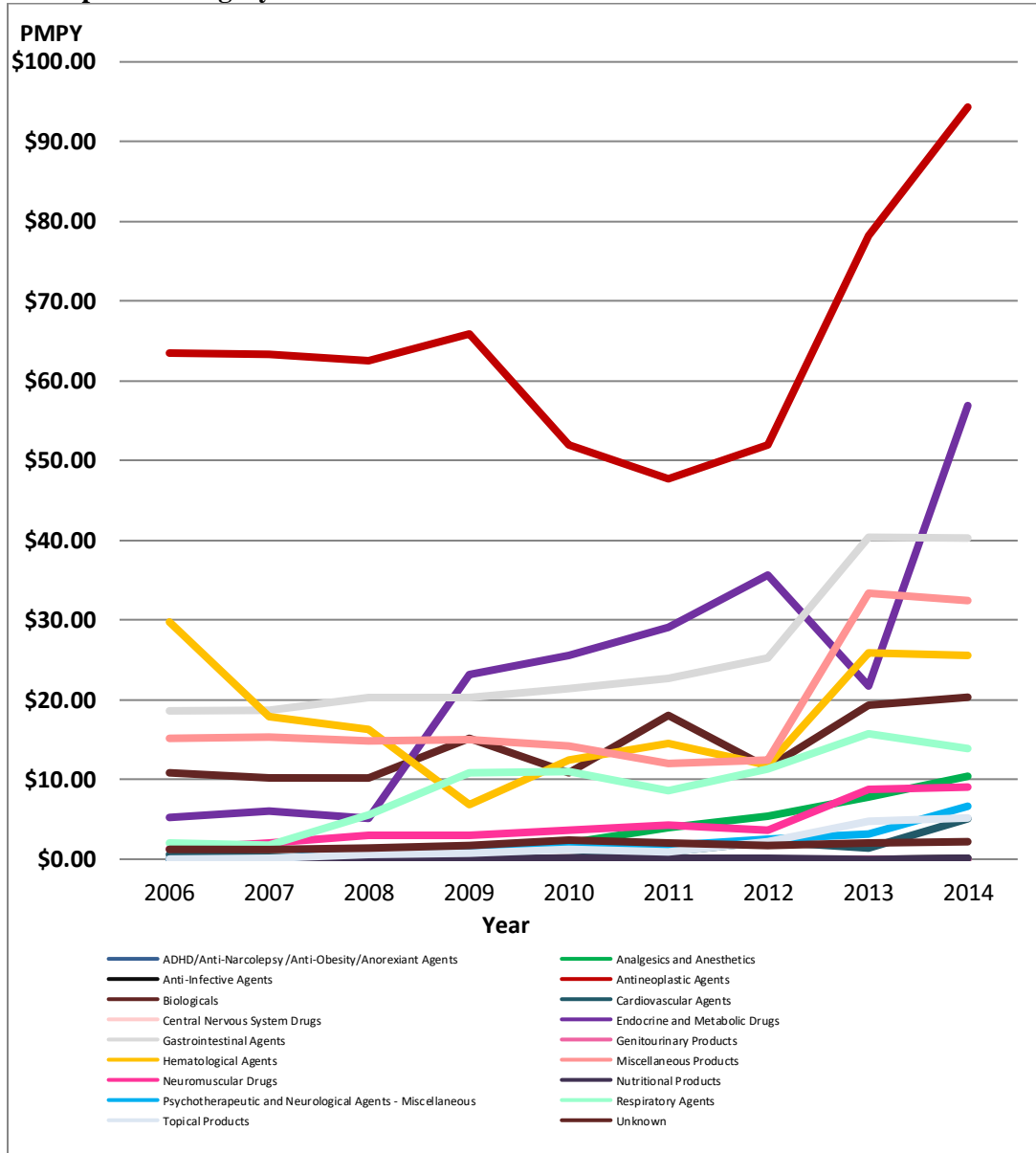
The PMPY growth from 2006 to 2014 for all therapeutic categories ranged from 0 percent to 2,930 percent. The specialty therapeutic categories under the pharmacy benefit with a greater than 500 percent growth from 2006 to 2014 were Topical products (955 percent), Cardiovascular Agents (2,567 percent), and Gastrointestinal Agents (2,930 percent).

**Table 4.10: PMPY Expenditure for Specialty under the Pharmacy Benefit: 2006 to 2014\***

Therapeutic Categories	2006	2007	2008	2009	2010	2011	2012	2013	2014
Psychotherapeutic and Neurological Agents - Miscellaneous	\$21.20	\$22.88	\$23.18	\$23.11	\$42.79	\$51.29	\$59.49	\$59.82	\$68.77
Analgesics and Anesthetics	\$20.16	\$26.04	\$22.65	\$21.07	\$39.01	\$57.73	\$72.42	\$87.75	\$100.47
Antineoplastic Agents	\$17.32	\$19.81	\$23.24	\$23.42	\$25.09	\$17.92	\$33.28	\$44.82	\$42.72
Endocrine and Metabolic Drugs	\$16.58	\$18.83	\$27.33	\$33.37	\$41.21	\$42.75	\$39.97	\$43.56	\$34.42
Miscellaneous Products	\$14.11	\$15.46	\$12.88	\$7.73	\$10.10	\$10.72	\$12.75	\$19.50	\$19.15
Hematological Agents	\$14.09	\$8.86	\$8.73	\$15.22	\$14.37	\$15.10	\$10.48	\$7.60	\$12.67
Anti-Infective Agents	\$13.96	\$17.14	\$20.18	\$24.86	\$24.64	\$30.34	\$30.82	\$33.63	\$84.24
Respiratory Agents	\$3.97	\$4.55	\$4.81	\$4.09	\$5.83	\$5.04	\$5.84	\$7.15	\$6.75
Topical Products	\$1.08	\$1.58	\$1.38	\$0.71	\$1.32	\$1.72	\$4.47	\$5.88	\$11.41
Neuromuscular Drugs	\$0.39	\$0.42	\$0.25	\$0.34	\$0.31	\$0.51	\$0.77	\$1.25	\$0.73
Gastrointestinal Agents	\$0.21	\$0.41	\$0.40	\$2.24	\$2.67	\$2.33	\$3.37	\$4.05	\$6.27
Cardiovascular Agents	\$0.14	\$1.09	\$1.64	\$2.99	\$1.56	\$2.53	\$4.60	\$3.30	\$3.83
ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Biologicals	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Central Nervous System Drugs	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.27	\$0.23
Genitourinary Products	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Nutritional Products	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Unknown	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00

\*Total expenditures include total drug and drug-related expenditures under the pharmacy benefit.

**Figure 4.40: PMPY Expenditure for Specialty Drugs under the Medical Benefit by Therapeutic Category: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.



For specialty drugs and drug-related products flowing through the medical benefit the top three therapeutic categories with the highest PMPY in 2006 were antineoplastic agents, hematological agents and gastrointestinal agents, as seen in Figure 4.40 and Table 4.11. In 2014 the top three categories included antineoplastic agents, endocrine and metabolic drugs, and gastrointestinal agents. One of the top expenditure drugs, Galsulfase, is in the endocrine and metabolic drug category. Galsulfase, an endocrine metabolic enzyme, is FDA indicated for an orphan condition, Maroteaux-Lamy syndrome. The gastrointestinal agents with high PMPY expenditures, such as Remicade, may be contributing to the overall high PMPY under the medical benefit. Remicade is used for several autoimmune conditions.

**Table 4.11: PMPY Expenditure for Specialty Drugs under the Medical Benefit by Therapeutic Category: 2006 to 2014\***

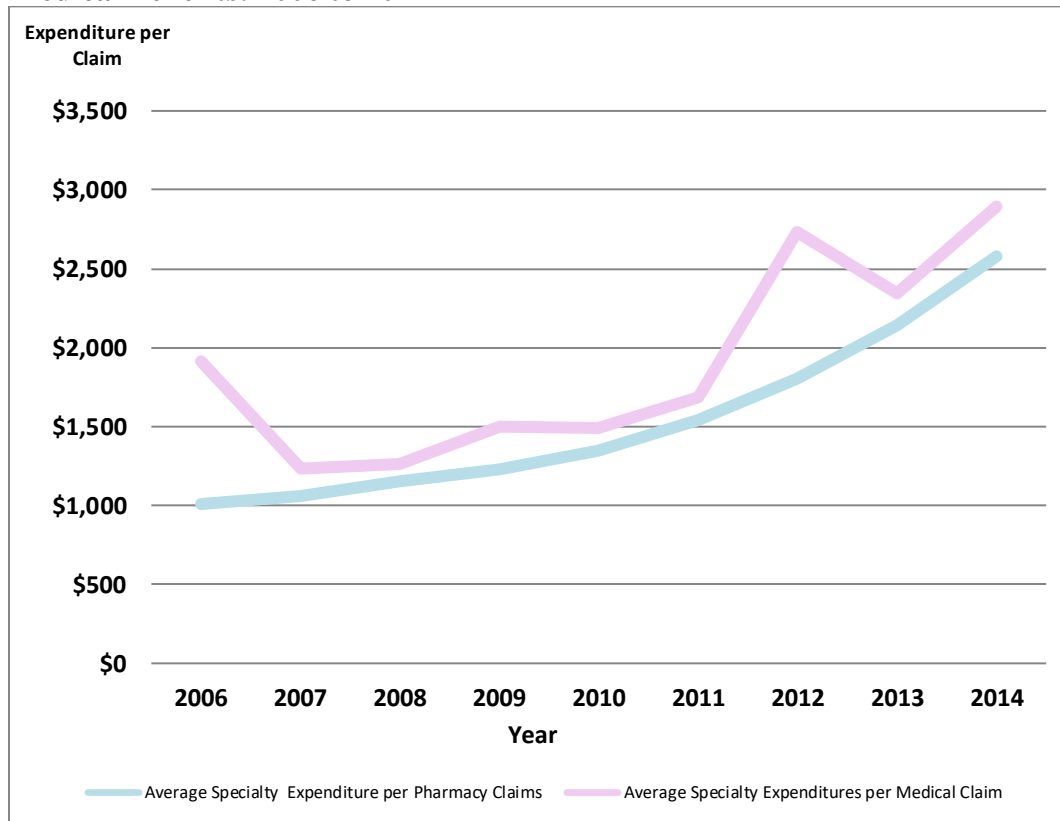
Therapeutic Category	2006	2007	2008	2009	2010	2011	2012	2013	2014
Antineoplastic Agents	\$63.54	\$63.39	\$62.48	\$65.83	\$52.00	\$47.71	\$51.97	\$78.21	\$94.33
Hematological Agents	\$29.75	\$17.82	\$16.30	\$6.85	\$12.36	\$14.52	\$11.77	\$25.90	\$25.60
Gastrointestinal Agents	\$18.61	\$18.72	\$20.32	\$20.20	\$21.47	\$22.67	\$25.27	\$40.38	\$40.31
Miscellaneous Products	\$15.08	\$15.24	\$14.89	\$15.00	\$14.20	\$12.01	\$12.46	\$33.36	\$32.46
Biologicals	\$10.78	\$10.20	\$10.18	\$15.24	\$10.79	\$18.05	\$11.45	\$19.39	\$20.31
Endocrine and Metabolic Drugs	\$5.31	\$5.96	\$5.12	\$23.16	\$25.55	\$29.03	\$35.64	\$21.66	\$56.89
Respiratory Agents	\$1.99	\$1.76	\$5.58	\$10.87	\$10.92	\$8.65	\$11.31	\$15.73	\$13.82
Neuromuscular Drugs	\$1.29	\$2.01	\$3.06	\$2.93	\$3.58	\$4.29	\$3.59	\$8.82	\$9.04
Unknown	\$1.21	\$1.21	\$1.32	\$1.70	\$2.40	\$1.97	\$1.75	\$1.99	\$2.12
Cardiovascular Agents	\$0.65	\$0.25	\$0.15	\$0.00	\$0.07	\$0.86	\$2.14	\$1.43	\$5.08
Nutritional Products	\$0.03	\$0.00	\$0.06	\$0.01	\$0.17	\$0.11	\$0.07	\$0.03	\$0.09
Topical Products	\$0.01	\$0.07	\$0.55	\$0.73	\$1.26	\$0.96	\$2.19	\$4.74	\$5.17
ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiants Agents	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Analgesics and Anesthetics	\$0.00	\$0.25	\$0.00	\$1.18	\$2.07	\$3.90	\$5.39	\$7.76	\$10.40
Anti-Infective Agents	\$0.00	\$0.00	\$0.00	\$0.12	\$0.01	\$0.00	\$0.00	\$0.02	\$0.05
Central Nervous System Drugs	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Genitourinary Products	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Psychotherapeutic and Neurological Agents - Miscellaneous	\$0.00	\$0.00	\$1.06	\$1.62	\$1.69	\$1.67	\$2.46	\$3.11	\$13.82

\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

From 2006 to 2014 PMPY expenditure change for drug and drug-related specialty drugs flowing through the medical benefit ranged from -14 percent to 50,286 percent. A greater than 500 percent growth in PMPY expenditures was noted from 2006 to 2014 for respiratory agents (593 percent), neuromuscular products (602 percent), cardiovascular agents (675 percent), endocrine and metabolic agents (971 percent), anti-infective agents (2,390 percent), and topical products (50,286) percent.

Figure 4.41 shows that average specialty drug and drug-related expenditures per claim were higher for claims under the medical benefit than expenditure per claim for the pharmacy benefit from 2006 to 2014.

**Figure 4.41: Average Specialty Expenditure per Claim under Pharmacy & Medical Benefits: 2006 to 2014\***



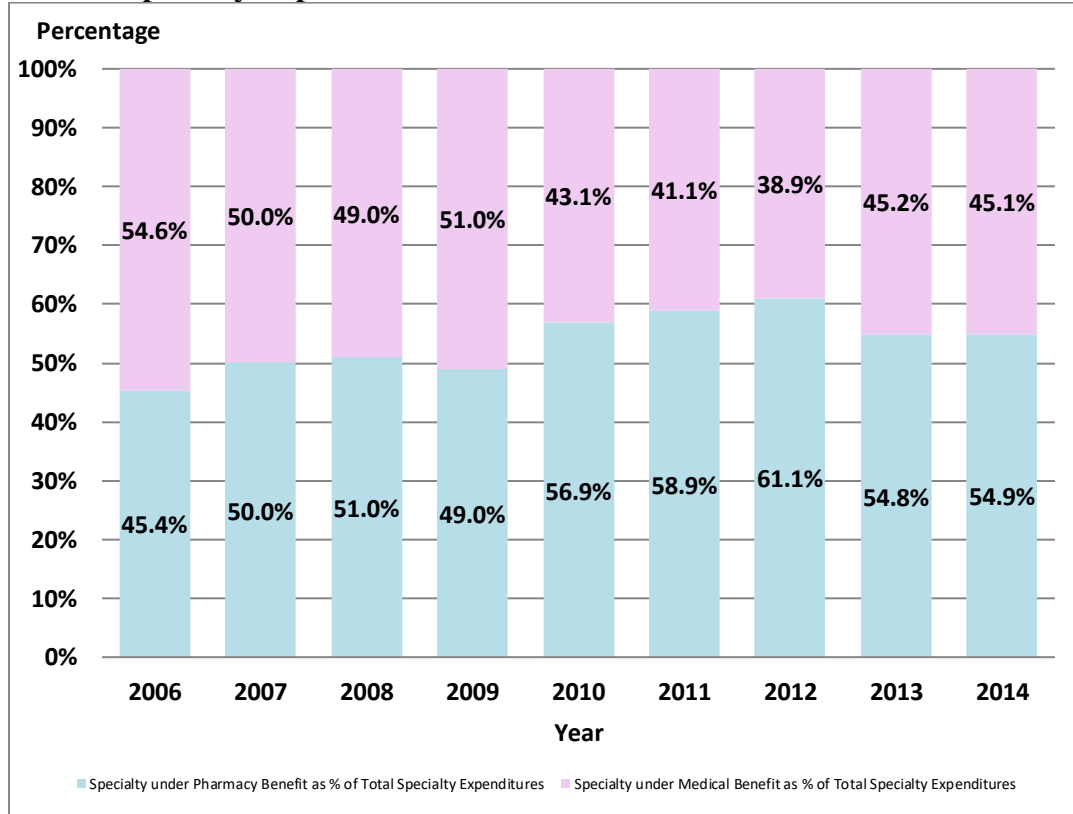
\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

However, the gap between per-claim expenditures for medical and pharmacy benefits fluctuated over time. The largest gaps in the average cost per specialty claim between pharmacy and medical benefits were noted in 2006 and 2012, with the cost of specialty medical claims being about \$900 more than specialty pharmacy claims.

The percent of total specialty drugs accounted for by the medical benefit fluctuated from 2006 to 2014. Figure 4.42 shows that the largest proportion of total specialty expenditures was accounted for by the medical benefit (55 percent), observed

in 2006; and for the pharmacy benefit the largest proportion (61 percent) is was observed in 2012.

**Figure 4.42: Specialty Pharmacy vs. Specialty Medical Expenditures as Percentage of Total Specialty Expenditures: 2006 to 2014\***

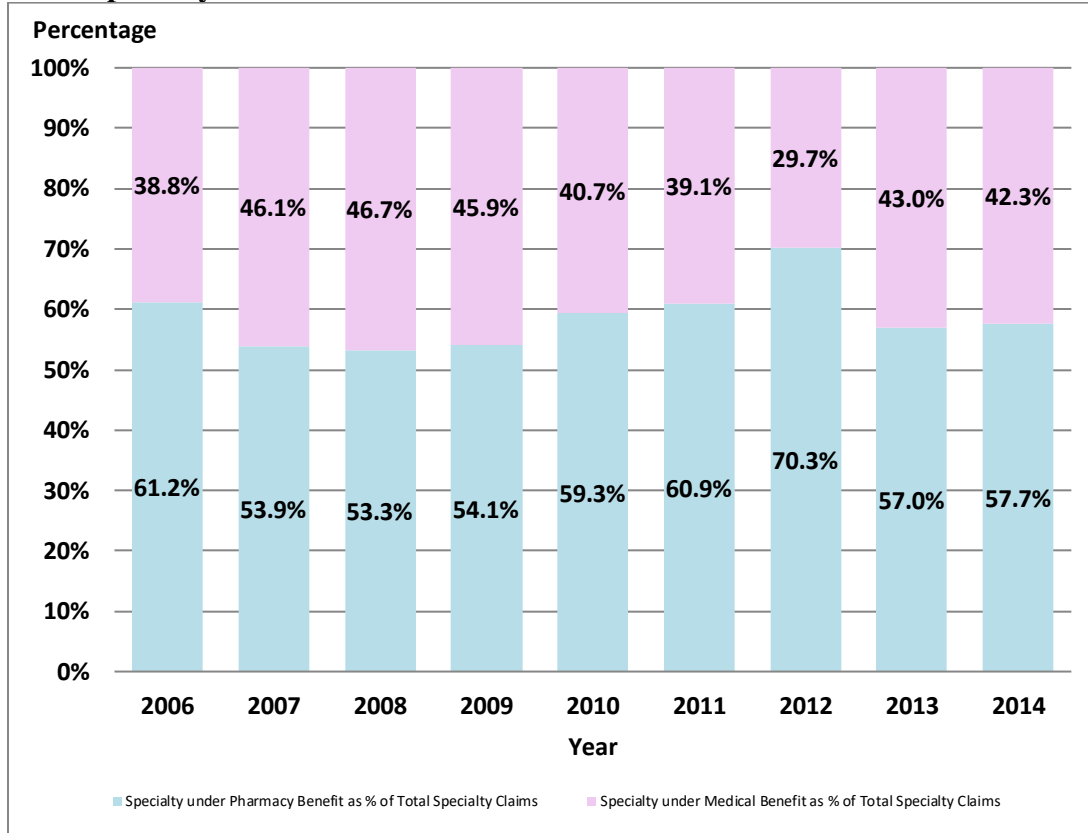


\*Total expenditures include total drug and drug-related expenditures under medical benefit.

From 2006 to 2014 specialty expenditures under the pharmacy benefit grew 251 percent while specialty expenditures under the medical benefit grew 140 percent.

Figure 4.43 shows that from 2006 to 2014 the pharmacy benefit accounted for a greater percent of total specialty drug claims than the medical benefit.

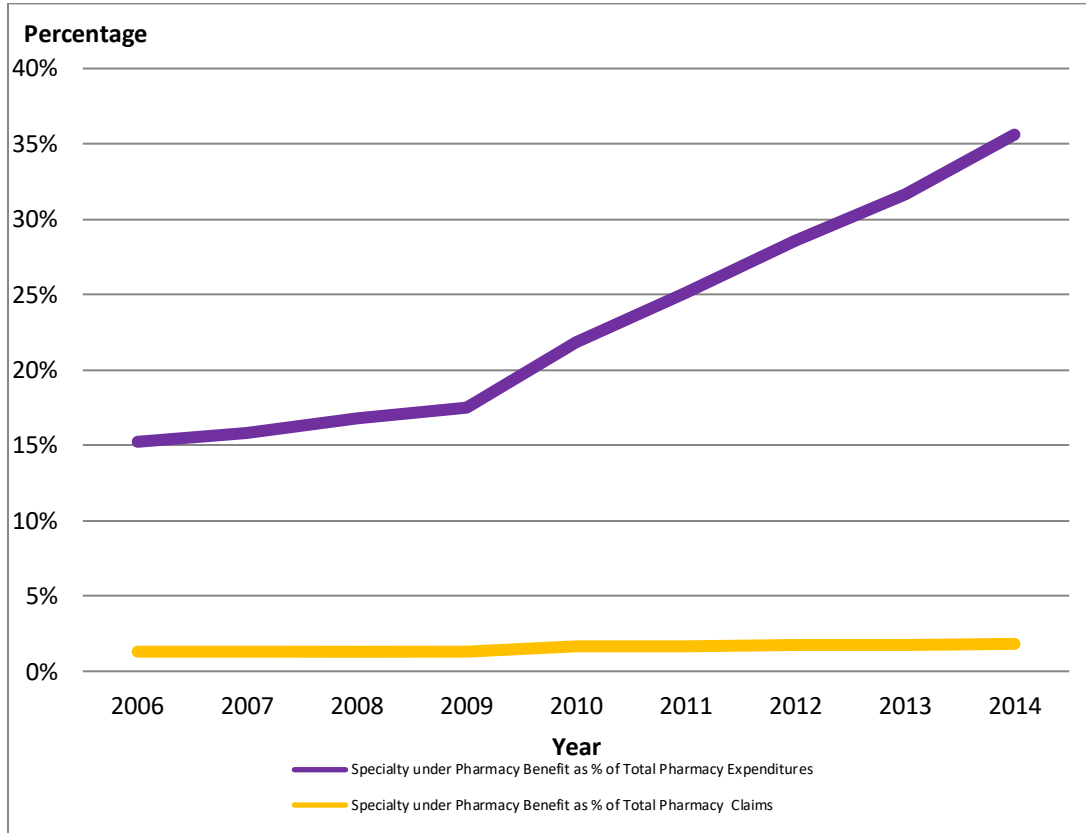
**Figure 4.43 Specialty Pharmacy & Specialty Medical Claims as Percentage of Total Specialty Claims: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under pharmacy and medical benefit.

Pharmacy claims accounted for greater than 53 percent of total specialty claims from 2006 to 2014. Both pharmacy and medical claims fluctuated in the percentage of claims contributing to total specialty claims across the two benefit types. However, pharmacy claims demonstrated growth over time in the number of claims the percentage of specialty claims accounting for by pharmacy decreased slightly. Medical claims as a percent of total specialty grew from 39 percent in 2006 to 42 percent in 2014. In contrast, pharmacy claims declined slightly from 61 percent of total specialty claims in 2006 to 58 percent of total specialty claims in 2014.

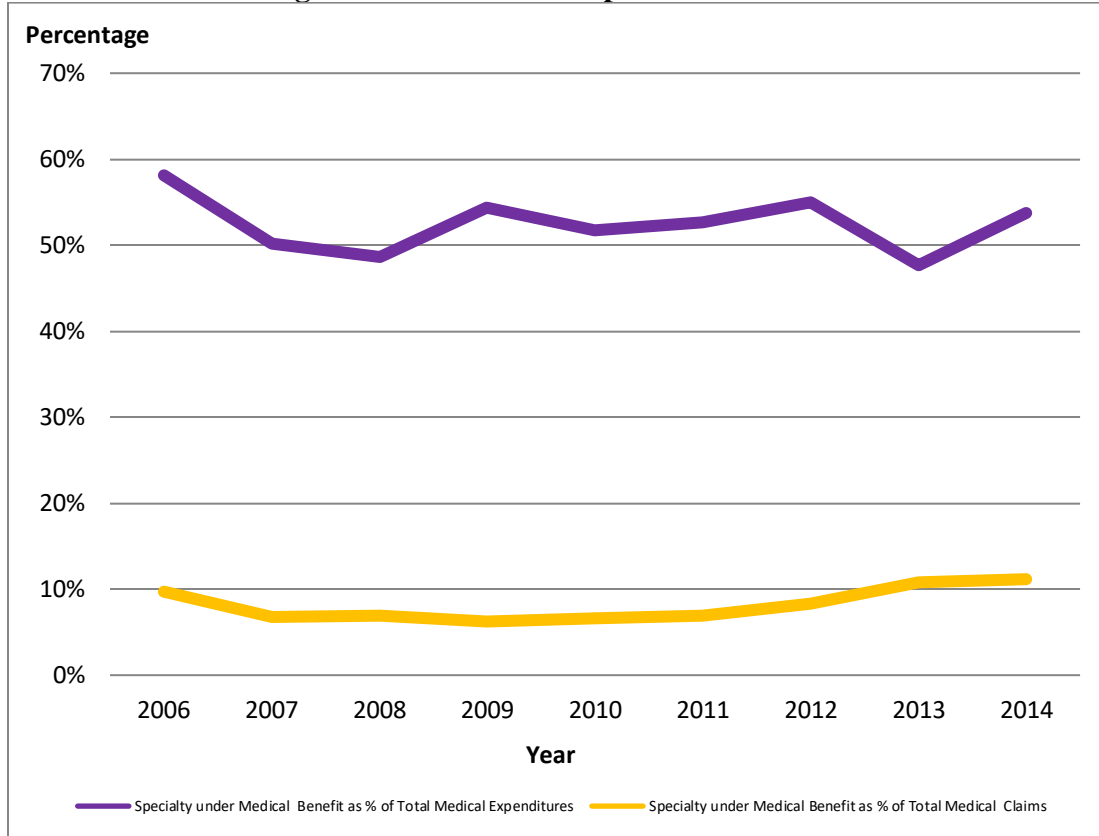
**Figure 4.44: Expenditures & Utilization for Specialty Drugs under the Pharmacy Benefit as a Percentage of Total Pharmacy Expenditures & Utilization: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy benefit.

While specialty claims under the pharmacy benefit account for a very small portion of total pharmacy claims at 2 percent, they accounted for 36 percent of the total pharmacy expenditures in 2014, as seen in Figure 4.44.

**Figure 4.45: Expenditures & Utilization for Specialty Drugs under the Medical Benefit as a Percentage of Total Medical Expenditures & Utilization: 2006 to 2014\***



\*Total expenditures & claims include total drug and drug-related expenditures & claims under the medical benefit.

Expenditures for specialty drugs and drug-related products under the medical benefit as a percentage of total drug and drug-related expenditures under the medical benefit decreased from 58 percent to 54 percent from 2006 to 2014, with the lowest proportion noted in 2013 at 48 percent, as seen in Figure 4.45.

Utilization for specialty drug and drug-related products under the medical benefit remained below 11 percent throughout the study period, with the lowest percentage noted in 2009 at 6 percent. Similar to what was observed with specialty drugs under the pharmacy benefit, specialty drugs under the medical benefit accounted for a small portion of the total medical drug and drug-related claims but represented greater than 48 percent of total medical drug expenditures. In 2014 specialty drug and drug-related products

under the medical benefit accounted for 11 percent of total medical drug and drug-related claims; however, they accounted for 54 percent of total medical drug and drug-related expenditures.



#### 4.2.2 Question 1b

What are the changes year to year in utilization and expenditures for specialty drugs and drug-related products in aggregate that flow through the pharmacy benefit and the medical benefit from 2006 to 2014?

**Table 4.12: Year to Year Change in Expenditures for Specialty Drugs and Drug-related Products in Aggregate for the Pharmacy Benefit and Medical Benefit from 2006 to 2014**

Year	Year to Year Change in Total Specialty Drug & Drug-related products Expenditure under Pharmacy Benefit	Year to Year Change in Total Specialty Drug & Drug-related products Expenditure under Medical Benefit
2006		
2007	13.43%	-5.87%
2008	11.22%	7.09%
2009	12.65%	21.77%
2010	32.92%	-2.97%
2011	14.53%	5.52%
2012	15.35%	5.23%
2013	14.16%	47.49%
2014	23.32%	23.15%

Specialty drugs and drug-related products under the pharmacy benefit saw their largest year to year change in expenditures from 2009 to 2010 with a 32.9 percent increase from \$6.14 million to \$8.16 million, respectively. Under medical benefits the specialty drugs and drug-related products saw their largest year to year change in expenditures from 2012 to 2013 with a 47.5 percent increase from \$6.88 million to \$10.14 million, respectively.

**Table 4.13: Year to Year Change in Claims for Specialty Drugs and Drug-related Products in Aggregate that Flow Through the Pharmacy Benefit and the Medical Benefit: 2006 to 2014**

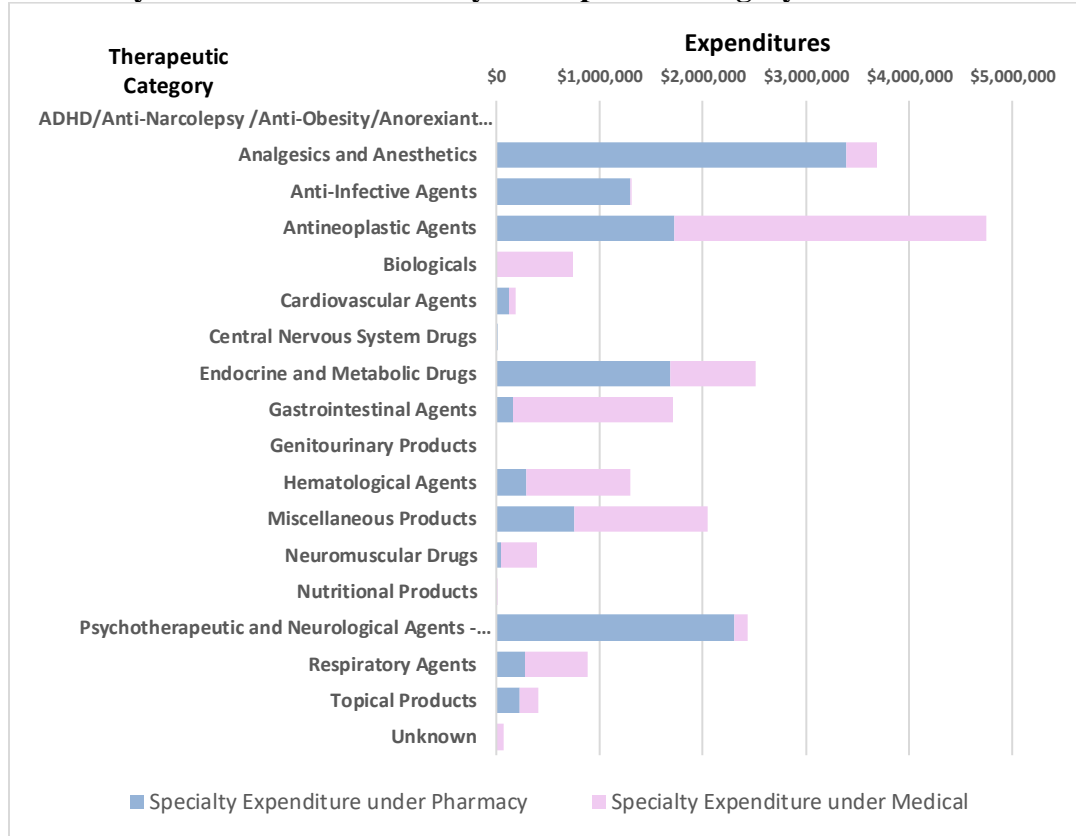
Year	Year to Year Change in Total Specialty Drug & Drug-related products Claims under Pharmacy Benefit	Year to Year Change in Total Specialty Drug & Drug-related products Claims under Medical Benefit
2006		
2007	8.34%	46.06%
2008	2.11%	4.61%
2009	5.77%	2.48%
2010	20.71%	-2.52%
2011	0.17%	-6.42%
2012	-1.49%	-35.05%
2013	-3.72%	41.76%
2014	2.51%	-0.25%

Specialty drugs and drug-related products under the medical benefit saw the largest year to year change in claims from 2006 to 2007 with a 46 percent increase from 2,716 to 3,967 claims, respectively. Under the pharmacy benefit the specialty drugs and drug-related products saw the largest year to year change in claims from 2009 to 2010 with a 20.7 percent increase from 2009 to 2010 from 5,008 to 6,045, respectively. Claims flowing under the medical benefit for specialty drug and drug-related products had more fluctuation than those flowing under pharmacy benefit. A steady increase upward was not observed from year to year for specialty drug and drug-related claims flowing under either the pharmacy or the medical benefit.

#### **4.3 Aim two results**

Describe specialty drug and drug-related product trends including expenditures, and utilization by therapeutic category and other characteristics from 2006 to 2014 for the University of Minnesota UPlan.

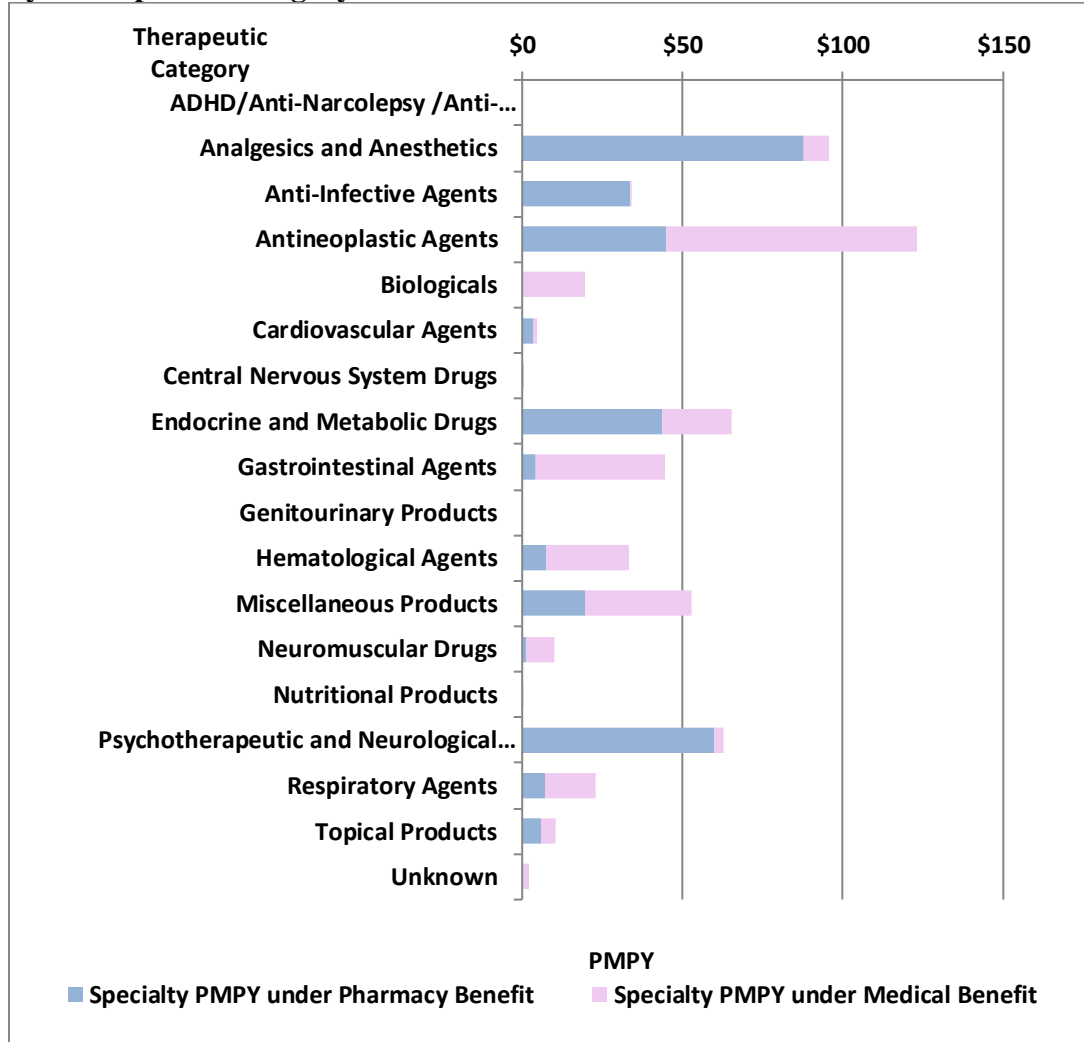
**Figure 4.46: Total Specialty Drug and Drug-Related Expenditures under Pharmacy and Medical Benefits by Therapeutic Category: 2013\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Figure 4.46 shows that in 2013 antineoplastic agents had the highest expenditures for specialty across pharmacy and medical benefits. Therapeutic categories such as gastrointestinal agents, hematological agents, neuromuscular drugs, biologics, miscellaneous products, anti-neoplastic agents, as well as unknown agents had expenditures predominantly under the medical benefit. In 2013, expenditures for analgesics and anesthetics, anti-infective agents, endocrine and metabolic agents, and psychotherapeutic, and neurological agents were greater under the pharmacy benefit than under the medical benefit.

**Figure 4.47: PMPY Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2013\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

In 2013, the PMPY found for pharmacy and medical benefits for specialty drugs and drug-related products for all therapeutic categories ranged from \$0.00 for ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents to \$123.03 for antineoplastic agents, as seen in Figure 4.47. and Table 4.14. The top three categories with the highest PMPY in 2013 were antineoplastic agents, analgesics and anesthetics, and endocrine and metabolic drugs. When looking at specialty categories under pharmacy and medical

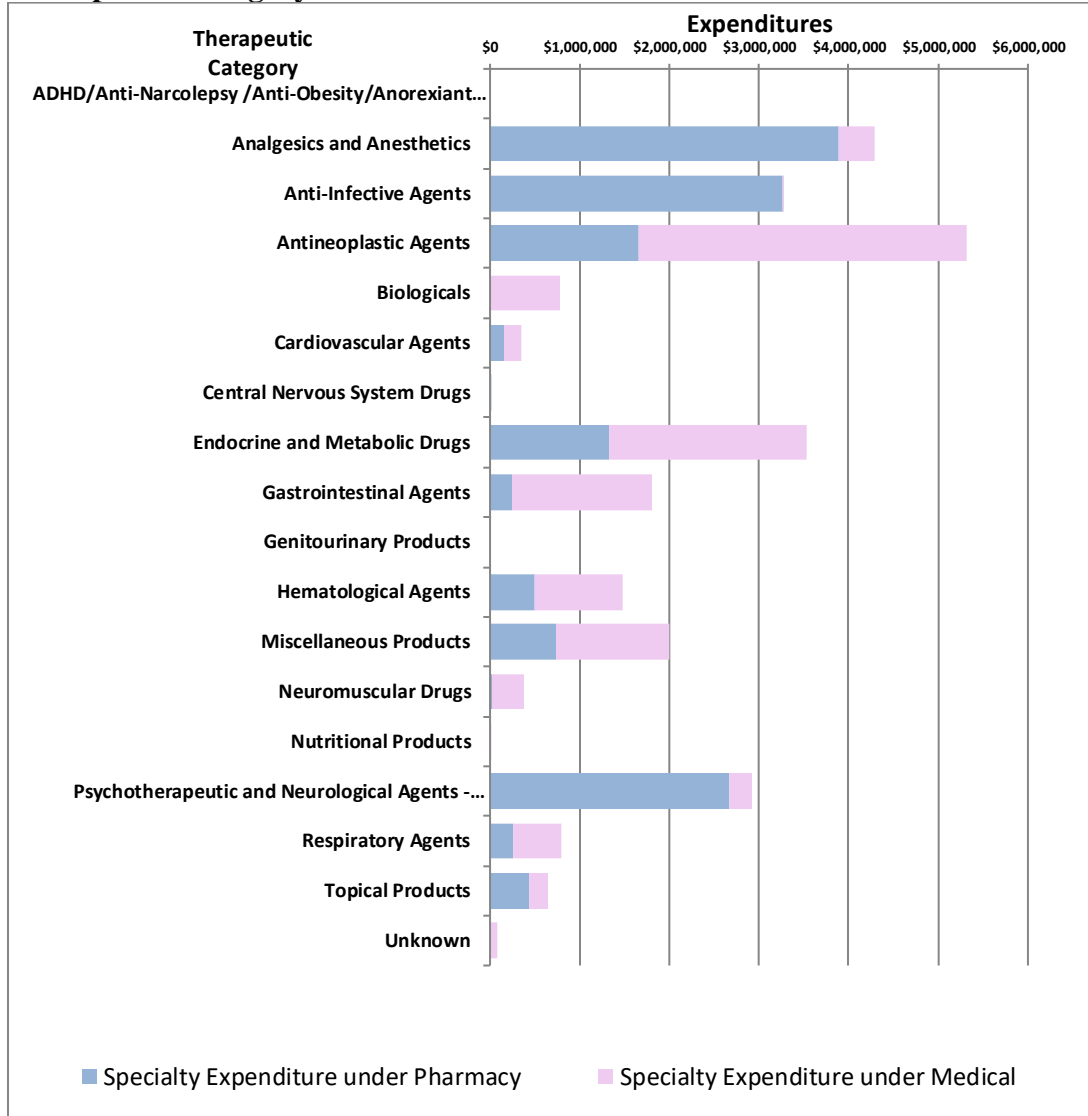
benefits, different categories present with the top three PMPYs. Under the medical benefit the top three categories by PMPY expenditures include antineoplastic agents, gastrointestinal agents, and miscellaneous products. Under the pharmacy benefit the top three categories by PMPY expenditures include analgesics and anesthetics, psychotherapeutic/neurological, and endocrine and metabolic drugs.

**Table 4.14: PMPY Specialty Drug Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2013\***

Therapeutic Category	Specialty PMPY under Pharmacy Benefit	Specialty PMPY under Medical Benefit	Total PMPY
ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiants Agents	\$0.00	\$0.00	\$0.00
Analgesics and Anesthetics	\$87.75	\$7.76	\$95.52
Anti-Infective Agents	\$33.63	\$0.02	\$33.66
Antineoplastic Agents	\$44.82	\$78.21	\$123.03
Biologicals	\$0.00	\$19.39	\$19.39
Cardiovascular Agents	\$3.30	\$1.43	\$4.74
Central Nervous System Drugs	\$0.27	\$0.00	\$0.27
Endocrine and Metabolic Drugs	\$43.56	\$21.66	\$65.22
Gastrointestinal Agents	\$4.05	\$40.38	\$44.43
Genitourinary Products	\$0.00	\$0.00	\$0.00
Hematological Agents	\$7.60	\$25.90	\$33.50
Miscellaneous Products	\$19.50	\$33.36	\$52.86
Neuromuscular Drugs	\$1.25	\$8.82	\$10.07
Nutritional Products	\$0.00	\$0.03	\$0.03
Psychotherapeutic and Neurological Agents - Miscellaneous	\$59.82	\$3.11	\$62.93
Respiratory Agents	\$7.15	\$15.73	\$22.88
Topical Products	\$5.88	\$4.74	\$10.62
Unknown	\$0.00	\$1.99	\$1.99

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefits.

**Figure 4.48: Total Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2014**

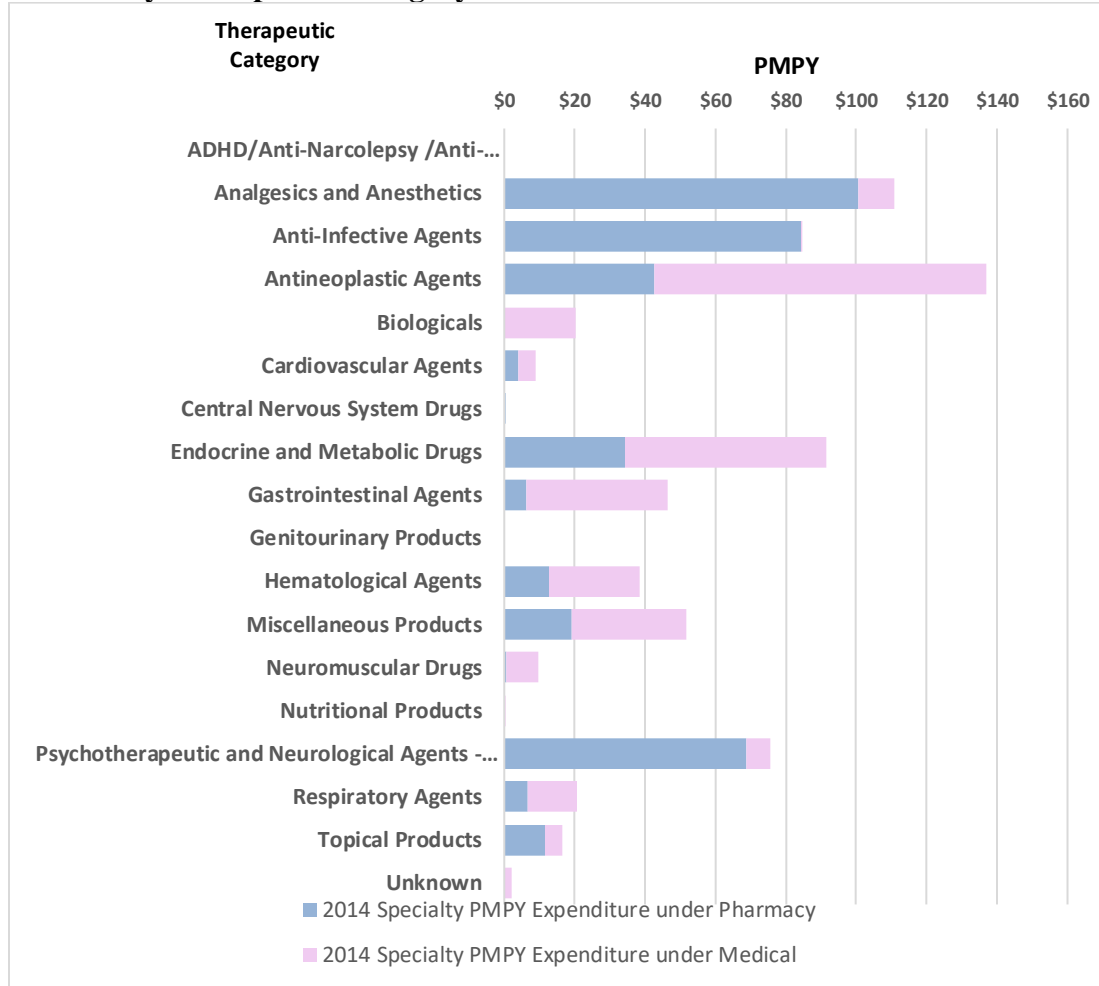


\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Similar to 2013, the therapeutic category with the highest expenditure in 2014 was antineoplastic agents. ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents, biologicals, genitourinary products, nutritional products, and unknown had negligible specialty drug and drug-related expenditures under the pharmacy benefit in 2014. ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents, central nervous system drugs, and genitourinary products had negligible specialty drug and drug-related expenditures under the medical benefit.



**Figure 4.49: PMPY Total Specialty Expenditures under the Pharmacy & Medical Benefits by Therapeutic Category: 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

The top three categories with the highest PMPY in 2014 were also antineoplastic agents, analgesics and anesthetics, and endocrine and metabolic drugs, similar to 2013. The PMPY across pharmacy and medical benefits for all therapeutic classes ranged from \$0.00 for ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants Agents and genitourinary products to \$137.05 for antineoplastic agents, as shown in Figure 4.49 and Table 4.15. When looking at specialty categories under the pharmacy and medical benefits we see different categories present as the top three PMPYs. Under the medical benefit the top

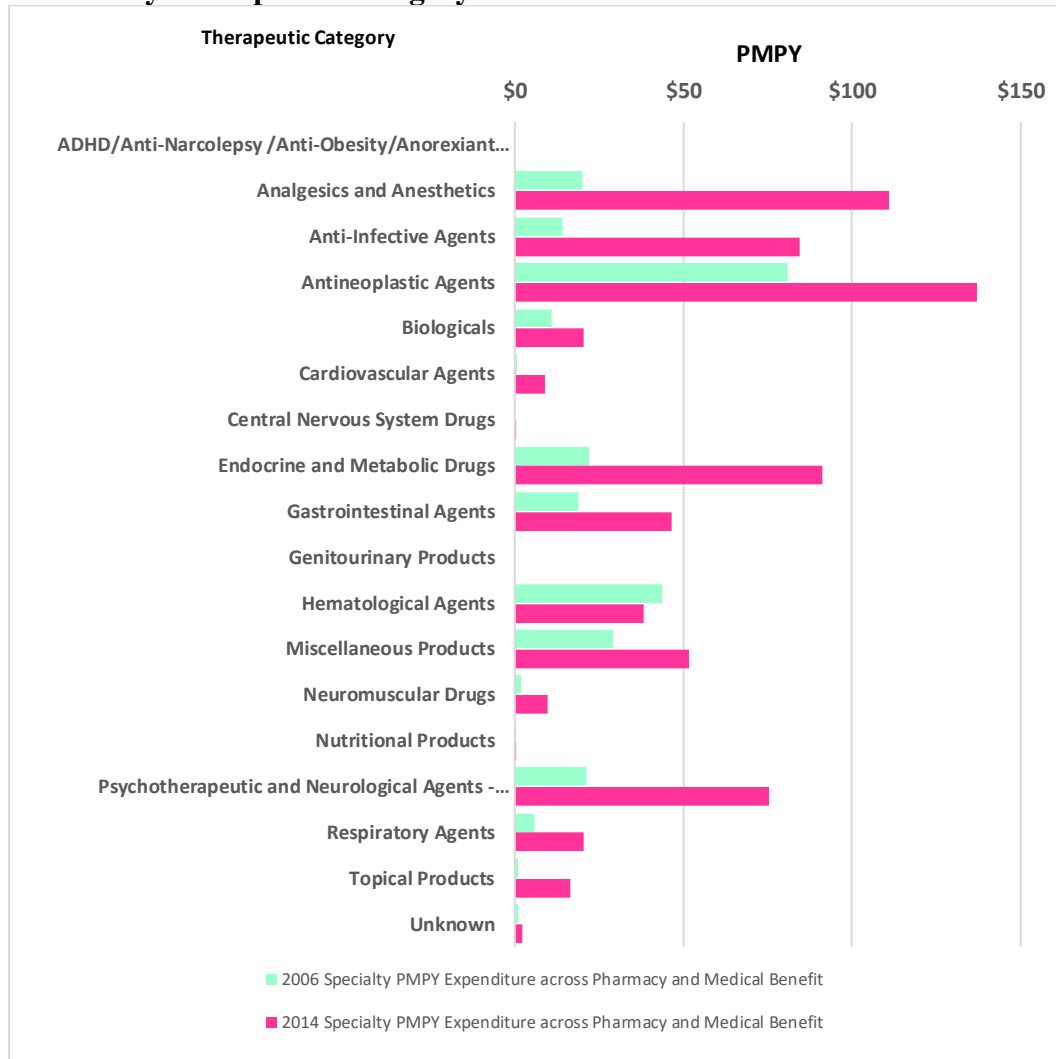
three categories by PMPY include antineoplastic agents, endocrine and metabolic drugs, and gastrointestinal agents. Under the pharmacy benefit the top three include analgesics and anesthetics, anti-infective agents, and psychotherapeutic and neurological agents.

**Table 4.15: PMPY Total Specialty Expenditures under Pharmacy & Medical Benefits by Therapeutic Category: 2014\***

<b>Therapeutic Category</b>	<b>Specialty PMPY under Pharmacy Benefit</b>	<b>Specialty PMPY under Medical Benefit</b>	<b>Total Specialty PMPY</b>
ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiants Agents	\$0.00	\$0.00	\$0.00
Analgesics and Anesthetics	\$100.47	\$10.40	\$110.87
Anti-Infective Agents	\$84.24	\$0.05	\$84.29
Antineoplastic Agents	\$42.72	\$94.33	\$137.05
Biologicals	\$0.00	\$20.31	\$20.31
Cardiovascular Agents	\$3.83	\$5.08	\$8.91
Central Nervous System Drugs	\$0.23	\$0.00	\$0.23
Endocrine and Metabolic Drugs	\$34.42	\$56.89	\$91.31
Gastrointestinal Agents	\$6.27	\$40.31	\$46.58
Genitourinary Products	\$0.00	\$0.00	\$0.00
Hematological Agents	\$12.67	\$25.60	\$38.27
Miscellaneous Products	\$19.15	\$32.46	\$51.61
Neuromuscular Drugs	\$0.73	\$9.04	\$9.77
Nutritional Products	\$0.00	\$0.09	\$0.09
Psychotherapeutic and Neurological Agents - Miscellaneous	\$68.77	\$6.64	\$75.41
Respiratory Agents	\$6.75	\$13.82	\$20.57
Topical Products	\$11.41	\$5.17	\$16.58
Unknown	\$0.00	\$2.12	\$2.12

\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

**Figure 4.50: PMPY Total Specialty Expenditures under the Pharmacy & Medical Benefits by Therapeutic Category: 2006 vs. 2014\***



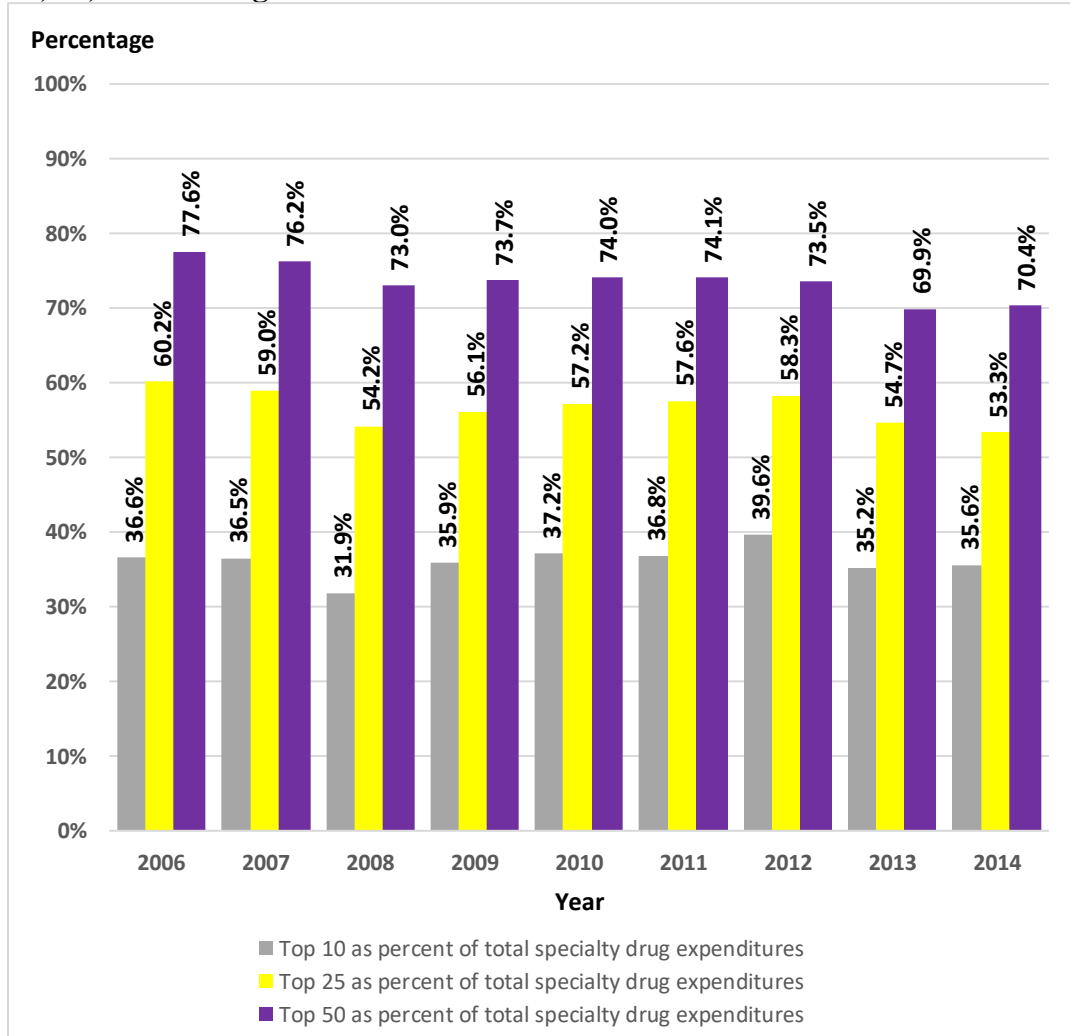
\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Figure 4.50 shows a comparison of PMPY expenditures for each therapeutic category in 2006 and 2014. All categories show a growth in a PMPY from 2006 to 2014, with the exception of hematological agents which had a higher PMPY in 2006 than in 2014.

### 4.3.1 Question 2a results

What percent of total specialty drug and drug-related expenditures are accounted for by the top 10, 25, and 50 drugs for the UPlan each year?

**Figure 4.51: Percent of Total Specialty Expenditures Accounted for by The Top 10, 25, and 50 drugs for the UPlan Each Year: 2006 to 2014\***



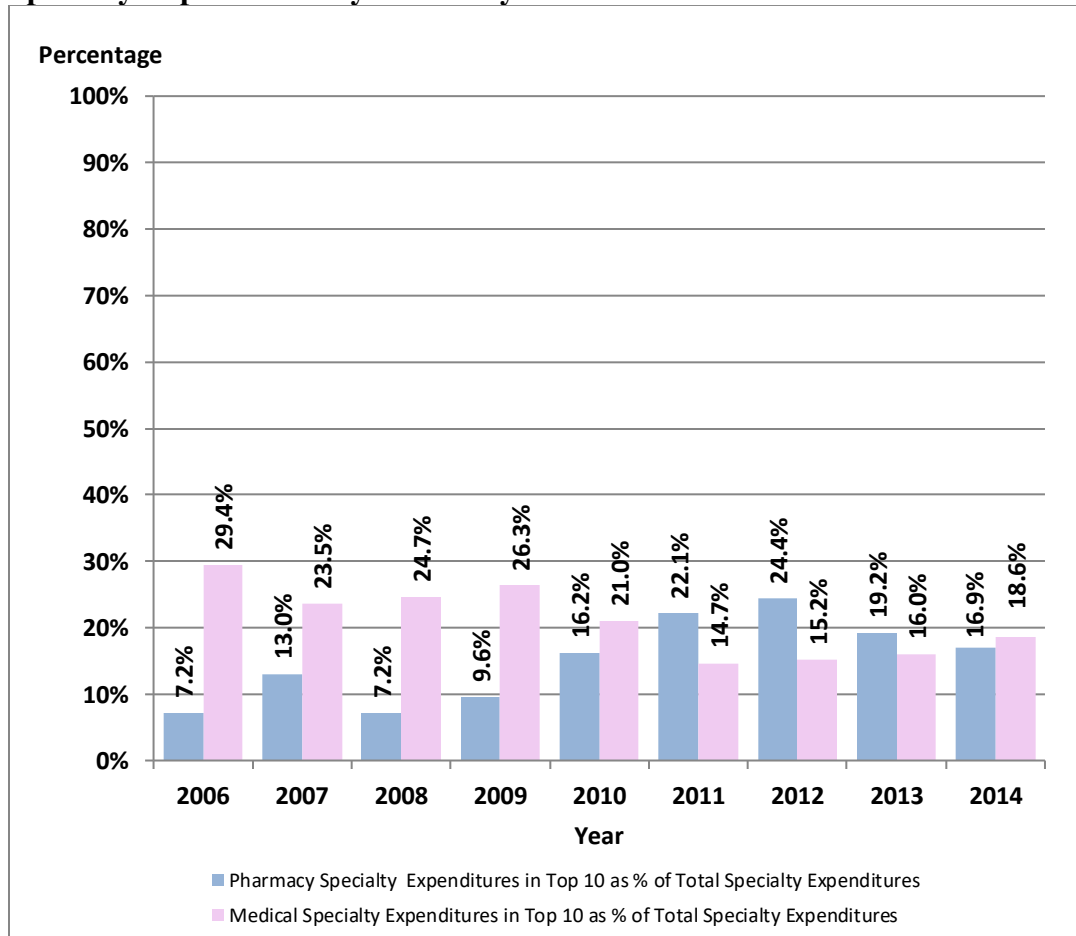
\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Figure 4.51 shows the percent of total drug expenditures accounted for by the top 10 specialty drugs across the pharmacy and medical benefits decreased from 37 percent to 36 percent from 2006 to 2014. A larger decline from 2006 to 2014 was seen for the top 25 and top 50 drugs with declines from 60 percent to 53 percent for the top 25 drugs and from 78 percent to 70 percent for the top 50 drugs.

The decrease in the impact of the top 10, 25, and 50 drugs on total specialty drugs and drug expenditures can be explained by the increase in the number of total unique specialty drugs between 2006 and 2014 from 366 drugs to 520 drugs. Thus, as the number of total specialty drugs present in each year increased, it resulted in the decreased percentage of total specialty drug expenditures represented by the top 10, 25, and 50 drugs.

Figure 4.52 shows that the top 10 specialty drugs under the medical benefit accounted for a greater percent of total specialty expenditures from 2006 to 2010 than did the top 10 specialty drugs under the pharmacy benefit from 2006 to 2010, and in 2014. From 2011 to 2013 the top 10 specialty drugs under the pharmacy benefit accounted for a greater percentage of total specialty expenditures than did the top 10 specialty drugs under the medical benefit.

**Figure 4.52: Top 10 Specialty Drugs by Total Expenditure as a Percent of Total Specialty Expenditures by Pharmacy Benefits & Medical Benefits: 2006 to 2014\***

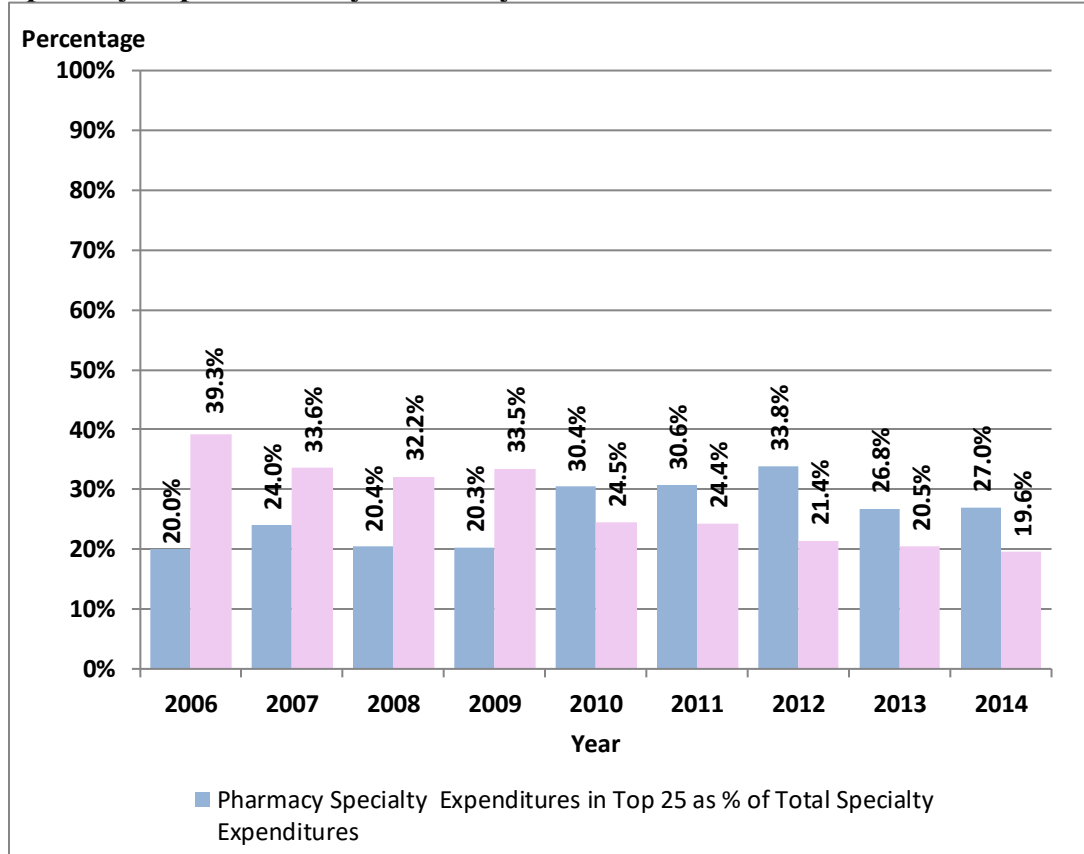


\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

From 2006 to 2010, the top 10 drugs in the medical benefit accounted for a larger percent of specialty drug expenditures than was seen for the top 10 drugs in the Pharmacy benefit. In 2011 to 2013, however, the top 10 specialty drugs under the pharmacy benefit accounted for a larger percent of total specialty expenditures than the Top 10 specialty drugs under the medical benefit. In 2014, the top 10 specialty drugs under the medical benefit was larger than the top 10 drugs under the pharmacy benefit. Over time the percent of total specialty expenditures accounted for by the top 10 drugs in the medical benefit decreased from 29.4 percent to 18.6 percent from 2006 to 2014. In contrast, the percent of total specialty expenditures accounted for by top 10 drugs in the pharmacy benefit increased from 7.2 percent to 16.9 percent from 2006 to 2014 with a spike to 24.4 percent in 2012.



**Figure 4.53: Top 25 Specialty Drugs by Total Expenditure as a Percent of Total Specialty Expenditures by Pharmacy Benefits & Medical Benefits: 2006 to 2014 \***

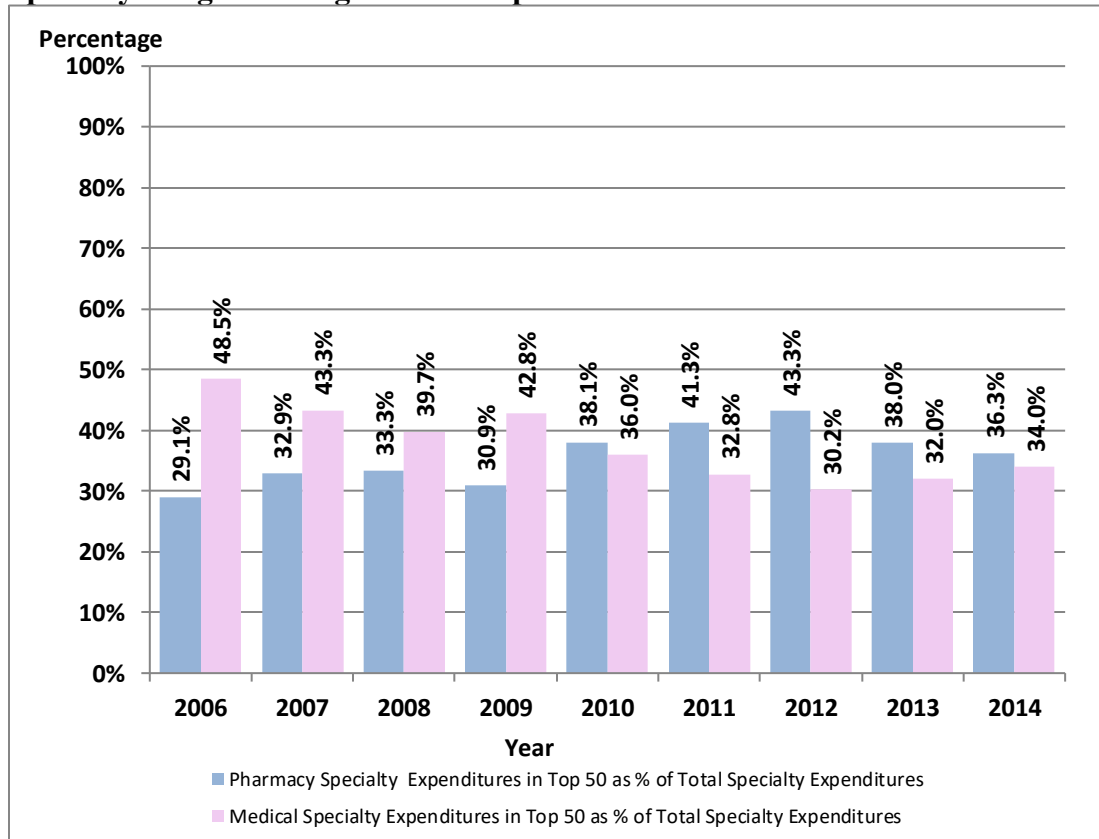


\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

The percent of total specialty drug expenditures accounted for by the top 25 drugs in the medical benefit was notably larger than the percent for the pharmacy benefit from 2006 to 2009. In 2010, expenditures for the top 25 drugs under the pharmacy benefit accounted for a larger percent of the total specialty drug expenditures than the top 25 drugs under the medical benefit, 30.4 percent vs. 24.5 percent. The top 25 specialty drugs accounted for under the medical benefit decreased from 39.3 percent to 19.6 percent during the study period from 2006 to 2014.

The top 25 specialty drugs under the pharmacy benefit accounted for an increasing percent with growth from 20.0 percent to 33.8 percent from 2006 to 2012, and then declined to 26.8 percent and 27.0 percent in 2013 and 2014.

**Figure 4.54: Top 50 Specialty Drugs by Total Expenditure as Percentage of Total Specialty Drug and Drug-Related Expenditures: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

The percent of total specialty drug expenditures for the top 50 drugs under the medical benefit decreased from 48.5 percent to 34.0 percent from 2006 to 2014. Total drug expenditures represented by the top 50 drugs under the pharmacy benefit grew from 29.1 percent to 43.3 percent in 2006 to 2012, with a decrease noted in 2013 and 2014 to 38.0 percent and 34.0 percent, Figure 4.54.

#### 4.3.2 Question 2b results

What number of specialty drugs and drug-related products account for 50%, 75%, and 90% of total specialty drug and drug-related expenditures for the UPlan?

**Table 4.16: Number of NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Drug and Drug-Related Expenditures for the UPlan\***

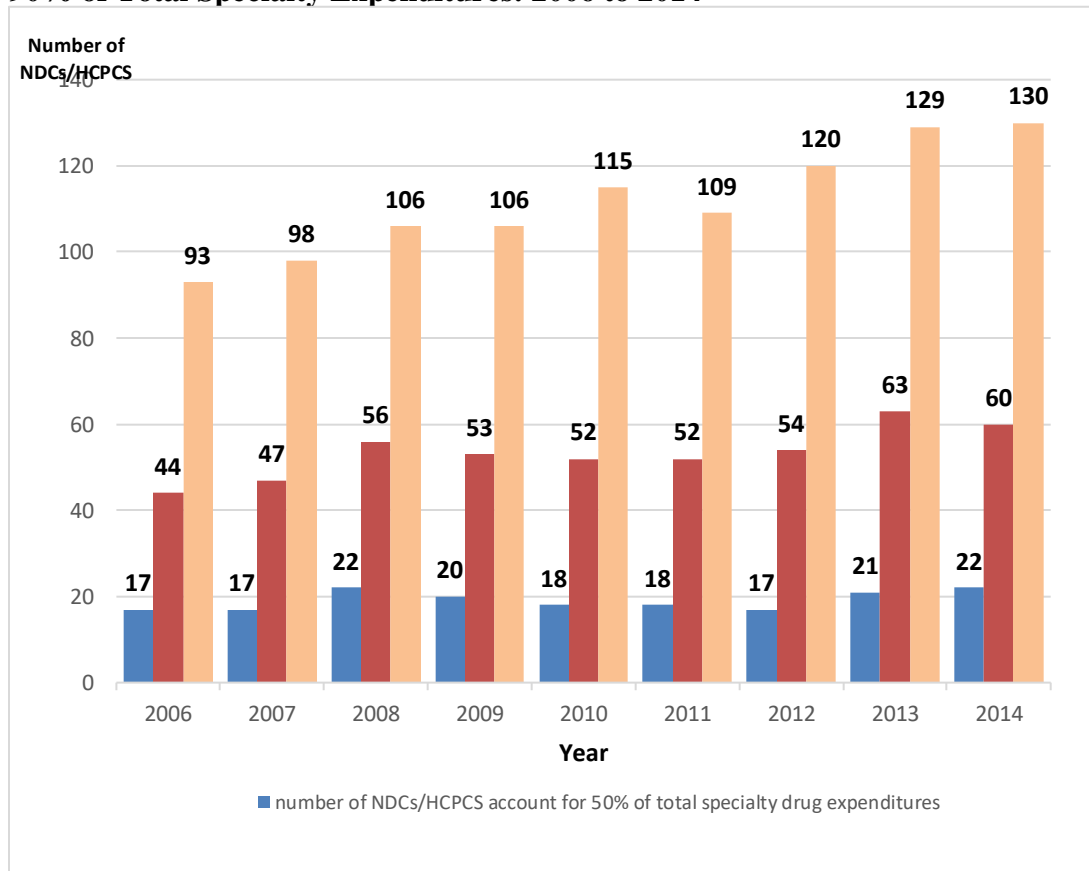
Year	Number of Drugs Accounting for 50% of Total Specialty Drug Expenditures	Number of Drugs Accounting for 75% of Total Specialty Drug Expenditures	Number of Drugs Accounting for 90% of Total Specialty Drug Expenditures	Total Number of Unique Drugs Across Pharmacy and Medical Benefit
2006	17	44	93	366
2007	17	47	98	375
2008	22	56	106	378
2009	20	53	106	425
2010	18	52	115	465
2011	18	52	109	452
2012	17	54	120	487
2013	21	63	129	530
2014	22	60	130	520

\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

The number of drugs accounting for 50 percent, 75 percent and 90 percent of the total specialty expenditures grew from 2006 to 2014, as seen in Table 4.16 and Figure 4.55. This is because the total number of unique drugs across the pharmacy and medical benefits also grew from 2006 to 2014. For example, in 2006, 17 drugs accounted for 50 percent of total specialty drug expenditures across the pharmacy and medical benefits.

However, in 2014, 22 drugs accounted for 50 percent of total specialty drug expenditures across the pharmacy and medical benefits. The total number of specialty drugs and drug-related products in 2014 across the pharmacy and medical benefits are 42 percent more than they were in 2006. From 2006 to 2014 the number of specialty drugs and drug-related products accounting for 50 percent, 75 percent and 90 percent of total specialty drug expenditures increased by 29 percent, 36 percent and 40 percent, respectively, from 2006 to 2014.

**Figure 4.55: Number of Specialty NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Expenditures: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

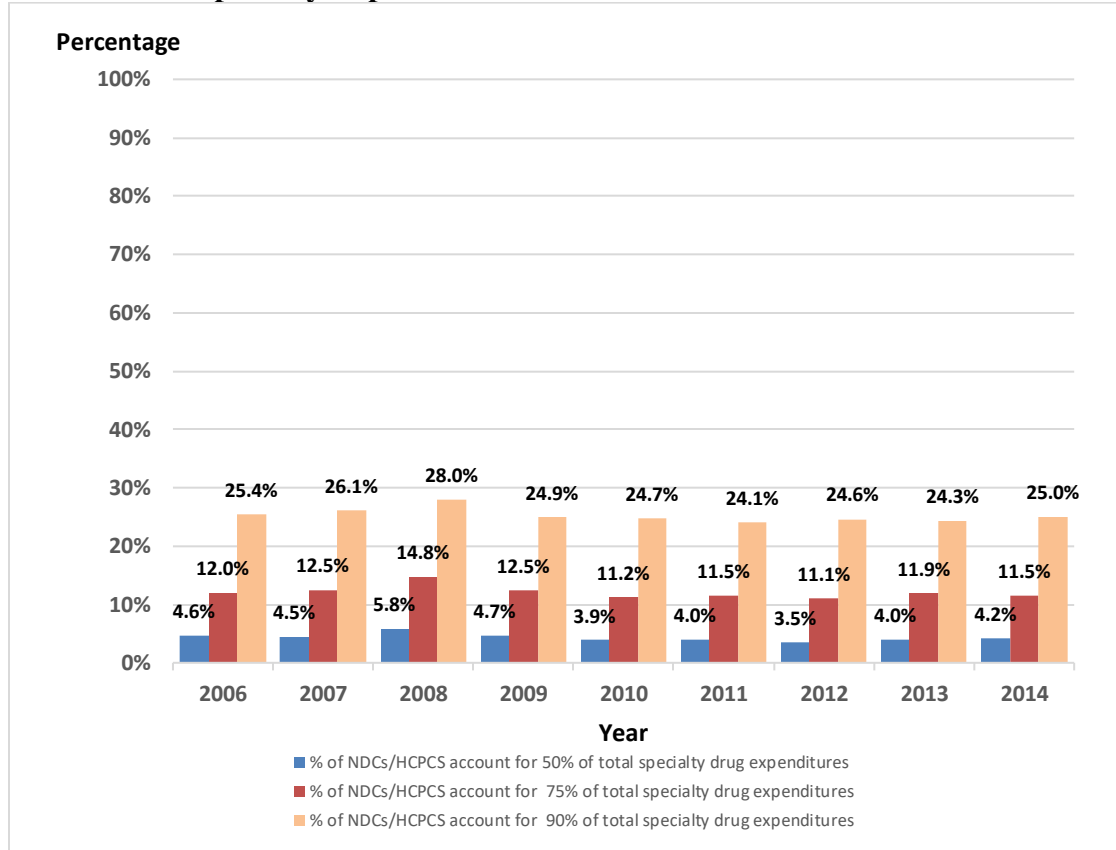
**Table 4.17: Percent of NDCs/HCPCS Accounting for 50%, 75%, 90% of Total Specialty Expenditures for the UPlan: 2006 to 2014\***

<b>Year</b>	<b>Percent of Drugs Accounting for 50% of Total Specialty Drug Expenditures</b>	<b>Percent of Drugs Accounting for 75% of Total Specialty Drug Expenditures</b>	<b>Percent of Drugs Accounting for 90% of Total Specialty Drug Expenditures</b>	<b>Total Number of Unique Drugs Across Pharmacy and Medical Benefit</b>
<b>2006</b>	4.6%	12.0%	25.4%	366
<b>2007</b>	4.5%	12.5%	26.1%	375
<b>2008</b>	5.8%	14.8%	28.0%	378
<b>2009</b>	4.7%	12.5%	24.9%	425
<b>2010</b>	3.9%	11.2%	24.7%	465
<b>2011</b>	3.9%	11.5%	24.1%	452
<b>2012</b>	3.5%	11.1%	24.6%	487
<b>2013</b>	3.9%	11.9%	24.3%	530
<b>2014</b>	4.2%	11.5%	25.0%	520

\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

A look at the percent of drugs that are accounting for 50 percent, 75 percent and 90 percent of total specialty drug and drug-related expenditures shows a consistent trend from 2006 to 2014, as presented in Table 4.17 and Figure 4.56. Between 3.5 percent and 5.8 percent of specialty NDCs/HCPCS account for 50 percent of total specialty expenditures, while 11.1 percent to 14.8 percent account for 75 percent of expenditures. Also, 24.1 percent to 28.0 percent of specialty drug and drug-related products account for 90 percent of total specialty drug and drug-related expenditures across 2006 to 2014.

**Figure 4.56: Percentage of Specialty NDCs/HCPCS Accounting for 50%, 75%, and 90% of Total Specialty Expenditures: 2006 to 2014\***



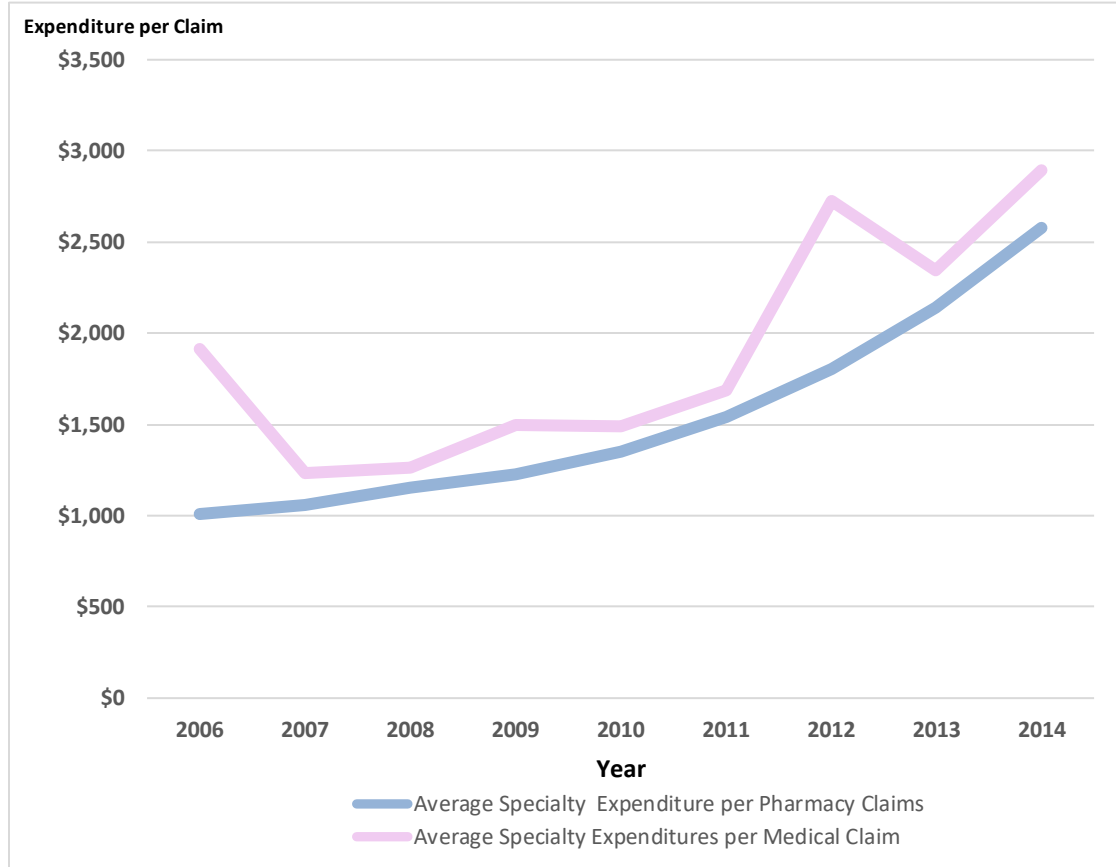
\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits

### 4.3.3 Question 2c results

What is the average total price paid per claim of each specialty drug under the UPlan by year?

The Average expenditure per claim of specialty drugs grew for both pharmacy and medical benefit drugs from 2006 to 2014, as seen in Figure 4.57.

**Figure 4.57: Average Expenditure per Claim under Pharmacy & Medical Benefits: 2006 to 2014\***

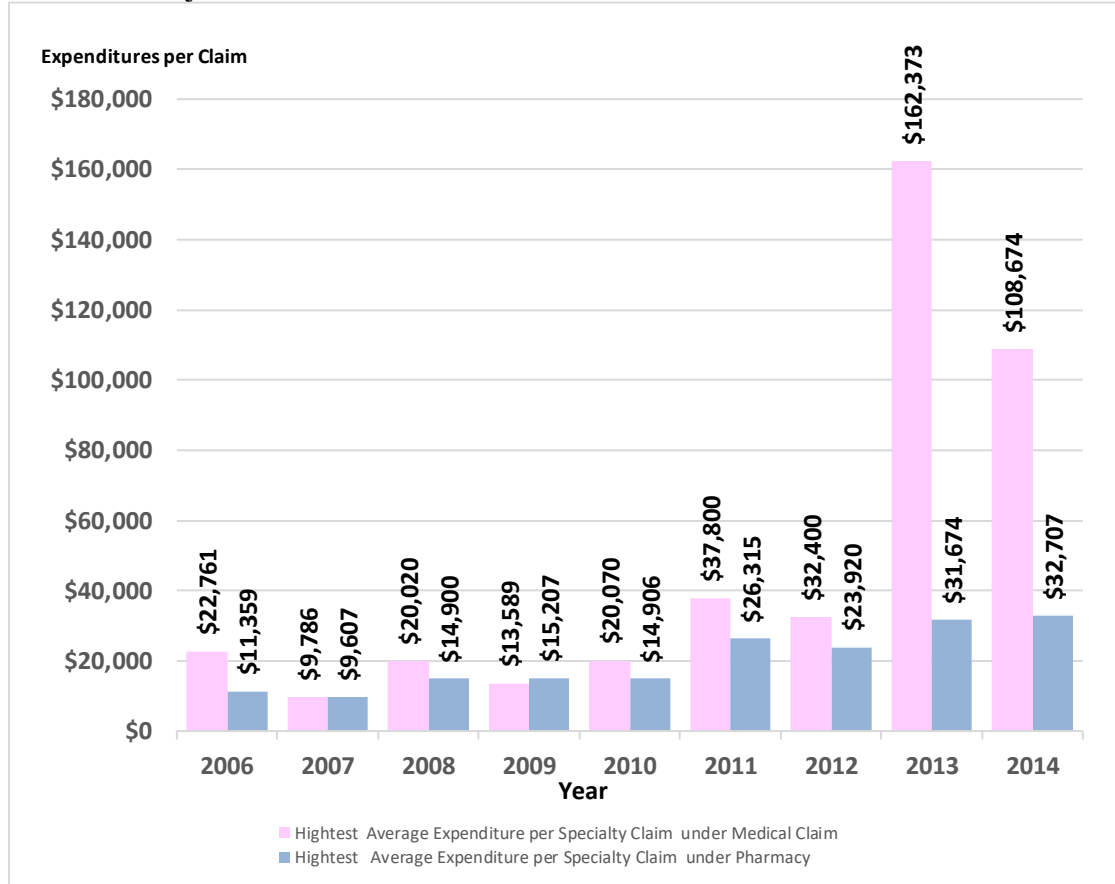


\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

The average expenditure per claim for specialty drugs and drug-related products under the medical benefit were higher than those noted under the pharmacy benefit. In 2006, the average specialty expenditure per claim was \$1,009 under the pharmacy benefit and \$1,914 under the medical benefit. In 2014 the average specialty expenditure per claim was \$2,578 under the pharmacy benefit and \$2,894 under the medical benefit. Figure 4.59 and Figure 4.60 show the top specialty drugs by expenditure per claim under the pharmacy and medical benefits from 2006 to 2014.



**Figure 4.58: Highest Average Expenditure per Claim for Specialty Drugs under the Pharmacy Benefit & the Medical Benefit: 2006 to 2014 \***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

**Table 4.18: Drugs with the Highest Average Expenditures per Claim for Specialty Drugs under the Pharmacy and Medical Benefits: 2006 to 2014**

Year	Pharmacy Claims	Expenditure per claim under Pharmacy Benefit	Pharmacy Claims	Expenditure per claim under Pharmacy Benefit
2006	NUTROPIN AQ INJ 10MG/2ML	\$11,358.53	NUTROPIN AQ INJ 10MG/2ML	\$11,358.53
2007	NEXAVAR TAB 200MG	\$9,606.86	NEXAVAR TAB 200MG	\$9,606.86
2008	THALOMID CAP 100MG	\$14,899.75	THALOMID CAP 100MG	\$14,899.75
2009	HUMATROPE INJ 24MG	\$15,206.77	HUMATROPE INJ 24MG	\$15,206.77
2010	HUMATROPE INJ 24MG	\$14,906.50	HUMATROPE INJ 24MG	\$14,906.50
2011	ACTHAR HP INJ 80UNIT	\$26,314.76	ACTHAR HP INJ 80UNIT	\$26,314.76
2012	STELARA INJ 90MG/ML	\$23,919.77	STELARA INJ 90MG/ML	\$23,919.77
2013	ACTHAR HP INJ 80UNIT	\$31,673.54	ACTHAR HP INJ 80UNIT	\$31,673.54
2014	HARVONI TAB 90-400MG	\$32,706.92	HARVONI TAB 90-400MG	\$32,706.92

**Table 4.19: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2006**

2006	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	NUTROPIN AQ INJ 10MG/2ML	\$11,359	FACTOR VIII RECOMBINANT	\$22,761
2	THALOMID CAP 200MG	\$7,706	INJIG IV NONLYOPHILIZD LIQD 500 MG	\$10,650
3	LEUKINE INJ 500 MCG	\$7,604	CHEMOTHERAPY DRUG	\$6,124
4	INTRON-A INJ 10MU PEN	\$6,981	INJECTION, PEGFILGRASTIM 6MG	\$5,941
5	SUTENT CAP 50MG	\$6,870	IMMUNE GLOBULIN, POWDER	\$5,515
6	SUTENT CAP 50MG	\$6,870	INFLIXIMAB INJECTION	\$5,329
7	REVLIMID CAP 25MG	\$6,637	DOXORUBICIN HCL LIPOSOME INJ	\$4,942
8	REVLIMID CAP 15MG	\$6,299	PEMETREXED INJECTION	\$4,089
9	THALOMID CAP 50MG	\$5,727	RITUXIMAB INJECTION	\$4,057
10	TEMODAR CAP 20MG	\$5,485	ALPHA 1 PROTEINASE INHIBITOR	\$4,021

In 2006, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$5,485 to a high of \$11,359. Under the medical benefit the top 10 drugs ranged in average cost per claim from a low of \$4,021 to a high of \$22,761. In 2006, the highest average cost per claim under medical benefit was twice as much as the highest average cost per claim under pharmacy benefit. The top 10 under pharmacy benefit represented drugs in endocrine and metabolic drugs, hematological agents, antineoplastic agents, and miscellaneous products. Under the medical benefit the top therapeutic categories represented were hematological agents, biologicals, antineoplastic agents, gastrointestinal agents, and respiratory agents.

**Table 4.20: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2007**

2007	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	NEXAVAR TAB 200MG	\$9,607	INJECTION, PEGFILGRASTIM 6MG	\$9,786
2	REVLIMID CAP 25MG	\$6,868	INJ IG IV NONLYOPHILIZD LIQD 500 MG	\$8,744
3	REVLIMID CAP 25MG	\$6,861	IMMUNE GLOBULIN, POWDER	\$8,454
4	REVLIMID CAP 15MG	\$6,361	DOXORUBICIN HCL LIPOSOME INJ	\$5,865
5	EXJADE TAB 250MG	\$6,336	INFLIXIMAB INJECTION	\$4,856
6	REVLIMID CAP 10MG	\$5,630	DOCETAXEL INJECTION	\$4,373
7	NUTROPIN INJ 10MG	\$5,215	PEMETREXED INJECTION	\$4,338
8	THALOMID CAP 100MG	\$5,207	RITUXIMAB INJECTION	\$3,998
9	ATRIPLA TAB	\$5,165	OXALIPLATIN	\$3,970
10	NEULASTA INJ 6MG/0.6M	\$5,008	ALPHA 1 PROTEINASE INHIBITOR	\$3,788

In 2007, the highest average cost per claim under the pharmacy and medical benefits were similar staying right below \$10,000. The top 10 drugs under pharmacy benefit ranged in average cost per claim from a low of \$5,008 to a high of \$9,607. Under the medical benefit the top 10 drugs ranged in average cost per claim from a low of \$3,788 to a high of \$9,786. The Top therapeutic categories represented by the top 10 drugs in 2007 under pharmacy and medical included hematological agents, biologicals, antineoplastic agents, gastrointestinal agents, miscellaneous products, and respiratory agents.

**Table 4.21: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2008**

2008	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	THALOMID CAP 100MG	\$14,900	GAMMAGARD LIQUID INJECTION	\$20,020
2	HUMATROPE INJ 24MG	\$14,144	VIVAGLOBIN, INJ	\$7,812
3	REVLIMID CAP 25MG	\$7,490	FACTOR VIII RECOMBINANT	\$6,327
4	REVLIMID CAP 15MG	\$6,673	DOXORUBICIN HCL LIPOSOME INJ	\$6,237
5	SUTENT CAP 50MG	\$6,361	INJECTION, PEGFILGRASTIM 6MG	\$6,185
6	THALOMID CAP 50MG	\$5,707	PEMETREXED INJECTION	\$5,805
7	ATRIPLA TAB	\$5,487	RITUXIMAB INJECTION	\$5,615
8	NEXAVAR TAB 200MG	\$5,478	INFLIXIMAB INJECTION	\$4,748
9	NEXAVAR TAB 200MG	\$5,304	BEVACIZUMAB INJECTION	\$4,358
10	GENOTROPIN INJ 13.8MG	\$5,023	CHEMOTHERAPY DRUG	\$3,780

In 2008, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$5,023 to a high of \$14,900. Under the medical benefit the top 10 drugs ranged in average cost per claim from a low of \$3,780 to a high of \$20,020. As seen in the finding for 2006 and 2007 the top 10 drugs in 2008 also represented drugs from hematological agents, biologicals, antineoplastic agents, gastrointestinal agents, miscellaneous products.

**Table 4.22: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2009**

2009		Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim	
1	HUMATROPE INJ 24MG	\$15,207	GALSULFASE INJECTION	\$13,589	
2	GENOTROPIN INJ 13.8MG	\$13,864	VIVAGLOBIN, INJ	\$8,473	
3	NEXAVAR TAB 200MG	\$11,854	UNCLASSIFIED BIOLOGICS	\$8,172	
4	SANDOSTATIN KIT LAR 30MG	\$9,914	GAMUNEX INJECTION	\$5,998	
5	NORDITROPIN INJ 30/3ML	\$9,077	INJECTION, PEGFILGRASTIM 6MG	\$5,755	
6	NUTROPIN AQ INJ 20MG/2ML	\$8,223	PEMETREXED INJECTION	\$5,110	
7	REVLIMID CAP 15MG	\$7,373	BEVACIZUMAB INJECTION	\$4,933	
8	REVLIMID CAP 10MG	\$7,074	RITUXIMAB INJECTION	\$4,889	
9	REVLIMID CAP 10MG	\$7,074	IMMUNE GLOBULIN, POWDER	\$4,699	
10	GENOTROPIN INJ 12MG	\$6,972	TOBRAMYCIN NON-COMP UNIT	\$4,596	

In 2009, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$6,972 to a high of \$15,207. Under the medical benefit, the top 10 drugs ranged in average cost per claim from a low of \$4,596 to a high of \$13,589. The top 10 drugs under the pharmacy benefit belong to three therapeutic categories endocrine and metabolic drugs, antineoplastic agents, and miscellaneous products.

**Table 4.23: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2010**

2010	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	HUMATROPE INJ 24MG	\$14,906	SUPPRELIN LA IMPLANT	\$20,070
2	GENOTROPIN INJ 12MG	\$14,780	INJECTION, PEGFILGRASTIM 6MG	\$16,742
3	STELARA INJ 90MG/ML	\$13,407	GALSULFASE INJECTION	\$15,153
4	SUTENT CAP 50MG	\$8,194	IXABEPILONE INJECTION	\$6,126
5	TEMODAR CAP 140MG	\$8,042	INFLIXIMAB INJECTION	\$5,992
6	NUTROPIN AQ INJ 20MG/2ML	\$7,414	LEUPROLIDE ACETATE SUSPNSION	\$5,059
7	NORDITROPIN INJ 30/3ML	\$6,854	PEMETREXED INJECTION	\$4,998
8	ATRIPLA TAB	\$6,340	C1 ESTERASE INHIBITOR INJ	\$4,500
9	AFINITOR TAB 10MG	\$6,189	ALPHA 1 PROTEINASE INHIBITOR	\$4,247
10	AVONEX PREFL KIT 30MCG	\$5,729	GAMMAGARD LIQUID INJECTION	\$4,193

In 2010, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$5,729 to a high of \$14,906. Under the medical benefit, the top 10 drugs ranged in average cost per claim from a low of \$4,193 to a high of \$20,070. The top 10 top pharmacy drugs belonged to the following therapeutic categories: endocrine and metabolic drugs, topical products, antineoplastic agents, anti-infective agents, and psychotherapeutic and neurological agents. Under the medical benefit the therapeutic categories represented by the top 10 drugs included endocrine and metabolic drugs, hematological agents, antineoplastic agents, respiratory agents, and biologicals.

**Table 4.24: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2011**

2011	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	ACTHAR HP INJ 80UNIT	\$26,315	CHEMOTHERAPY DRUG	\$37,800
2	STELARA INJ 90MG/ML	\$20,819	GALSULFASE INJECTION	\$32,298
3	ENOXAPARIN INJ 100MG/ML	\$18,066	INJECTION, PEGFILGRASTIM 6MG	\$18,700
4	INCIVEK TAB 375MG	\$17,200	PEMETREXED INJECTION	\$14,083
5	SUPPRELIN LA KIT 50MG	\$16,068	SUPPRELIN LA IMPLANT	\$9,541
6	NORDITROPIN INJ 10/1.5ML	\$14,284	C-1 ESTERASE, BERINERT	\$7,403
7	ATRIPLA TAB	\$14,173	RITUXIMAB INJECTION	\$6,858
8	REVLIMID CAP 10MG	\$9,642	IMMUNE GLOBULIN, POWDER	\$6,668
9	REYATAZ CAP 300MG	\$9,559	FACTOR IX COMPLEX	\$6,465
10	AVONEX PREFL KIT 30MCG	\$9,448	DOXORUBICIN HCL LIPOSOME INJ	\$6,447

In 2011, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$9,448 to a high of \$26,315. Under the medical benefit the top 10 drugs ranged in average cost per claim from a low of \$6,447 to a high of \$37,800. Therapeutic categories for the top 10 pharmacy drugs included endocrine and metabolic drugs, topical products, antineoplastic agents, anti-infective agents, miscellaneous products, and psychotherapeutic and neurological agents. Under the medical benefit, the therapeutic categories represented by the top 10 drugs were endocrine and metabolic drugs, hematological agents, antineoplastic agents, respiratory agents, and biologicals.



**Table 4.25: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2012**

2012	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	STELARA INJ 90MG/ML	\$23,920	IPILIMUMAB INJECTION	\$32,400
2	ZELBORAF TAB 240MG	\$20,965	GALSULFASE INJECTION	\$22,170
3	STELARA INJ 45MG/0.5	\$17,680	BORTEZOMIB INJECTION	\$17,053
4	SUPPRELIN LA KIT 50MG	\$16,189	USTEKINUMAB INJECTION	\$14,616
5	ATRIPLA TAB	\$16,110	GAMMAGARD LIQUID INJECTION	\$11,902
6	AFINITOR TAB 5MG	\$14,586	TREPROSTINIL, NON-COMP UNIT	\$11,902
7	NORDITROPIN INJ 10/1.5ML	\$13,509	PEMETREXED INJECTION	\$10,347
8	REVLIMID CAP 10MG	\$11,238	IMMUNE GLOBULIN, POWDER	\$8,504
9	CAYSTON INH 75MG	\$10,823	RITUXIMAB INJECTION	\$7,887
10	EXJADE TAB 500MG	\$10,771	C-1 ESTERASE, BERINERT	\$7,808

In 2012, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$10,771 to a high of \$23,920. Under the medical benefit, the top 10 drugs ranged in average cost per claim from a low of \$7,808 to a high of \$32,400. Therapeutic categories for the top 10 pharmacy drugs included endocrine and metabolic drugs, topical products, antineoplastic agents, anti-infective agents, and miscellaneous products. Under medical benefit, the therapeutic categories represented by the top 10 drugs were endocrine and metabolic drugs, hematological agents, antineoplastic agents, topical products, cardiovascular agents and biologicals.

**Table 4.26: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2013**

2013	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	ACTHAR HP INJ 80UNIT	\$31,674	INJECTION IPILIMUMAB 1MG	\$162,373
2	STELARA INJ 90MG/ML	\$26,941	HISTRELIN IMPL (SUPPRELIN LA) 50 MG	\$62,650
3	TECFIDERA CAP 240MG	\$23,264	INJECTION, INFLIXIMAB,10 MG	\$49,319
4	BUPHENYL TAB 500MG	\$22,151	INJ IG GAMMAGARD LIQ IV NONLYOPHILIZED 500 MG	\$39,992
5	STELARA INJ 45MG/0.5	\$19,954	INJECTION BRENTUXIMABVEDOTIN 1 MG	\$35,279
6	ATRIPLA TAB	\$18,586	TREPROSTINIL INHAL SOLUTION UNIT DOSE 1.74 MG	\$27,374
7	NORDITROPIN INJ 10/1.5ML	\$14,083	INJECTION DOXORUBICIN HCl LIPOSOMAL DOXIL 10 MG	\$27,342
8	EXJADE TAB 500MG	\$13,178	INJECTION USTEKINUMAB1 MG	\$24,451
9	SUTENT CAP 50MG	\$11,060	RADIOPHARMACEUTICAL THERAPEUTIC NOC	\$23,413
10	POMALYST CAP 2MG	\$10,985	INJECTION RITUXIMAB 100 MG	\$22,454

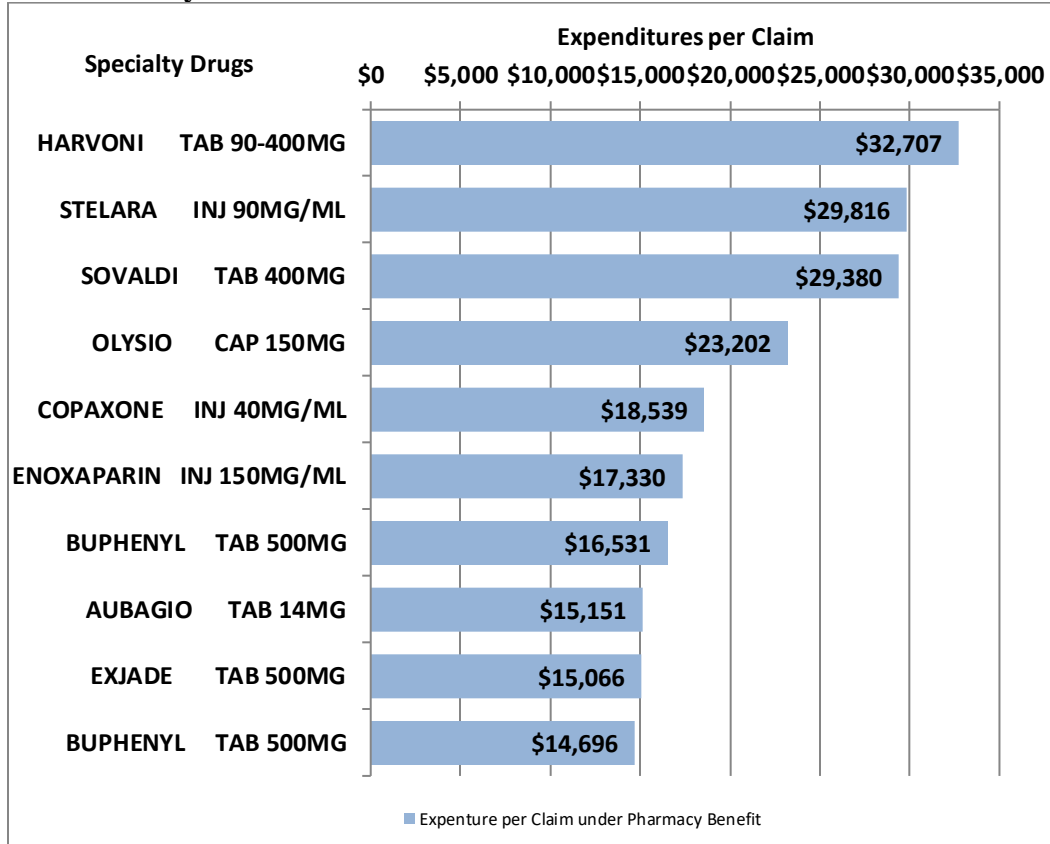
In 2013, the top 10 drugs under the pharmacy benefit ranged in average cost per claim from a low of \$10,958 to a high of \$31,674. Under the medical benefit, the top 10 drugs ranged in average cost per claim from a low of \$22,454 to a high of \$162,373. Compared to the previous year, the average cost per claim under medical benefit is significantly higher for 2013. The top drug under medical benefit is Ipilimumab-- an antineoplastic agent used for melanoma. Ipilimumab had an average cost per claim of \$162,373—a 400 percent increase from the average cost per claim of the top drugs under medical benefit in 2012.

**Table 4.27: Expenditure per Claim for Top 10 Drugs under the Pharmacy and Medical Benefits: 2014**

2014	Pharmacy Benefit		Medical Benefit	
Rank	Drug Name	Average Cost Per Claim	Drug Name	Average Cost Per Claim
1	HARVONI TAB 90-400MG	\$32,707	INJECTION IPILIMUMAB 1MG	\$108,674
2	STELARA INJ 90MG/ML	\$29,816	INJECTION, INFLIXIMAB,10 MG	\$47,369
3	SOVALDI TAB 400MG	\$29,380	INJECTION BEVACIZUMAB10 MG	\$37,692
4	OLYSIO CAP 150MG	\$23,202	INJECTION RITUXIMAB 100 MG	\$37,350
5	COPAXONE INJ 40MG/ML	\$18,539	INJECTION PEMETREXED 10 MG	\$36,382
6	ENOXAPARIN INJ 150MG/ML	\$17,330	HISTRELIN IMPL (SUPPRELIN LA) 50 MG	\$34,681
7	BUPHENYL TAB 500MG	\$16,531	INJECTION GALSULFASE 1MG	\$33,750
8	AUBAGIO TAB 14MG	\$15,151	INJECTION TRASTUZUMAB 10 MG	\$31,554
9	EXJADE TAB 500MG	\$15,066	INJECTION BRENTUXIMABVEDOTIN 1 MG	\$31,230
10	BUPHENYL TAB 500MG	\$14,696	INJECTION NATALIZUMAB 1 MG	\$28,506

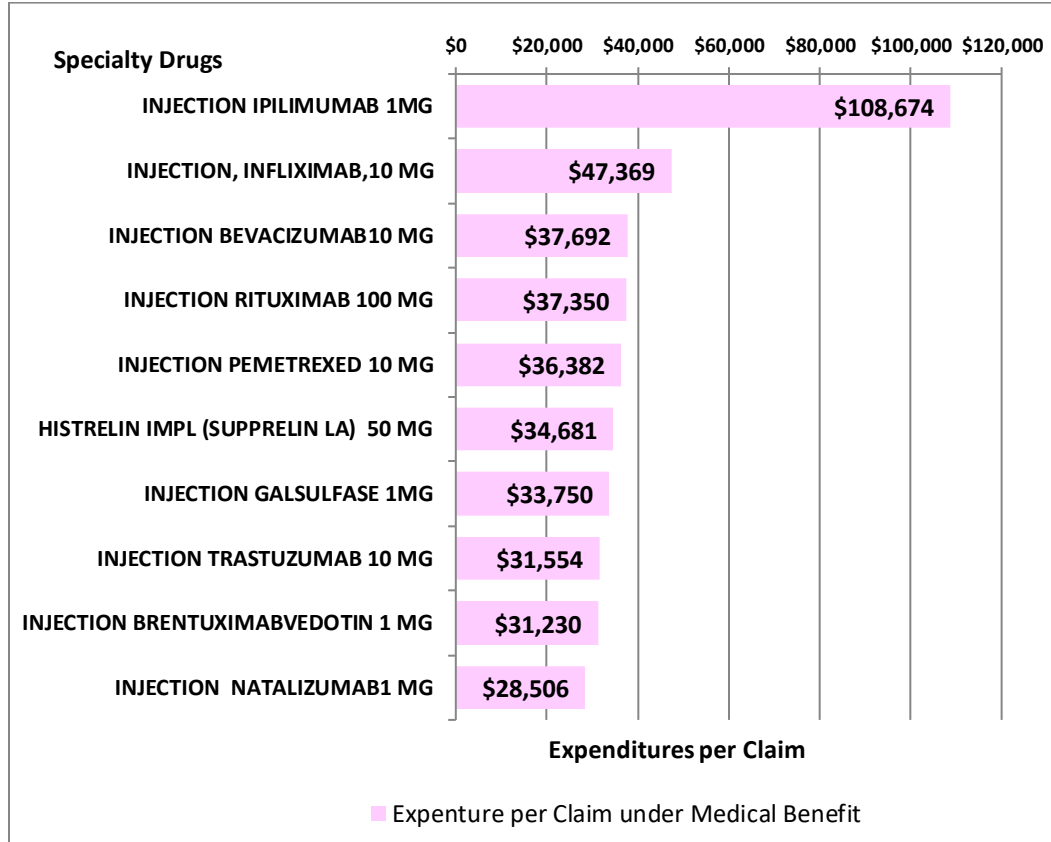
Under the pharmacy benefit, Harvoni was the No. 1 drug in 2014. Harvoni and Sovaldi are near-curative therapy for hepatitis C. FDA approved Harvoni in 2014, and it was a hot topic for all payers including self-insured employers in 2014 and 2015 at a per-claim price of more than \$28,000 and a course of therapy cost of about \$83,000. Another drug for hepatitis C, Olysio, is the fourth on the list under the pharmacy benefit. Unlike Harvoni, Sovaldi and Olysio were approved in the late 2013. Under the medical benefit, the No. 1 drug for per-claim expenditure in 2014 was Ipilimumab, an antineoplastic agent used for melanoma. Figures 4.59 and 4.60 show the average expenditures per claim for the top 10 specialty drugs under the pharmacy and medical benefits for 2014.

**Figure 4.59: Top 10 Specialty Drugs by Average Expenditures per Claim under the Pharmacy Benefit: 2014**



The top 10 specialty drugs under the pharmacy benefit included treatments for hepatitis C, multiple sclerosis, inflammatory conditions, growth deficiency, and HIV. The top 10 specialty list for Fairview Specialty included treatments for inflammatory conditions, multiple sclerosis, oncology, hepatitis C, HIV, miscellaneous specialty conditions, growth deficiency, hemophilia, pulmonary arterial hypertension, and transplants.<sup>20</sup> Prime’s top therapeutic categories were hepatitis C, diabetes, biologic anti-inflammatories, HIV, multiple sclerosis (MS), pain, cancer (pills), hemophilia, psychosis, high cost other, seizures, and blood thinners.<sup>11</sup>

**Figure 4.60: Top 10 Specialty Drugs by Average Expenditures per Claim under the Medical Benefit: 2014**



The top 10 drugs under the medical benefit are shown in Figure 4.60.

#### 4.3.4 Question 2d results

What percent of total specialty drugs and drug-related expenditures are accounted for by each therapeutic category each year?

**Table 4.28: Percent of Total Specialty Expenditures Accounted for by Each Therapeutic Category Each Year Across the Pharmacy and Medical Benefits: 2006 to 2014\***

Therapeutic Category	2006	2007	2008	2009	2010	2011	2012	2013	2014
ADHD/Anti-Narcolepsy /Anti-Obesity/Anorexiant Agents	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Analgesics and Anesthetics	7.43%	9.60%	7.87%	6.86%	11.18%	15.24%	17.07%	16.44%	15.53%
Anti-Infective Agents	5.14%	6.26%	7.01%	7.70%	6.71%	7.50%	6.76%	5.79%	11.81%
Antineoplastic Agents	29.79%	30.37%	29.79%	27.50%	20.98%	16.23%	18.71%	21.17%	19.20%
Biologicals	3.97%	3.73%	3.54%	4.70%	2.94%	4.46%	2.51%	3.34%	2.85%
Cardiovascular Agents	0.29%	0.49%	0.62%	0.92%	0.44%	0.84%	1.48%	0.81%	1.25%
Central Nervous System Drugs	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.03%
Endocrine and Metabolic Drugs	8.06%	9.05%	11.28%	17.41%	18.17%	17.75%	16.59%	11.22%	12.79%
Gastrointestinal Agents	6.93%	6.98%	7.20%	6.91%	6.57%	6.18%	6.28%	7.65%	6.52%
Genitourinary Products	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Hematological Agents	0.00%	9.74%	8.70%	6.80%	7.28%	7.32%	4.88%	5.76%	5.36%
Miscellaneous Products	10.75%	11.21%	9.65%	7.00%	6.61%	5.62%	5.53%	9.10%	7.23%
Neuromuscular Drugs	0.62%	0.89%	1.15%	1.01%	1.06%	1.19%	0.96%	1.73%	1.37%
Nutritional Products	0.01%	0.00%	0.02%	0.00%	0.05%	0.03%	0.01%	0.01%	0.01%
Psychotherapeutic and Neurological Agents - Miscellaneous	7.81%	8.35%	8.43%	7.62%	12.11%	13.10%	13.59%	10.83%	10.56%
Respiratory Agents	2.20%	2.30%	3.61%	4.61%	4.56%	3.39%	3.76%	3.94%	2.88%
Topical Products	0.40%	0.61%	0.67%	0.44%	0.70%	0.66%	1.46%	1.83%	2.32%
Unknown	0.45%	0.44%	0.46%	0.52%	0.65%	0.49%	0.38%	0.34%	0.30%

\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

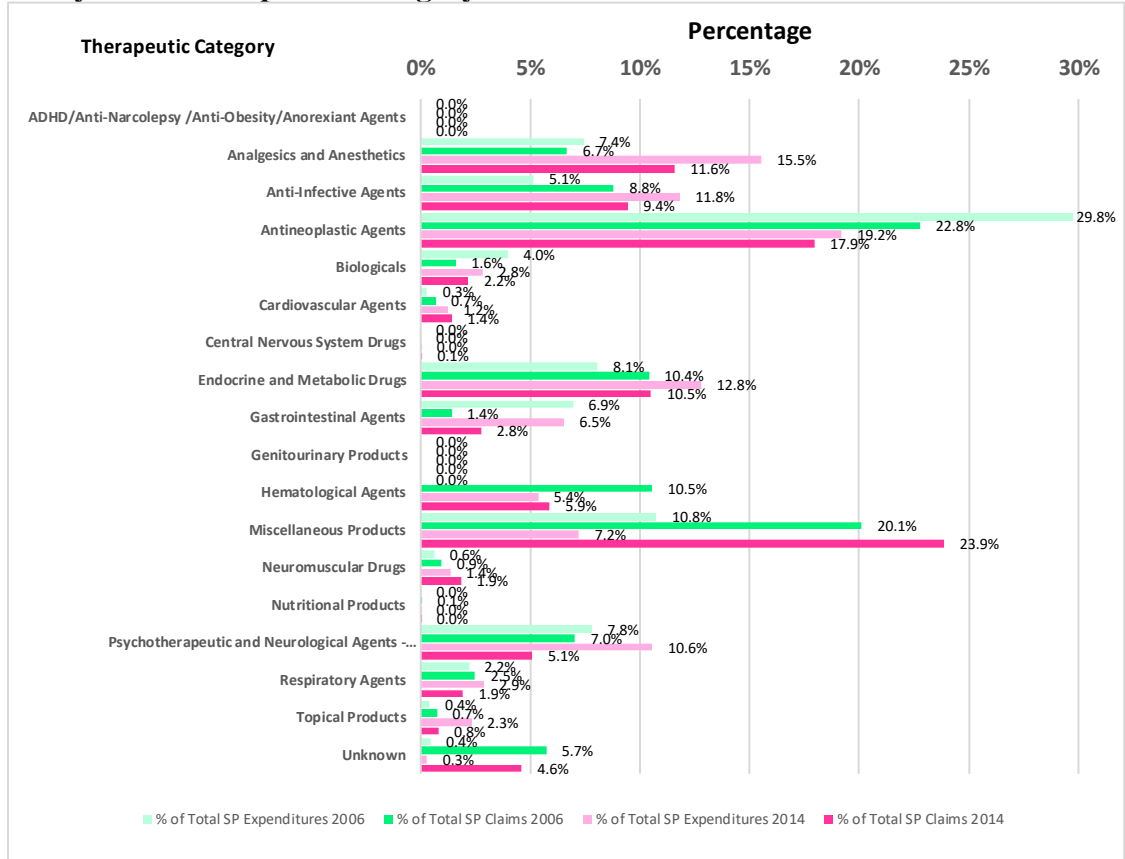
Antineoplastic agents accounted for the greatest percent of total specialty expenditures across the Pharmacy and Medical benefit from 2006 to 2014. However, the percentage of total specialty accounted for by antineoplastic agents declined from 2006 to 2014, dropping from 29.8 percent to 19.2 percent. Antineoplastic agents reached its lowest percent of total specialty expenditures in 2011 at 16.2 percent.

Analgesics and Anesthetics as a percent of total specialty drugs accounted for 6.86 percent to 17.07 percent from 2006 to 2014, respectively. The percent of total specialty expenditures accounted for by gastrointestinal agents was relatively constant

between 6.18 percent and 7.65 percent from 2006 to 2014. Psychotherapeutic and neurological agents miscellaneous, including drugs used for multiple sclerosis, accounted for 7.62 percent to 13.59 percent of total specialty expenditures from 2006 to 2014.



**Figure 4.61: Percentage of Total Specialty Claims and Expenditures Accounted for by Each Therapeutic Category in 2006 vs. 2014\***



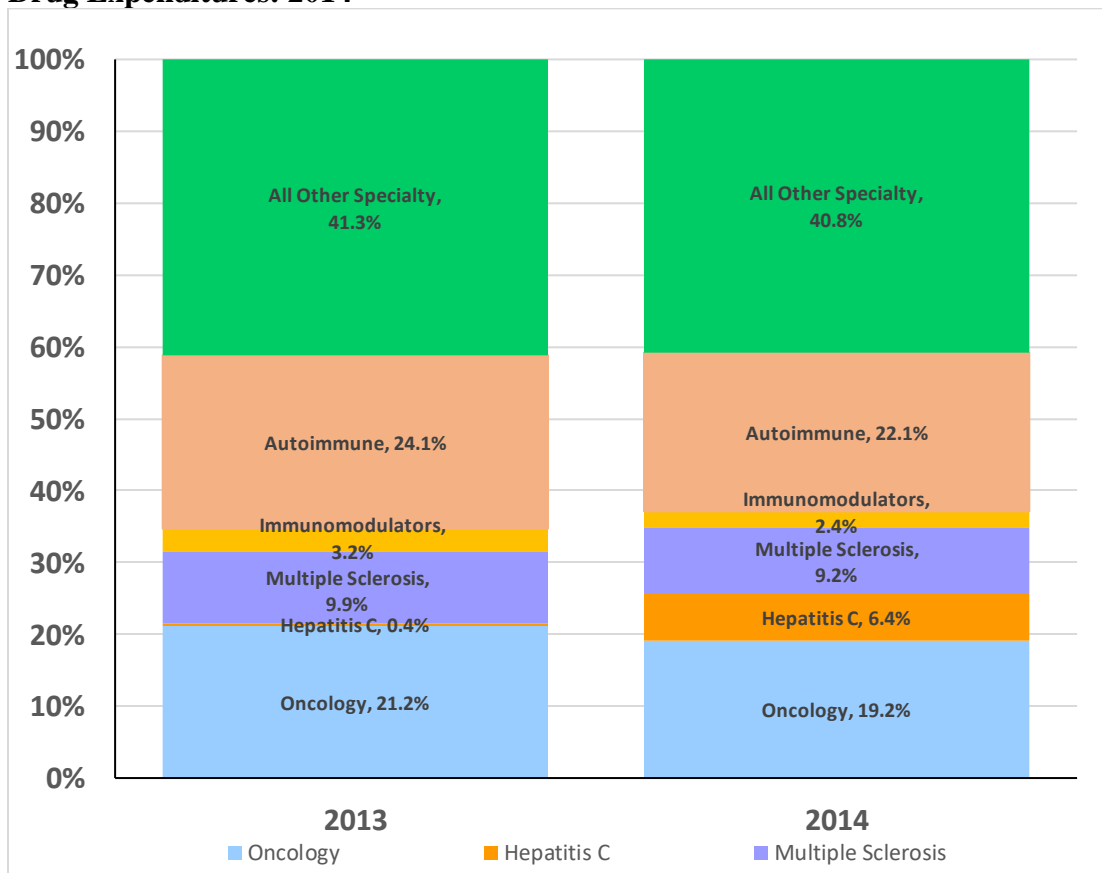
\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Both in 2006 and 2014 antineoplastic agents, biologicals, gastrointestinal agents, psychotherapeutic and neurological agents, and analgesic and anesthetics accounted for a greater percentage of total special expenditures compared to their respective percentage of total specialty claims, Figure 4.61.

#### 4.3.5 Question 2e results

For 2013 and 2014, what percent of total specialty drug expenditures do the following four therapeutic categories account for in the UPlan? The four therapeutic categories include: immunomodulators, multiple sclerosis, oncology, and hepatitis C, as well as all other specialty drugs.

**Figure 4.62 Five Specialty Therapeutic Categories as Percent of Total Specialty Drug Expenditures: 2014**

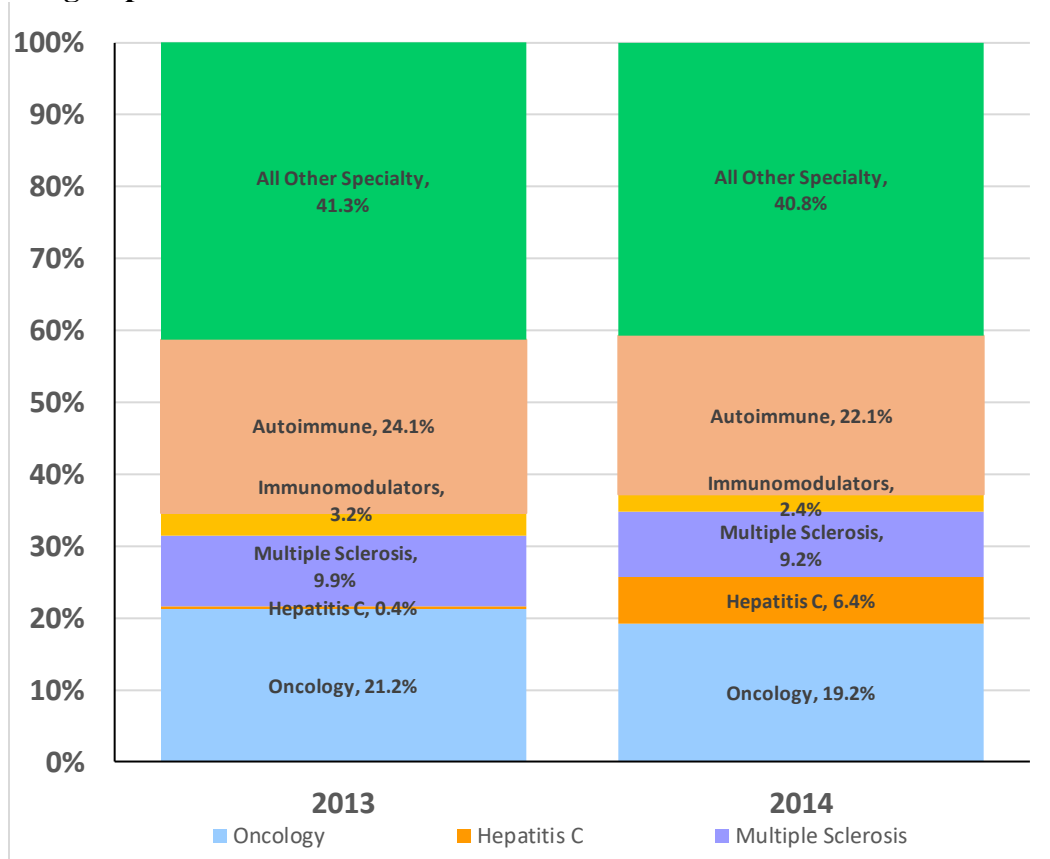


Hepatitis C drugs saw a big jump from 2013 to 2014 as a percent of total specialty expenditures accounting for 0.43 percent to 6.41, respectively. This spike in Hepatitis C as the percent of total specialty expenditures was also observed in the industrywide EMD Serono report.<sup>2</sup> Immunomodulators represented about 20 to 25 percent of total

specialty expenditures for Prime Therapeutics in 2012 and ESI in 2014; however, for the UPlan the immunomodulators accounted for only 2.35 percent of total specialty drug expenditures in 2013 and 2014.<sup>57</sup>

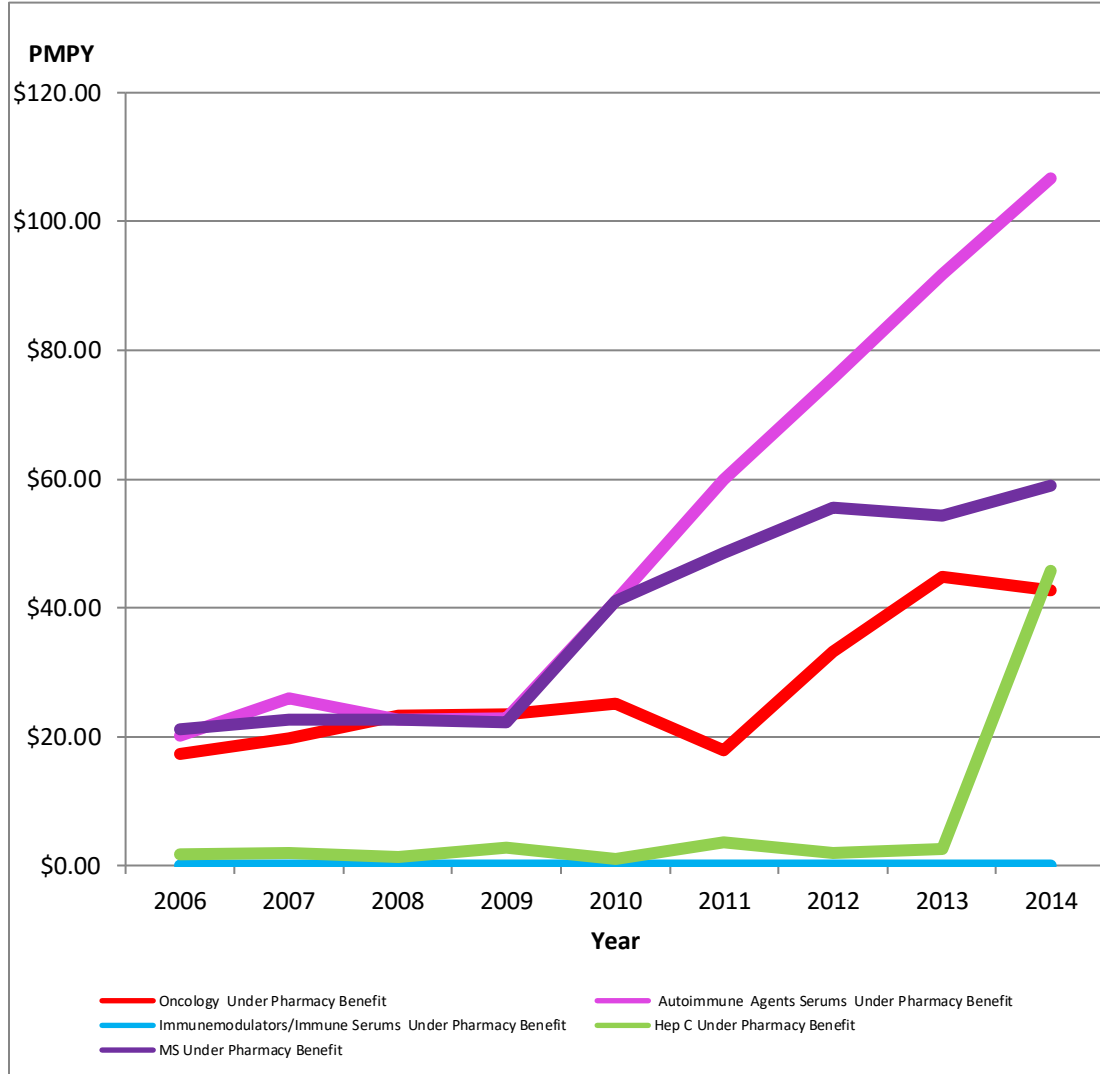
Figure 4.63 shows that five therapeutic categories accounted for a total of 58.7 percent of the specialty drug expenditures in 2013 and 59.2 percent of the total specialty expenditures in 2014. Autoimmune drugs which includes drugs for inflammatory disorders, was the therapeutic category accounting for the largest share of specialty drugs experienced by the UPlan and is consistent with data reported by EMD Serono.<sup>2</sup> Drugs for autoimmune disease accounted for 24.1 percent and 22.1 percent of the total specialty drug expenditures in 2013 and 2014.

**Figure 4.63 Five Specialty Therapeutic Categories as Percent of Total Specialty Drug Expenditures: 2014**



Figures 4.64 to 4.67 show specialty drug expenditures, PMPY and total, for the five therapeutic categories discussed above.

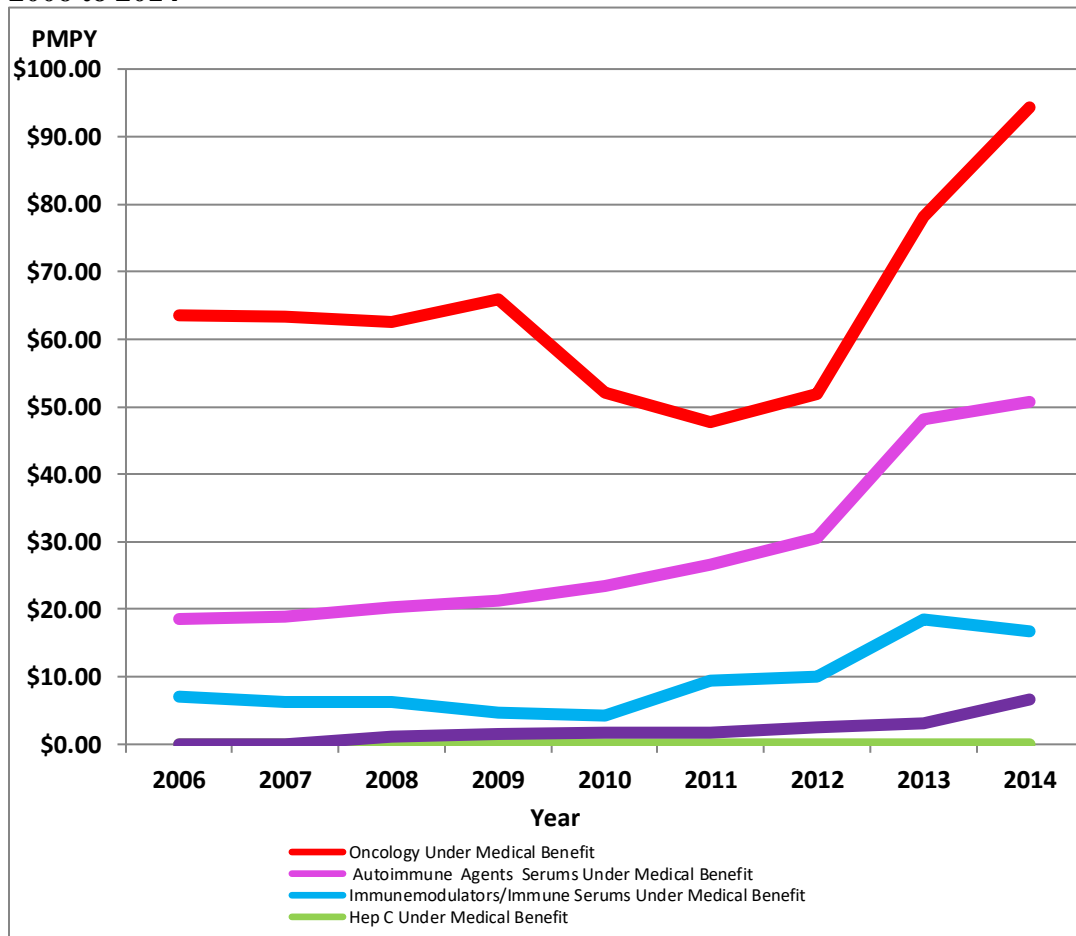
**Figure 4.64: PMPY by Selected Therapeutic Category under the Pharmacy Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Within the pharmacy benefit, drugs for autoimmune diseases had the highest PMPY expenditure from 2010 to 2014. The PMPY expenditures for autoimmune disease agents from 2006 to 2014 were \$20.16 to \$106.70, a 429 percent growth. For oncology agents the PMPY ranged from \$17.32 to \$42.72, a 147 percent growth from 2006 to 2014, respectively. Hepatitis C drugs had the greatest percentage growth in PMPY from 2006 to 2014 at 2,631 percent, from \$1.68 to \$45.75. The PMPY for multiple sclerosis agents ranged from \$21.15 to \$58.98 from 2006 to 2014, showing a 179 percent growth.

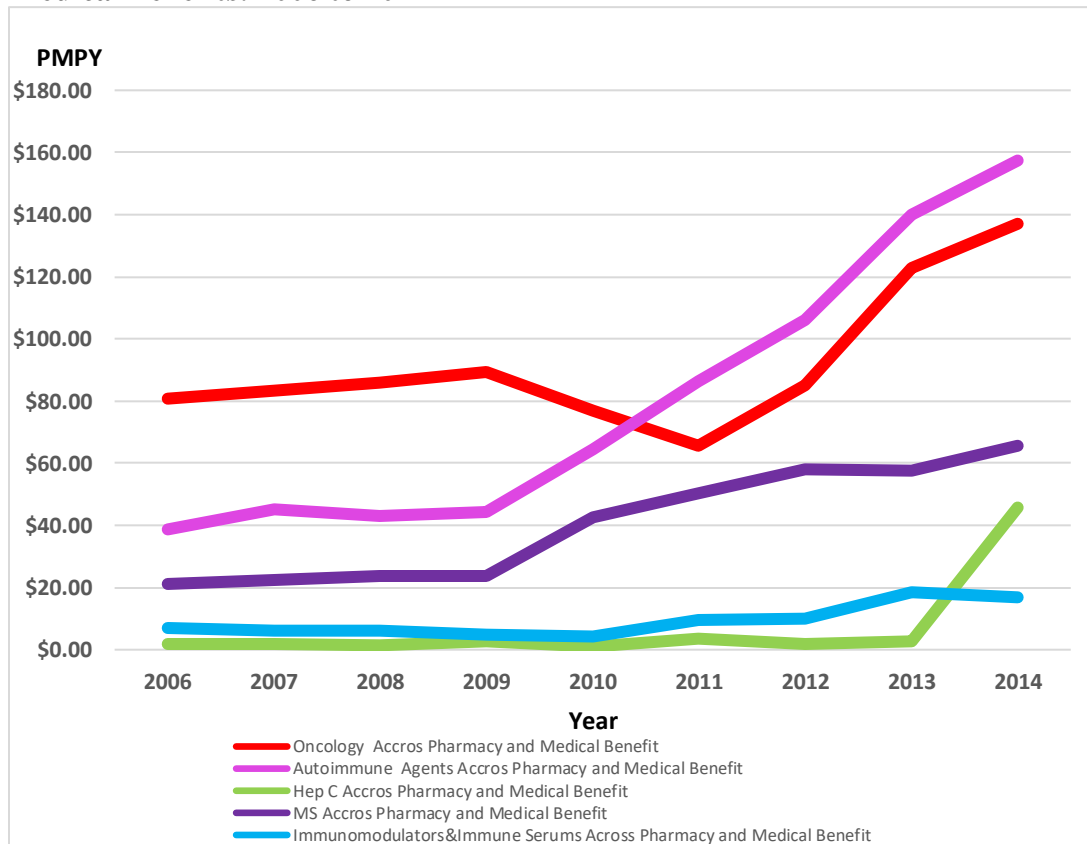
**Figure 4.65 PMPY by Selected Therapeutic Category under the Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

Under the medical benefit, oncology agents had the highest PMPY expenditure from 2006 to 2014, from \$63.54 to \$94.33, a growth of 48 percent. The therapeutic category with the second highest PMPY under the medical benefit was autoimmune agents, with a growth of 173 percent from 2006 to 2014, and ranging from \$18.56 to \$50.71. Multiple sclerosis PMPY ranged from \$0.00 to \$6.64, and immune modulators ranged from \$6.98 to \$16.76, a 140 percent growth from 2006 to 2014.

**Figure 4.66: PMPY by Selected Therapeutic Category under the Pharmacy & Medical Benefits: 2006 to 2014\***



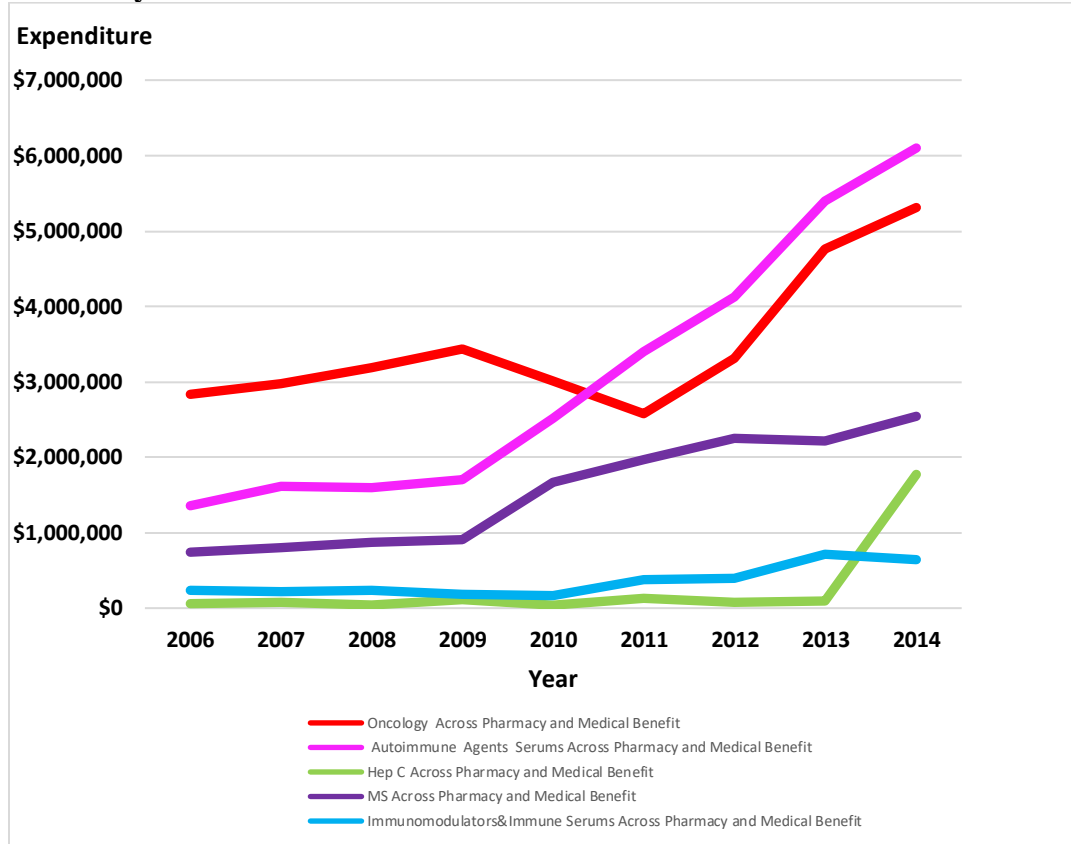
\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Across the pharmacy and medical benefits, oncology agents had the highest PMPY expenditure from 2006 to 2009 and from 2010 to 2014 the autoimmune agents had the highest PMPY. The therapeutic category with the third highest PMPY under the medical benefit were agents for MS with a growth of 140 percent from 2006 to 2014, Figure 4.66.

Figures 4.67 shows total expenditures for five selected therapeutic categories. We see that the expenditures for oncology were the highest from 2006 to 2009. When looking at claims, oncology also maintained the top spot with the most claims from 2006 to 2014. However, from 2010 to 2014 autoimmune agents have the highest expenditures of the five selected therapeutic categories.

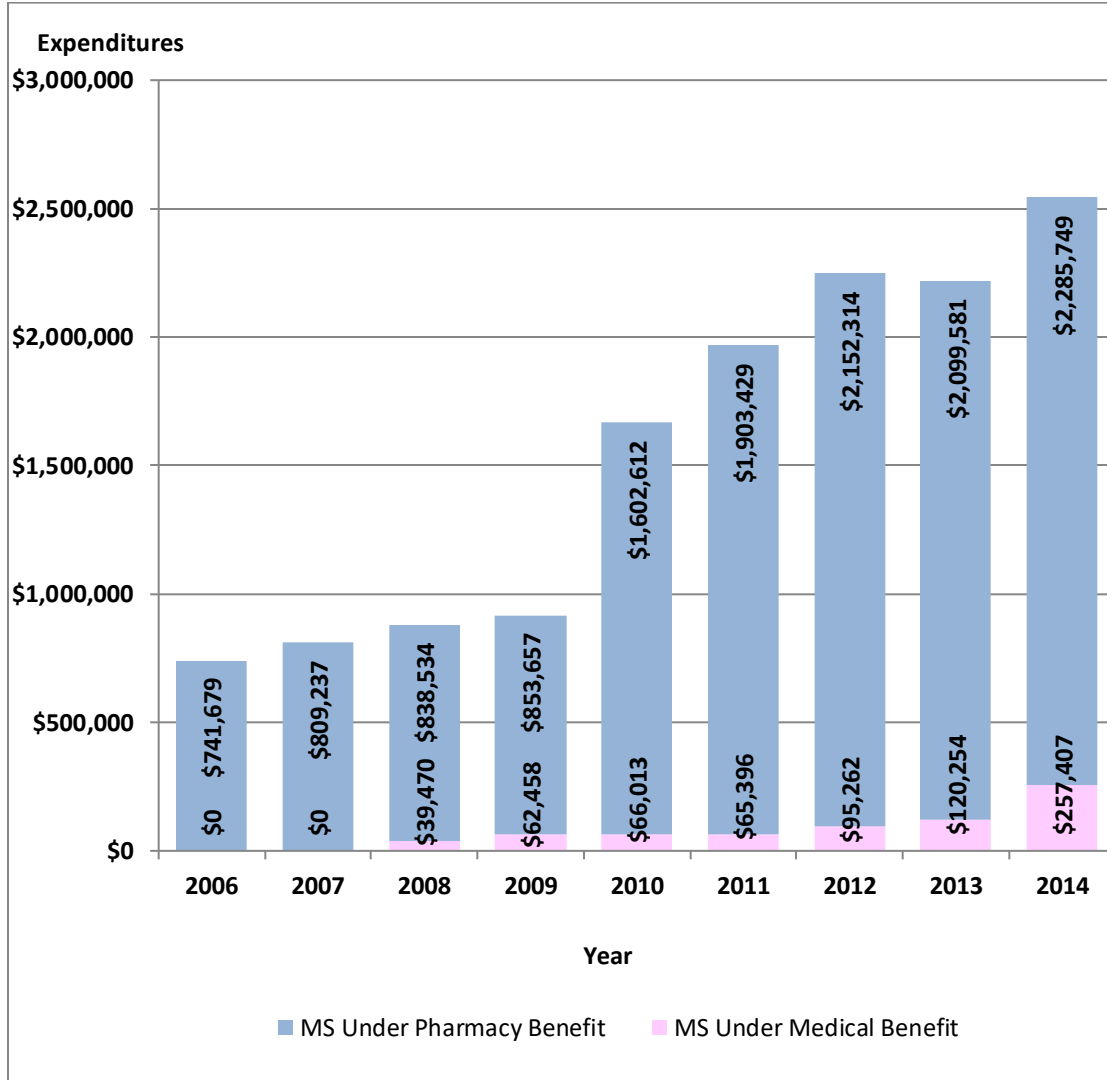


**Figure 4.67: Total Specialty Expenditure by Selected Therapeutic Category under Pharmacy & Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

**Figure 4.68: Total Multiple Sclerosis Specialty Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

Total expenditures for multiple sclerosis grew from 2006 to 2014. The majority of total expenditures for multiple sclerosis were accounted for by drugs flowing through the pharmacy benefit. A closer look at specialty drug expenditures for multiple sclerosis reveals that 90 percent of total specialty MS expenditures were accounted for under the pharmacy benefit, while 10 percent were under the medical benefit. Overall expenditures for multiple sclerosis grew under both the pharmacy and medical benefits. Total

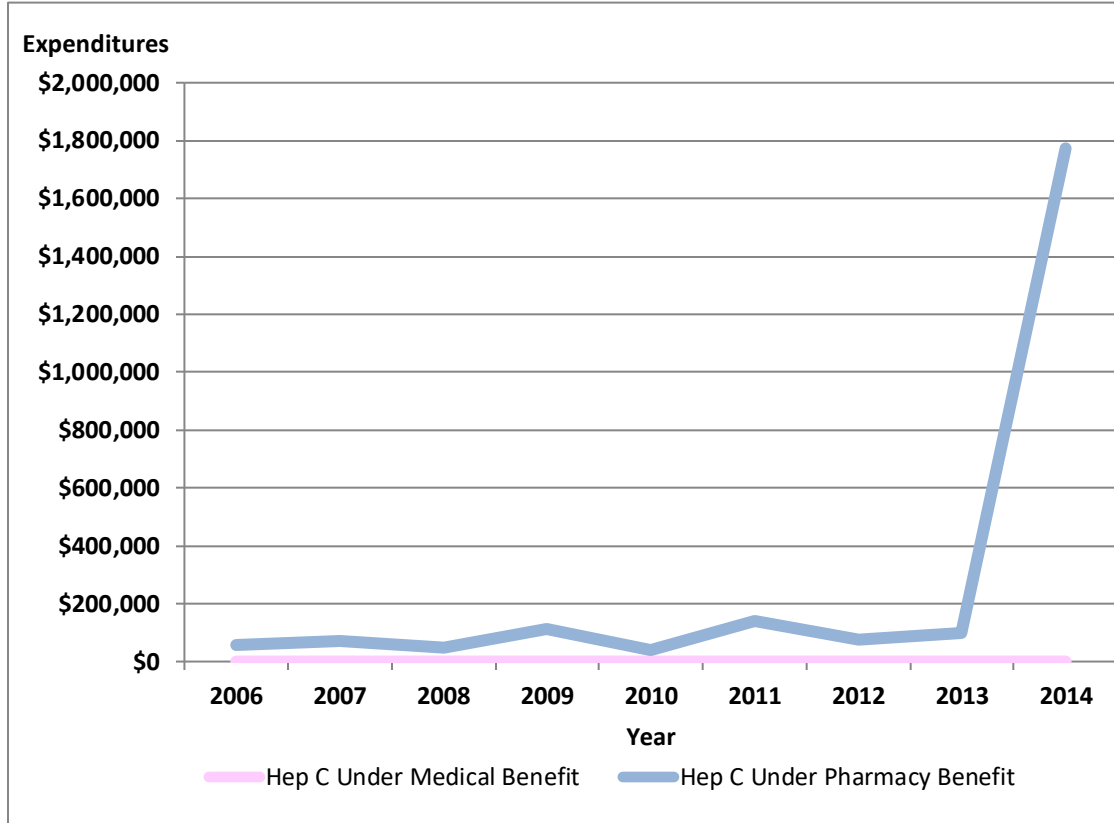
expenditures for MS specialty drugs across the pharmacy and medical benefits grew by 243 percent from 2006 to 2014. High expenditure drugs for multiple sclerosis include Copaxone, Rebif, Betaseron, Tecfidera, and Avonex.

**Table 4.29: PMPY Expenditure for Multiple Sclerosis Drugs under the Pharmacy & Medical Benefits: 2014**

<b>MS Drugs under Pharmacy Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditure</b>
COPAXONE KIT 20MG/ML	\$17.63	\$683,212.02
COPAXONE INJ 40MG/ML	\$8.30	\$321,785.85
REBIF INJ 44/0.5	\$8.17	\$316,536.21
TECFIDERA CAP 240MG	\$6.94	\$269,004.30
BETASERON INJ 0.3MG	\$6.10	\$236,515.70
AVONEX PEN KIT 30MCG	\$3.83	\$148,513.30
AVONEX PREFL KIT 30MCG	\$3.19	\$123,514.54
GILENYA CAP 0.5MG	\$1.58	\$61,224.09
AMPYRA TAB 10MG	\$1.55	\$60,180.89
AUBAGIO TAB 14MG	\$0.78	\$30,301.00
TECFIDERA MIS STARTER	\$0.40	\$15,418.13
REBIF TITRTN SOL PACK	\$0.25	\$9,615.98
REBIF REBIDO INJ 44/0.5	\$0.13	\$4,987.87
REBIF REBIDO SOL TITRATN	\$0.13	\$4,938.78
<b>Total Specialty MS Drugs Pharmacy Benefit</b>	<b>\$58.98</b>	<b>\$2,285,748.66</b>
<b>MS Drugs under Medical Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditure</b>
INJECTION NATALIZUMAB 1 MG	\$6.64	\$257,406.97
<b>Total Specialty MS Drugs Medical Benefit Total</b>	<b>\$6.64</b>	<b>\$257,406.97</b>
<b>Total Specialty MS Drugs across Pharmacy &amp; Medical Benefit</b>	<b>\$65.62</b>	<b>\$2,543,155.63</b>

Table 4.29 shows PMPY expenditures for specific multiple sclerosis drugs. In 2014, Copaxone had the highest and second highest PMPY and specialty expenditure for MS drugs across both the pharmacy and medical benefits. The overall PMPY for MS drugs under the pharmacy benefit was \$58.98 and for the medical benefit was \$6.64. The PMPY for MS drugs under both the pharmacy and medical benefits was \$65.62

**Figure 4.69 Total Expenditures on Hepatitis C Agents under the Pharmacy & Medical Benefits: 2006 to 2014**



Specialty drug expenditures for hepatitis C drugs were not present under the medical benefit from 2006 to 2014. Expenditures for hepatitis C drugs under the pharmacy benefit were steadily below \$200,000 annually from 2006 to 2013. However, in 2014 a huge jump in specialty drug expenditures for hepatitis C was noted with a growth rate of 2,918 percent from 2006 to 2014, increasing from \$58,000 to \$1.77 million. This jump in hepatitis C expenditures is in line with what was observed across the industry in 2014 when new near-cure hepatitis C therapies were approved by the FDA for market entry.

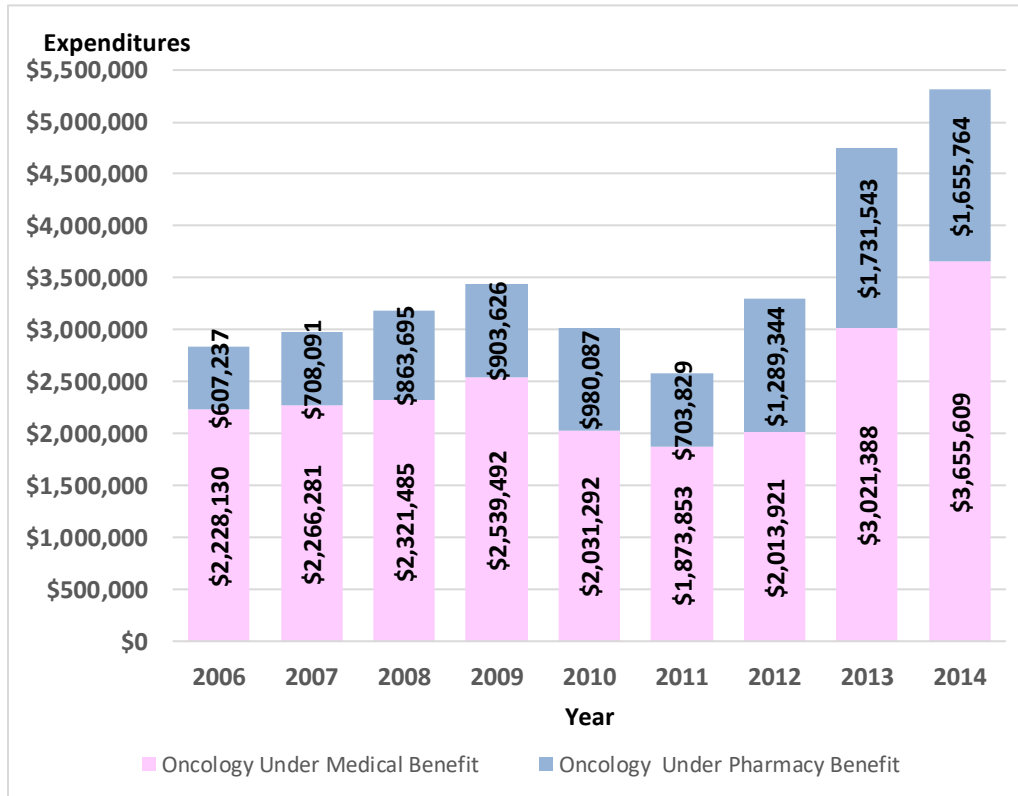
For the UPlan, the major hepatitis C drugs driving up expenditures in 2014 were Sovaldi, Olysio, and Harvoni, as noted in Table 4.30. Sovaldi had the highest cost PMPY

at \$29.57 for 2014 followed by Olysio at \$10.78 PMPY. Total expenditures for Sovaldi and Olysio combined were about \$1.5 million for 2014.

**Table 4.30 PMPY Expenditures for Specific Hepatitis C Drugs under the Pharmacy Benefit: 2014**

Hepatitis C Drug under the Pharmacy Benefit	2014 PMPY	2014 Expenditure
SOVALDI TAB 400MG	\$29.57	\$1,145,837.11
OLYSIO CAP 150MG	\$10.78	\$417,631.78
HARVONI TAB 90-400MG	\$2.53	\$98,120.76
PEGASYS INJ PROCLICK	\$1.10	\$42,804.80
PEG-INTRON KIT 80MCG RP	\$1.01	\$38,972.35
PEG-INTRON KIT 120 RP	\$0.69	\$26,612.32
RIBAVIRIN CAP 200MG	\$0.07	\$2,523.80
RIBAVIRIN TAB 200MG	\$0.02	\$671.34
<b>Total Hepatitis C Pharmacy Benefit</b>	<b>\$45.75</b>	<b>\$1,773,174.26</b>

**Figure 4.70: Total Specialty Oncology Expenditures under the Pharmacy & Medical Benefits: 2006 to 2014**



\*Total expenditures include total drug and drug-related expenditures under the pharmacy and medical benefits.

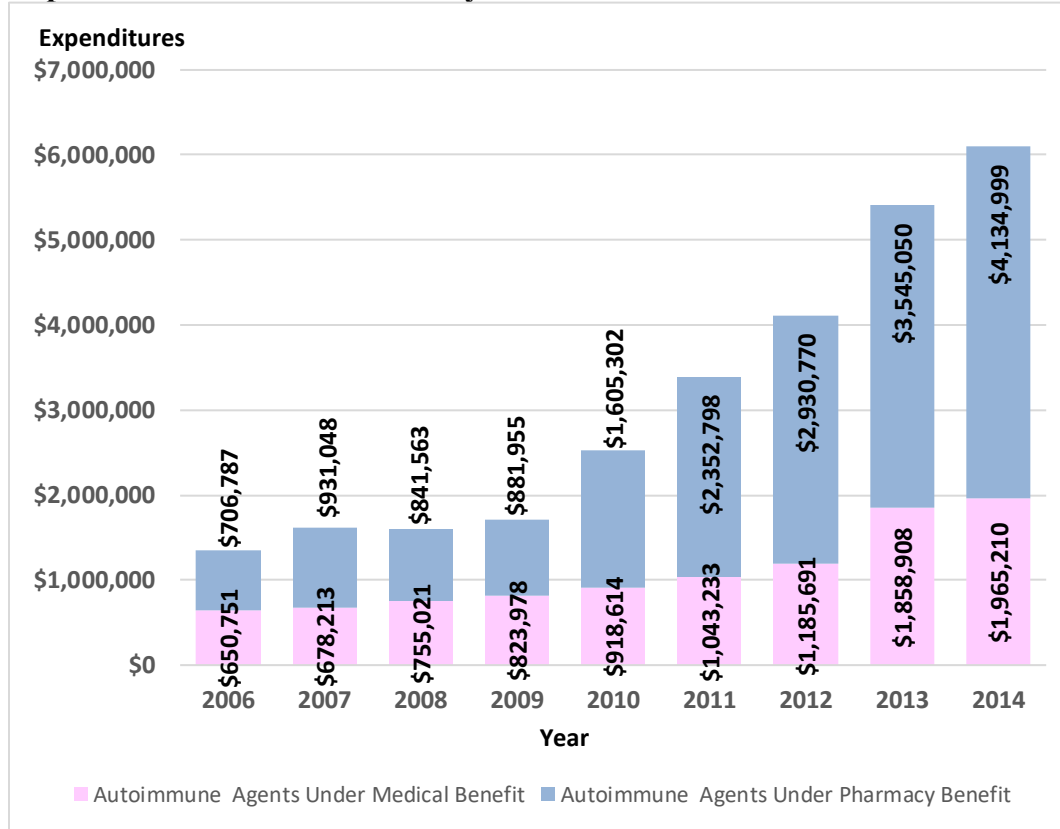
For oncology (antineoplastic drugs), the major driver of total specialty expenditures was claims under the medical benefit from 2006 to 2014, as seen in Figure 4.70. Total antineoplastic expenditures across pharmacy and medical benefit grew 79 percent from 2006 to 2014, from \$2,835,366 to \$5,311,372. Table 4.31 lists the top 10 pharmacy and top 10 medical benefit oncology drugs that accounted for the most oncology spending for 2014. As expected, the top 10 oncology drugs under the medical benefit were injectables or infusions. On the other hand, the top 10 specialty oncology drugs under the pharmacy benefit were all oral products. The PMPY for the top 10 oncology drugs under the pharmacy benefit ranged from \$1.33 to \$7.71, with a total PMPY of \$27.86 for the top 10 oncology drugs under the pharmacy benefit. The top 10 oncology drugs under the medical benefit had a PMPY that ranged from \$3.07 to \$14.98 in 2014. The total PMPY for the top 10 oncology drugs under the medical benefit (\$72.41) was significantly larger than what was observed under the pharmacy benefit.

**Table 4.31 PMPY & Total Expenditures for Top 10 Oncology Drugs under the Pharmacy & Medical Benefits: 2014**

<b>Top 10 Oncology Drugs under the Pharmacy Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditures</b>
GLEEVEC TAB 400MG	\$7.72	\$299,355.06
TAFINLAR CAP 75MG	\$3.45	\$133,757.12
XTANDI CAP 40MG	\$2.87	\$111,232.69
AFINITOR TAB 10MG	\$2.65	\$102,865.04
TEMOZOLOMIDE CAP 100MG	\$2.46	\$95,523.43
CAPECITABINE TAB 500MG	\$2.12	\$82,055.61
IMBRUVICA CAP 140MG	\$1.96	\$75,961.82
POMALYST CAP 1MG	\$1.78	\$69,030.89
SPRYCEL TAB 100MG	\$1.50	\$58,223.92
TASIGNA CAP 150MG	\$1.33	\$51,508.02
<b>Total of Top 10 Oncology Drugs under the Pharmacy Benefit</b>	<b>\$27.86</b>	<b>\$1,079,513.60</b>
<b>Top 10 Oncology Drugs under the Medical Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditures</b>
INJECTION RITUXIMAB 100 MG	\$14.98	\$580,407.92
INJECTION BEVACIZUMAB 10 MG	\$11.26	\$436,516.75
INJECTION TRASTUZUMAB 10 MG	\$10.95	\$424,184.58
INJECTION BRENTUXIMABVEDOTIN 1 MG	\$8.86	\$343,525.37
INJECTION IPILIMUMAB 1MG	\$7.72	\$299,053.96
INJECTION OXALIPLATIN0.5 MG	\$4.72	\$182,741.99
INJECTION ERIBULIN MESYLATE 0.1 MG	\$4.62	\$179,074.80
INJECTION DOXORUBICIN HCL LIPOSOMAL NOS 10 MG	\$3.14	\$121,743.85
INJECTION PEMETREXED 10 MG	\$3.10	\$120,163.64
INJECTION PANITUMUMAB 10 MG	\$3.07	\$118,887.34
<b>Total of Top 10 Oncology Drugs under the Medical Benefit</b>	<b>\$72.41</b>	<b>\$2,806,300.20</b>
<b>Total of Top 10 Oncology Drugs Under Pharmacy &amp; Medical Benefit</b>	<b>\$100.27</b>	<b>\$3,885,813.80</b>



**Figure 4.71: Total Specialty Inflammatory Agents (Autoimmune Disease) Expenditures under the Pharmacy and Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under pharmacy and medical benefit.

Expenditures for autoimmune disease specialty drugs grew by 343 percent from 2006 to 2014, Figure 4.71. With high priced and commonly used therapies such as Enbrel, Humira, and Remicade, the growth in this class is in line with what is observed with industry trends.

**Table 4.32 PMPY and Total Expenditures for Autoimmune Drugs under the Pharmacy & Medical Benefits: 2014**

<b>Autoimmune Drugs under Pharmacy Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditures</b>
HUMIRA PEN KIT 40MG/0.8	\$38.14	\$1,477,899.16
ENBREL SRCLK INJ 50MG/ML	\$35.61	\$1,380,129.93
ENBREL INJ 50MG/ML	\$10.77	\$417,548.45
HUMIRA KIT 40MG/0.8	\$5.96	\$230,846.23
CIMZIA PREFL KIT 200MG/ML	\$5.78	\$223,967.65
ENBREL INJ 25MG	\$3.92	\$152,017.30
ORENCIA INJ 125MG/ML	\$2.08	\$80,486.85
HUMIRA PEN KIT CROHNS	\$1.04	\$40,467.30
HUMIRA KIT 20MG/0.4	\$0.83	\$32,152.74
HUMIRA PEN KIT PSORIASI	\$0.58	\$22,561.65
XELJANZ TAB 5MG	\$0.53	\$20,512.46
OTEZLA TAB 30MG	\$0.50	\$19,432.98
CIMZIA KIT STARTER	\$0.45	\$17,445.40
SIMPONI INJ 50MG	\$0.35	\$13,663.22
SIMPONI INJ 50/0.5ML	\$0.15	\$5,867.77
<b>Total Autoimmune Agents under Pharmacy Benefit</b>	<b>\$106.69</b>	<b>\$4,134,999.09</b>
<b>Autoimmune Drugs under Medical Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditures</b>
INJ ABATACEPT 10 MG USED MEDICARE ADM SUPV PHYS	\$6.43	\$249,064.67
INJECTION TOCILIZUMAB1 MG	\$3.97	\$154,019.23
INJECTION, INFLIXIMAB,10 MG	\$40.31	\$1,562,125.86
<b>Total Autoimmune Agents under Medical Benefit</b>	<b>\$50.71</b>	<b>\$1,965,209.76</b>
<b>Total Autoimmune Agents across Pharmacy &amp; Medical Benefit</b>	<b>\$157.40</b>	<b>\$6,100,208.85</b>

The top three drugs contributing to autoimmune disease drug expenditures include Remicade, Humira and Enbrel. In industry, as well as for the UPlan, Humira and Enbrel are commonly seen flowing through the pharmacy benefit, while Remicade (infliximab) flows through the medical benefit. Between these three autoimmune drugs, Humira has the most FDA approved indications, and Enbrel has the lowest number of indications. Common indications across all three drugs include ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, and rheumatoid arthritis. Additional common indications between Humira and Remicade include Crohn's disease (moderate to severe) and ulcerative colitis (moderate to severe). Examining the PMPY for the three top drugs in this class is important, as they have several common indications. In general, the 2014 PMPY for Remicade is highest at \$40.31, followed by Humira at \$38.14, and Enbrel at \$35.61.

**Figure 4.72: Total Specialty Immunomodulator and Immune Serum Expenditures under the Pharmacy and Medical Benefits: 2006 to 2014**

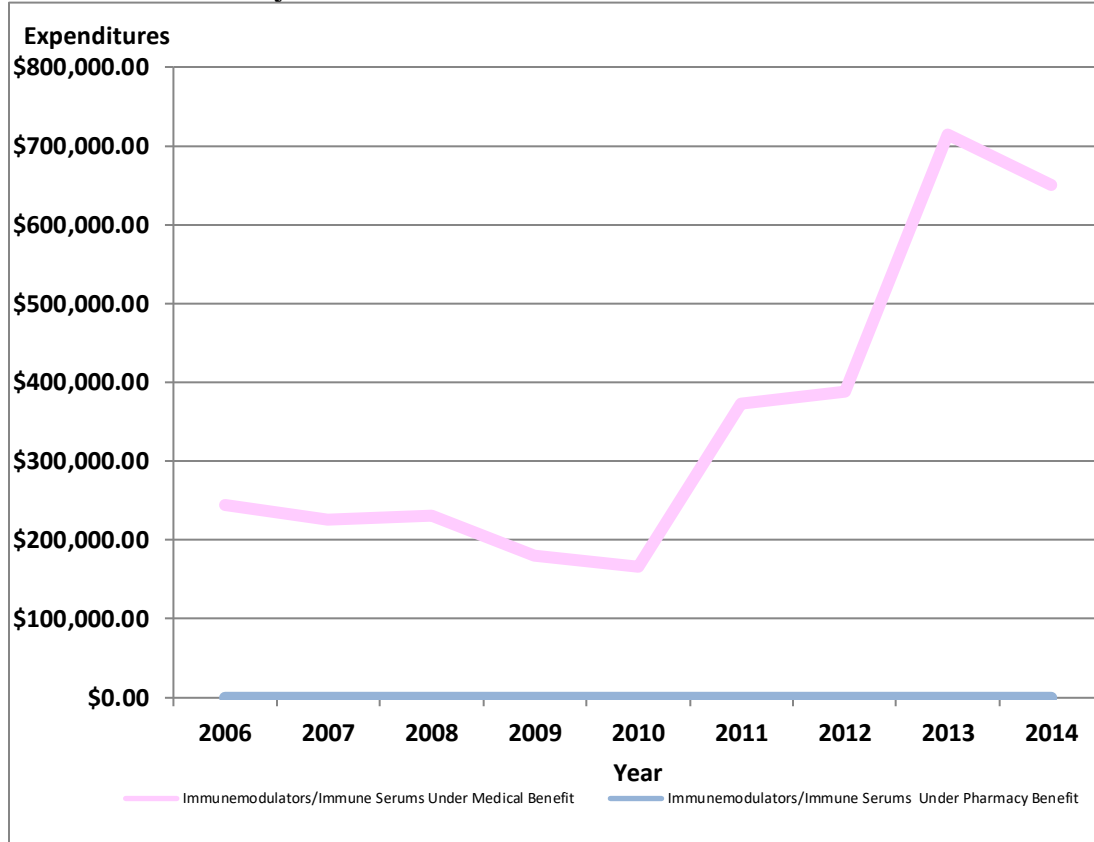


Figure 4.72 shows that expenditures for Immunomodulators and immune serums grew over time from 2006 to 2014. Expenditures for immunomodulators and immune serums were all accounted for under the medical benefit. The top products driving expenditures for immunomodulators and immune serums were immune globulins. The PMPY for the top 10 immunomodulators and immune serums ranged from \$0.01 to \$6.17, with a total of \$16.75 for the top 10 in 2014, Table 4.33.

**Table 4.33 PMPY and Total Expenditures for Top 10 Immunomodulators & Immune Serums under the Medical Benefit: 2014**

<b>Immunomodulators/Immune Serums under the Medical Benefit</b>	<b>2014 PMPY</b>	<b>2014 Expenditures</b>
INJ IG GAMMAGARD LIQ IV NONLYOPHILIZED 500 MG	\$6.17	\$239,258.17
INJ IMMUNE GLOBULIN IV NONLYOPHILIZED 500 MG	\$3.26	\$126,342.47
INJECTION IMMUNE GLOBULIN HIZENTRA 100 MG	\$3.13	\$121,192.64
INJ IG IV LYPHILIZED NOT OTHERWISE SPEC 500 MG	\$1.90	\$73,617.72
INJECTION IMMUNE GLOBULIN NONLYOPHILIZED 500 MG	\$1.35	\$52,485.06
RABIES IMMUNE GLOBULINRIG HUMAN IM/SUBQ	\$0.45	\$17,512.34
INJECTION RHO D IG HUMAN FULL DOSE 300 MCG	\$0.25	\$9,669.95
RHO(D) IMMUNE GLOBULIN HUMAN FULL-DOSE IM	\$0.11	\$4,260.07
RABIES IG HEAT-TREATED HUMAN IM/SUBQ	\$0.11	\$4,213.78
TETANUS IMMUNE GLOBULIN,HUMAN,UP TO 250 UNITS	\$0.01	\$508.09
<b>Total Immunomodulators/Immune Serums under the Medical Benefit</b>	<b>\$16.75</b>	<b>\$649,060.29</b>

#### **4.4 Aim three results**

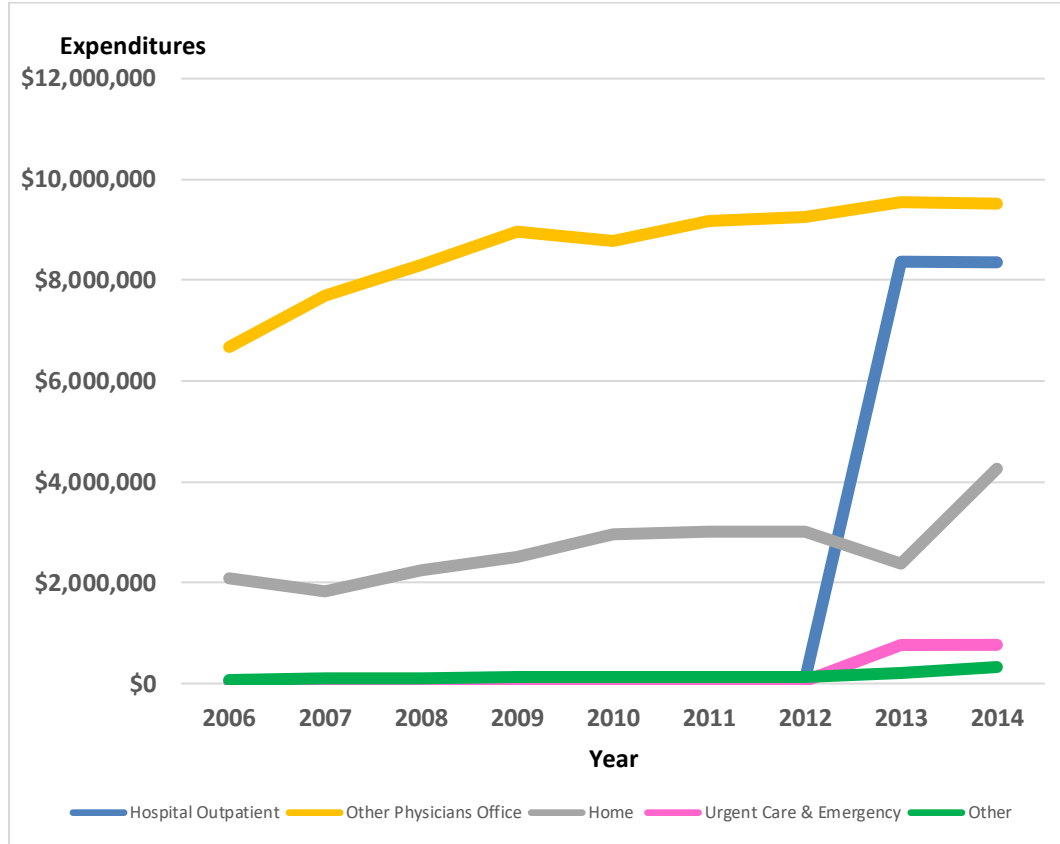
Identify and assess the utilization and expenditures by channels of distribution of specialty drugs and drug-related products that flow through the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

##### **4.4.1 Question 3a results**

What are total expenditures by year for specialty drug and drug-related products utilized in outpatient hospital, physician's office, home infusion, and all other sites of care identified in UPlan medical claims data?

Claims and expenditures from the physician's office accounted for the majority of total medical, medical specialty, medical traditional claims expenditures, as shown in Figure 4.73, Figure 4.74 and Figure 4.75. During the study period from 2006 to 2014, the physician's office accounted for medical specialty expenditures ranging from a low of \$4.5 million in 2006 to a high of \$5.38 million in 2013. From 2006 to 2014 claims for medical specialty drugs accounted for by the physician's office ranged from a low of \$1,739 in 2012 to a high of \$3,558 in 2008.

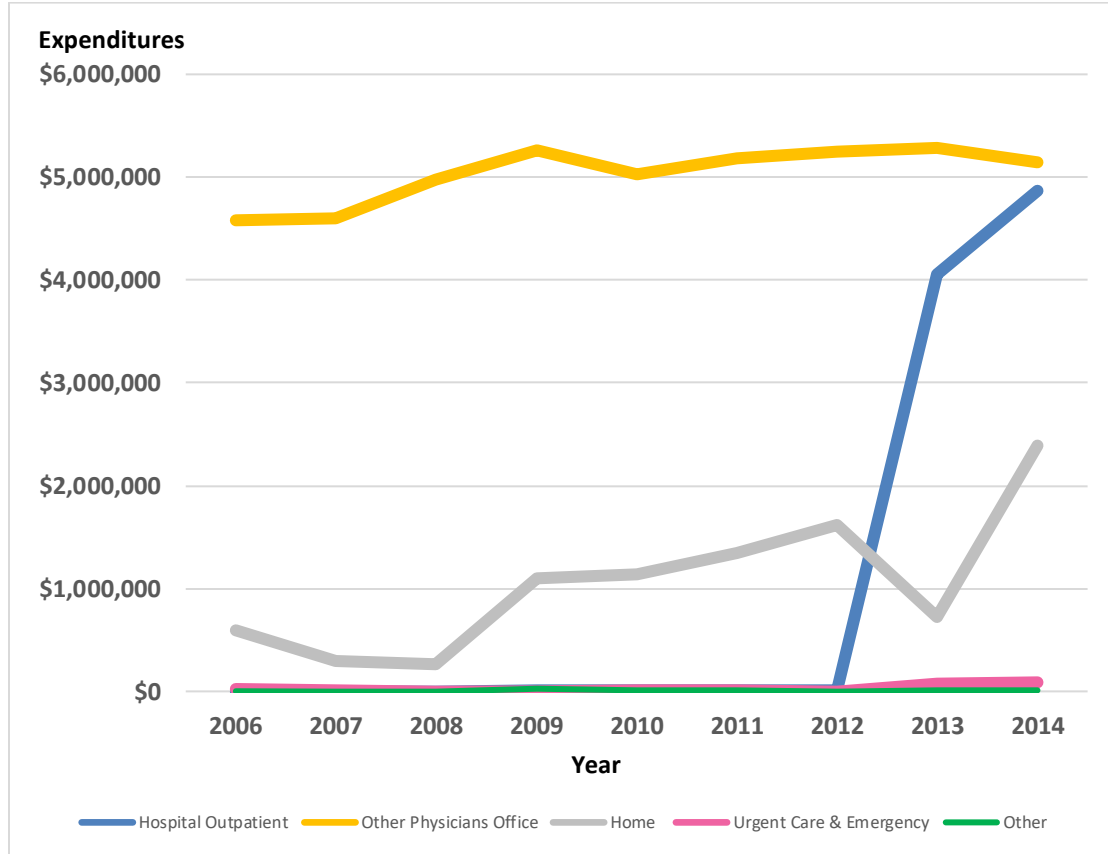
**Figure 4.73: Total Drug Expenditures by Place of Service under Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

Physician's offices accounted for a greater share of the total medical (specialty medical and traditional medical) drug and drug-related expenditures than other sites of service from 2006 to 2014. The exception was 2013 for traditional drug and drug-related expenditures, where expenditures for hospital outpatient accounted for a greater share of total medical expenditures.

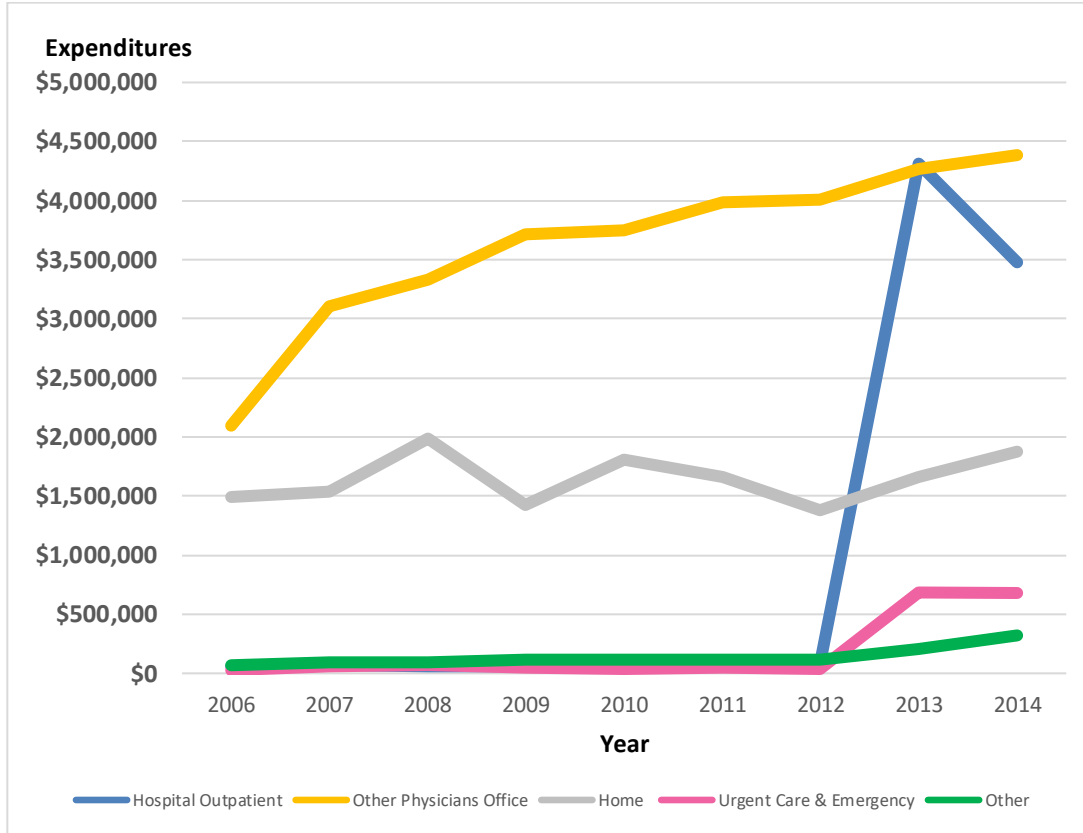
**Figure 4.74: Total Specialty Expenditures by Place of Service under the Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.



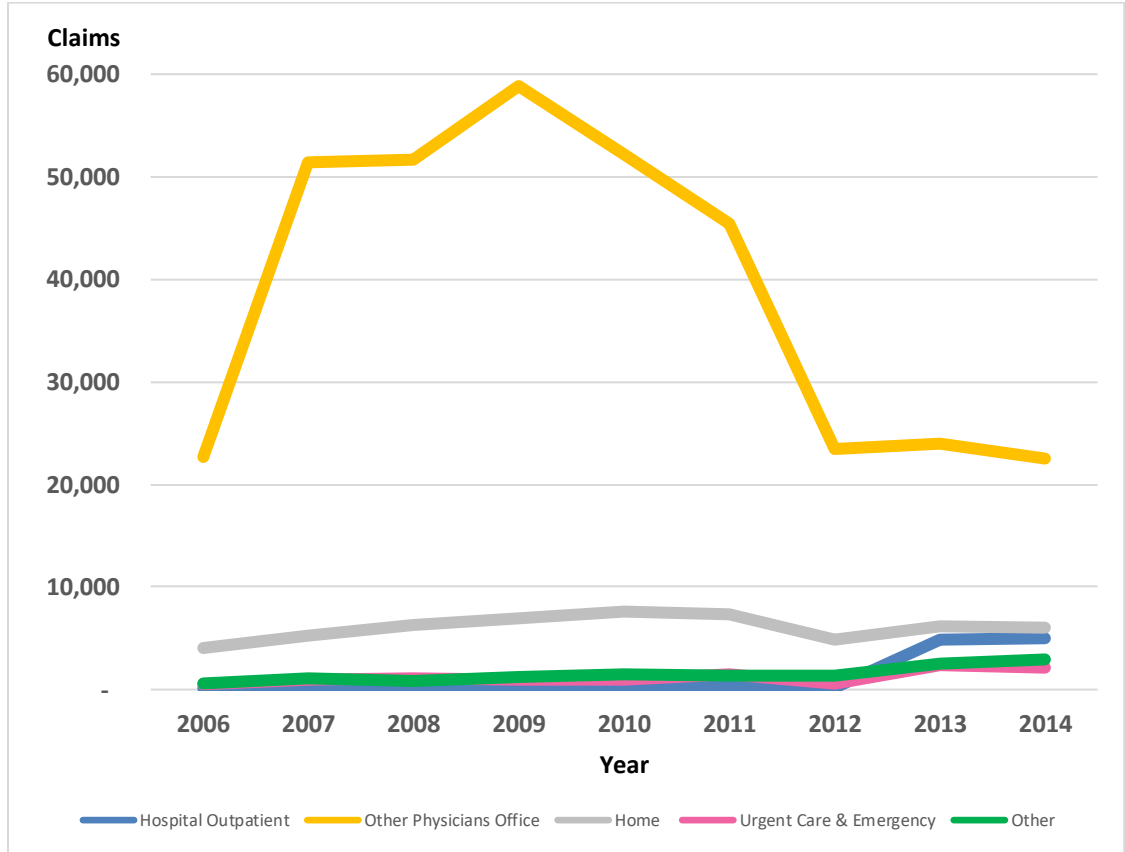
**Figure 4.75: Traditional Expenditures by Place of Service under the Medical Benefit: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

As shown in Figure 4.76 total medical drug and drug-related claims accounted for by hospital outpatient, urgent care, emergency, and other settings remained low, around 5,000 claims or less from 2006 to 2014. Total medical claims accounted for by home were slightly higher ranging from a low of 4,050 in 2006 to a high of 7,602 in 2010 during the study period of 2006 to 2014. Total medical claims were predominantly accounted for by claims flowing out of a physician’s office, ranging from a low of 22,520 in 2014 to a high of 58,840 in 2009 during the study period from 2006 to 2014. Over time the number of total medical claims accounted for by a physician’s office went down from 2010 to 2014, as can be observed in Figure 4.76 and Table 4.34.

**Figure 4.76: Total Claims by Place of Service under Medical Benefit: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

**Table 4.34 Number of Total Medical Claims Accounted for by Site of Care**

Site of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	136	240	237	242	343	320	217	4,905	5,002
Other Physician's Office	22,716	51,365	51,698	58,840	52,189	45,437	23,501	23,934	22,520
Home	4,050	5,268	6,248	6,884	7,602	7,326	4,817	6,166	6,084
Other	1,113	2,035	1,923	2,174	2,471	2,809	1,923	4,865	5,052

\*Total claims include total drug and drug-related claims under the medical benefit.

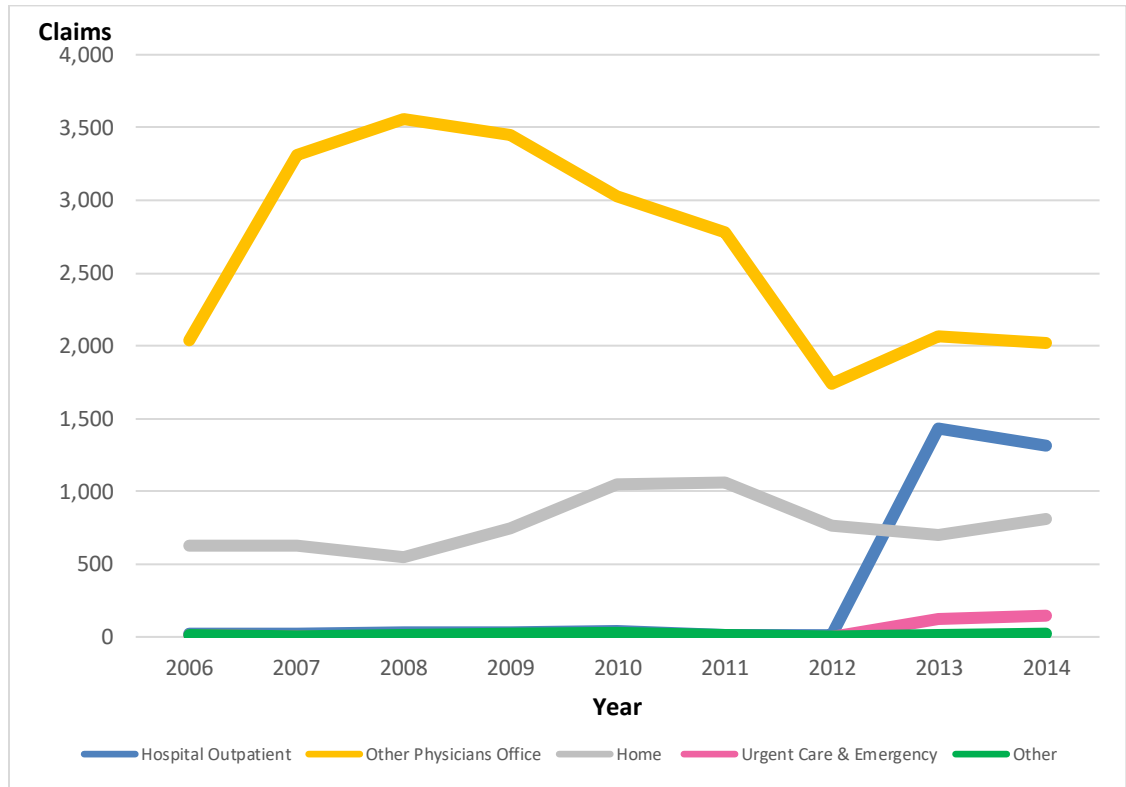
**Table 4.35 Percent of Total Medical Claims Accounted for by Site of Care**

Site of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	0.49%	0.41%	0.39%	0.36%	0.55%	0.57%	0.71%	12.30%	12.94%
Other Physician's Office	81.09%	87.20%	86.01%	86.35%	83.36%	81.29%	77.16%	60.03%	58.25%
Home	14.46%	8.94%	10.39%	10.10%	12.14%	13.11%	15.82%	15.47%	15.74%
Other	3.97%	3.45%	3.20%	3.19%	3.95%	5.03 %	6.31%	12.20%	13.07%

\*Total claims include total drug and drug-related claims under the medical benefit.

As observed in Figure 4.77, medical specialty drug and drug-related claims accounted for by home, hospital outpatient, urgent care and emergency, and other remained low, below 1,500 claims from 2006 to 2014. Medical specialty claims accounted for by hospital outpatient remained below 0.5 percent of total medical specialty claims from 2006 to 2012. However, in 2013 and 2014, there was a significant jump in the total number of medical specialty claims from the hospital outpatient setting, accounting for 33 percent of specialty medical claims in 2013, and 30 percent of the specialty medical claims in 2014, as noted in Table 4.36. The majority of the claims for medical specialty drug and drug-related products were coming from the physician's office, with 75 percent of medical specialty claims in 2006 and dropping to 46 percent in 2014. Medical specialty claims accounted for by physician's offices grew from 2006 to 2008 and have gone down from 2009 to 2014, as noted in Table 4.36.

**Figure 4.77: Specialty Claims by Place of Service under the Medical Benefit: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

**Table 4.36 Number of Total Medical Specialty Claims Accounted by Site of Care\***

Site of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	26	20	28	28	43	17	12	1432	1316
Other Physician's Office	2041	3314	3558	3450	3024	2783	1739	2062	2016
Home	627	624	548	750	1045	1061	766	696	814
Urgent Care & Emergency	11	1	3	1	6	5	0	123	146
Other	11	8	13	24	28	14	3	14	24

\*Total claims include total drug and drug-related claims under the medical benefit.

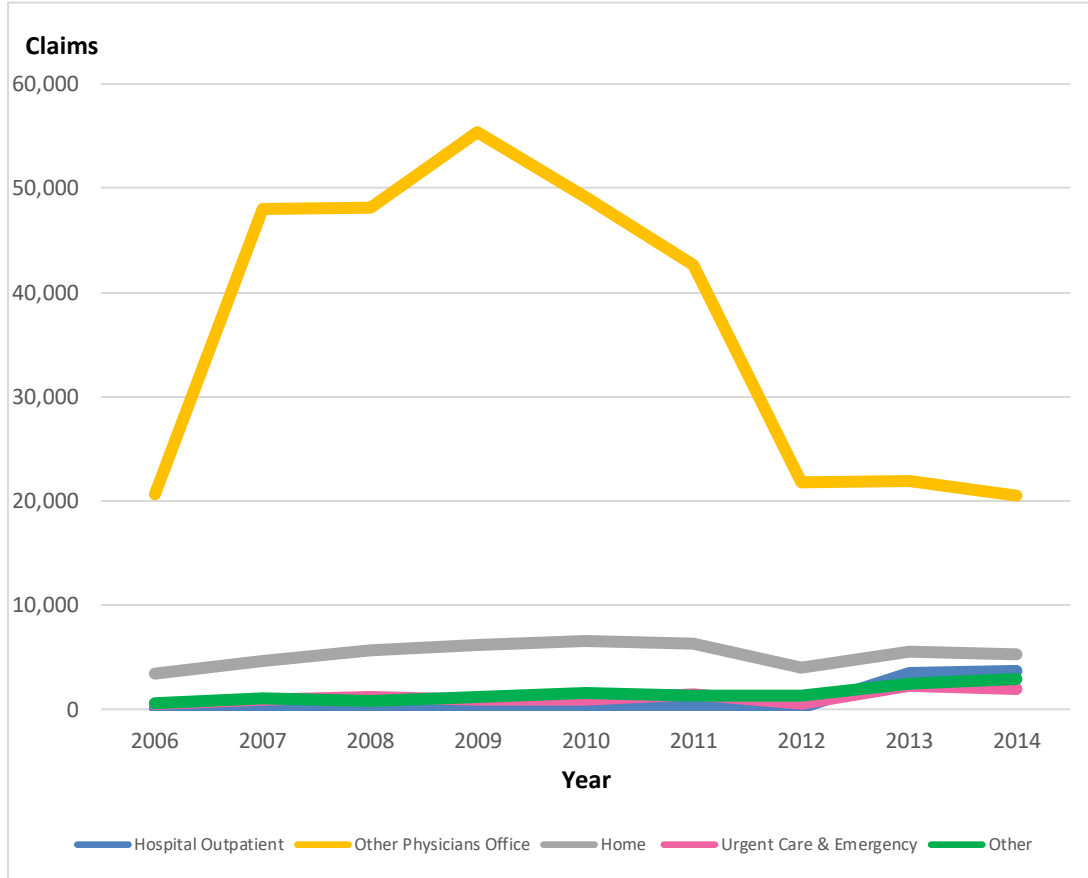
**Table 4.37 Percent of Total Medical Specialty Claims Accounted for by Each Site of Care\***

Site of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	0.96%	0.50%	0.67%	0.66%	1.04%	0.44%	0.48%	33.09%	30.49%
Other Physician's Office	75.15%	83.54%	85.73%	81.12%	72.94%	71.73%	69.01%	47.65%	46.71%
Home	23.09%	15.73%	13.20%	17.63%	25.21%	27.35%	30.40%	16.09%	18.86%
Urgent Care & Emergency	0.41%	0.03%	0.07%	0.02%	0.14%	0.13%	0.00%	2.84%	3.38%
Other	0.41%	0.20%	0.31%	0.56%	0.68%	0.36%	0.12%	0.32%	0.56%

\*Total claims include total drug and drug-related claims under the medical benefit.

As observed in Figure 4.78, medical traditional drug and drug-related claims accounted for by hospital outpatient, urgent care, and emergency, and other remained low, below 4,000 in claims from 2006 to 2014. Medical traditional claims accounted for by home were slightly higher, ranging from a low of 3,423 in 2006 to a high of 6,557 in 2010 during the study period of 2006 to 2014. Medical traditional claims were predominantly accounted for by claims flowing out of physician's offices, ranging from a low of 20,675 in 2006 to a high of 55,390 in 2010 during the study period from 2006 to 2014. Over time the number of medical traditional claims accounted for by physician's offices went down.

**Figure 4.78 Traditional Claims by Place of Service under Medical Benefit: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit

**Table 4.38 Number of Total Medical Traditional Claims Accounted by Site of Care\***

Sire of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	110	220	209	214	300	303	205	3473	3686
Other Physician's Office	20,675	48,051	48,140	55,390	49,165	42,654	21,762	21,872	20,504
Home	3423	4644	5700	6134	6557	6265	4051	5470	5270
Urgent Care & Emergency	507	969	1150	982	928	1440	596	2257	1972
Other	584	1057	757	1167	1509	1350	1324	2471	2910

\*Total claims include total drug and drug-related claims under the medical benefit.

**Table 4.39 Percentage of Total Medical Traditional Claims Accounted for by Each Site of Care\***

Sire of Care	2006	2007	2008	2009	2010	2011	2012	2013	2014
Hospital Outpatient	0.43%	0.40%	0.37%	0.33%	0.51%	0.58%	0.73%	9.77%	10.73%
Other Physician's Office	81.72%	87.46%	86.03%	86.70%	84.10%	82.01%	77.89%	61.54%	59.71%
Home	13.53%	8.45%	10.19%	9.60%	11.22%	12.05%	14.50%	15.39%	15.35%
Urgent Care & Emergency	2.00%	1.76%	2.06%	1.54%	1.59%	2.77%	2.13%	6.35%	5.74%
Other	2.31%	1.92%	1.35%	1.83%	2.58%	2.60%	4.74%	6.95%	8.47%

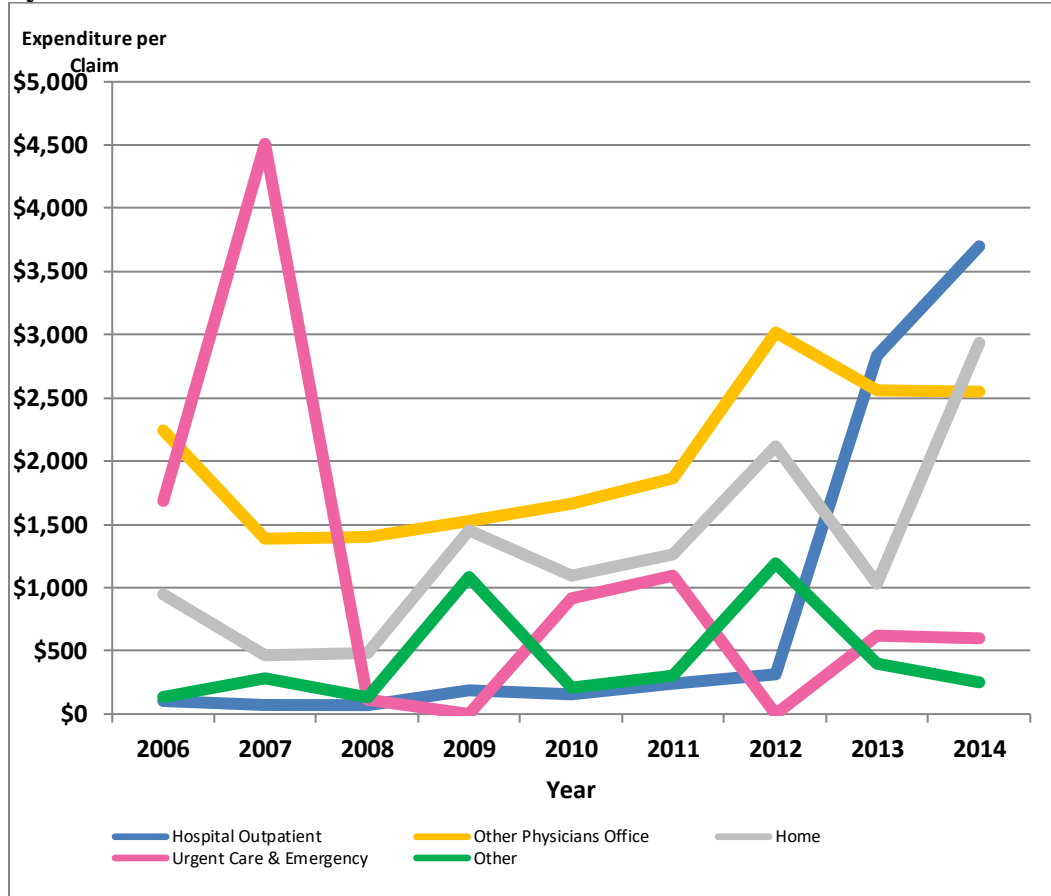
\*Total claims include total drug and drug-related claims under the medical benefit.

#### 4.4.2 Question 3b results

What channel of distribution has the highest year to year growth in expenditures for specialty drug and drug-related products utilized under the medical benefit from 2006 to 2014?

The average cost per specialty claim fluctuated over the study period from 2006 to 2014 for every site of care, as noted on Figure 4.79. Hospital outpatient has a consistently low average cost per claim from 2006 to 2012, ranging from a low of \$70 in 2007 to \$316 in 2012. However, in 2013 we see a significant jump of 796 percent from 2012 in the average cost per claim for drugs flowing through hospital outpatient at \$2,832 and going up again in 2014 to \$3,699. From 2006 to 2014 the average cost per claim for claims flowing through hospital outpatient increased by 3,477 percent, as noted in Figure 4.81.

**Figure 4.79: Average Expenditure per Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014\***

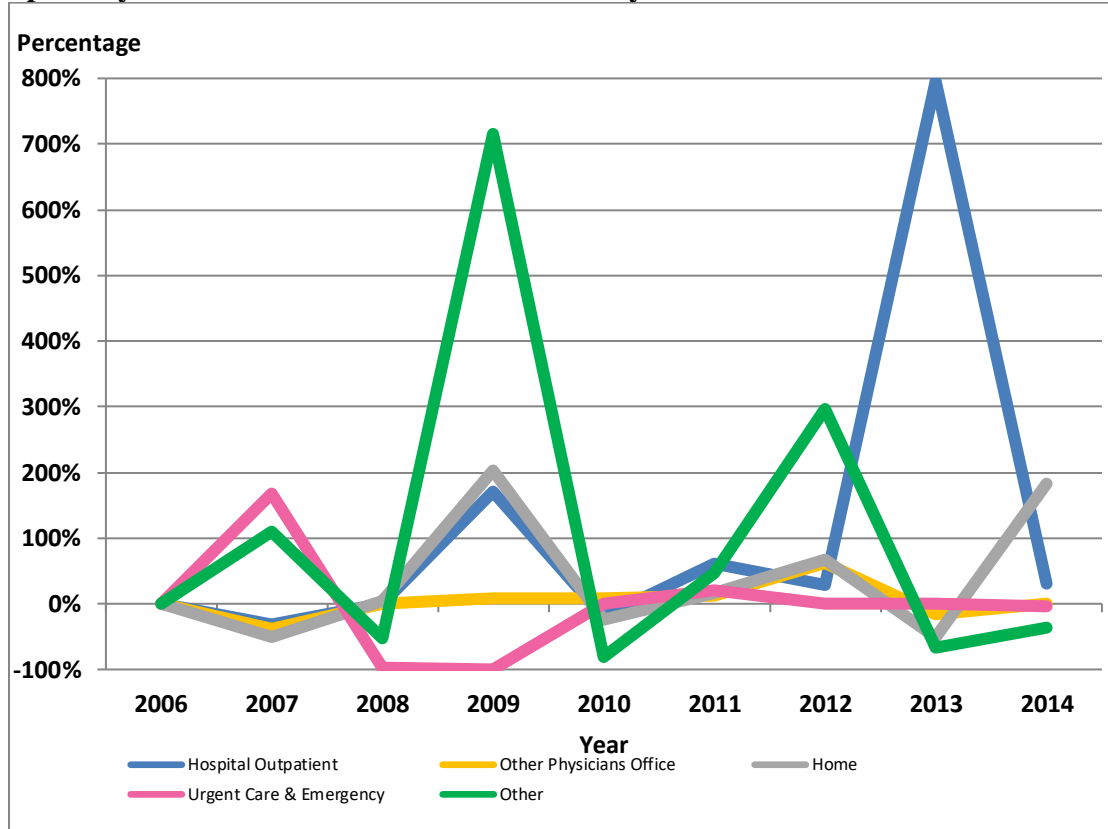


\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

The year-to-year percentage change for the average expenditure per specialty claim remains low and consistent for claims flowing out of the physician’s office, urgent care and emergency, and home. There were fluctuations noted for the percentage change of average expenditure per specialty claim for hospital outpatient and other sites of care, as noted in Figure 4.80.



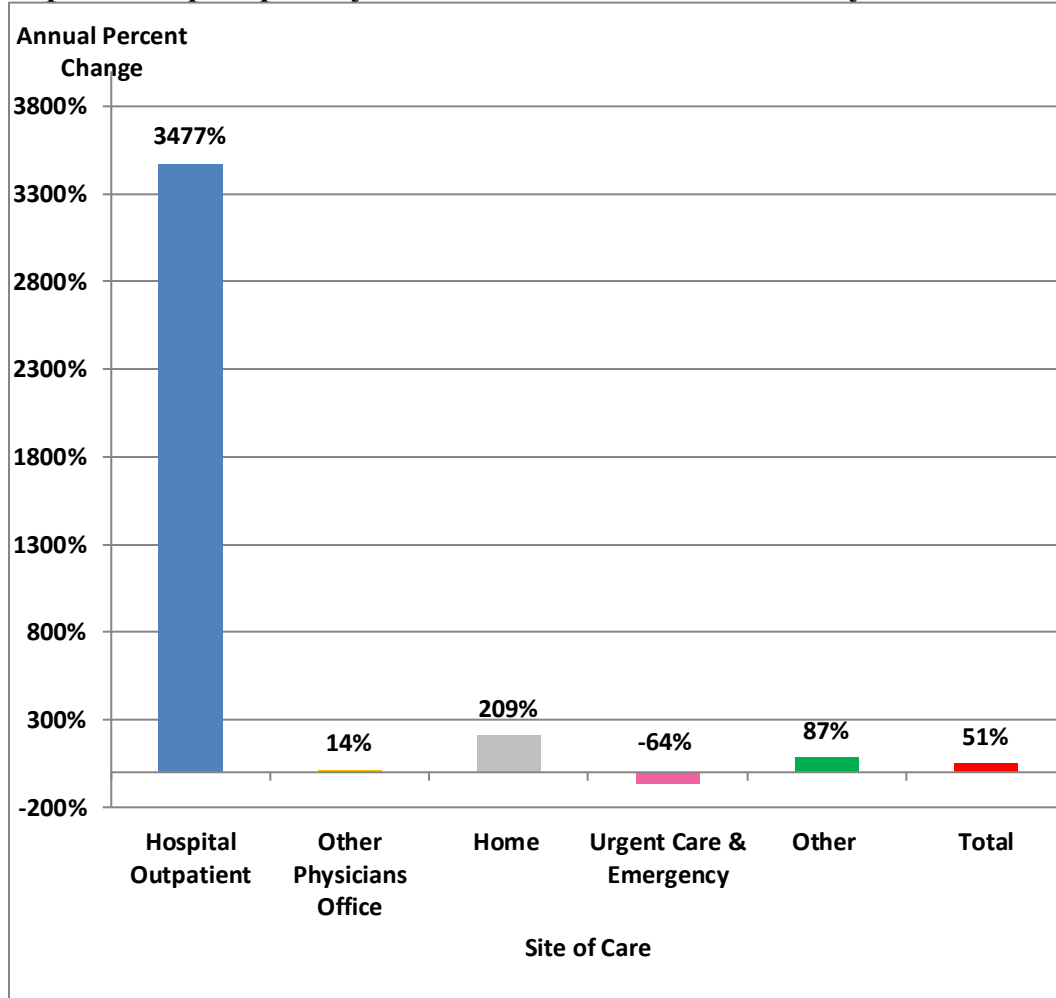
**Figure 4.80: Percent Change from Year to Year in Average Expenditure per Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

During the study period, hospital outpatient had the largest percent increase in the average expenditure per specialty claim from 2006 to 2014, at 3,477 percent. Home had the next largest percentage increase at 209 percent from 2006 to 2014. Physician’s office had a much lower percentage increase for average expenditures per specialty claim at 14 percent from 2006 to 2014, as shown in Figure 4.81.

**Figure 4.81: Overall Percentage Change from 2006 to 2014 in Average Expenditure per Specialty Claim under the Medical Benefit by Site of Care\***



\*Total claims include total drug and drug-related claims under the medical benefit.

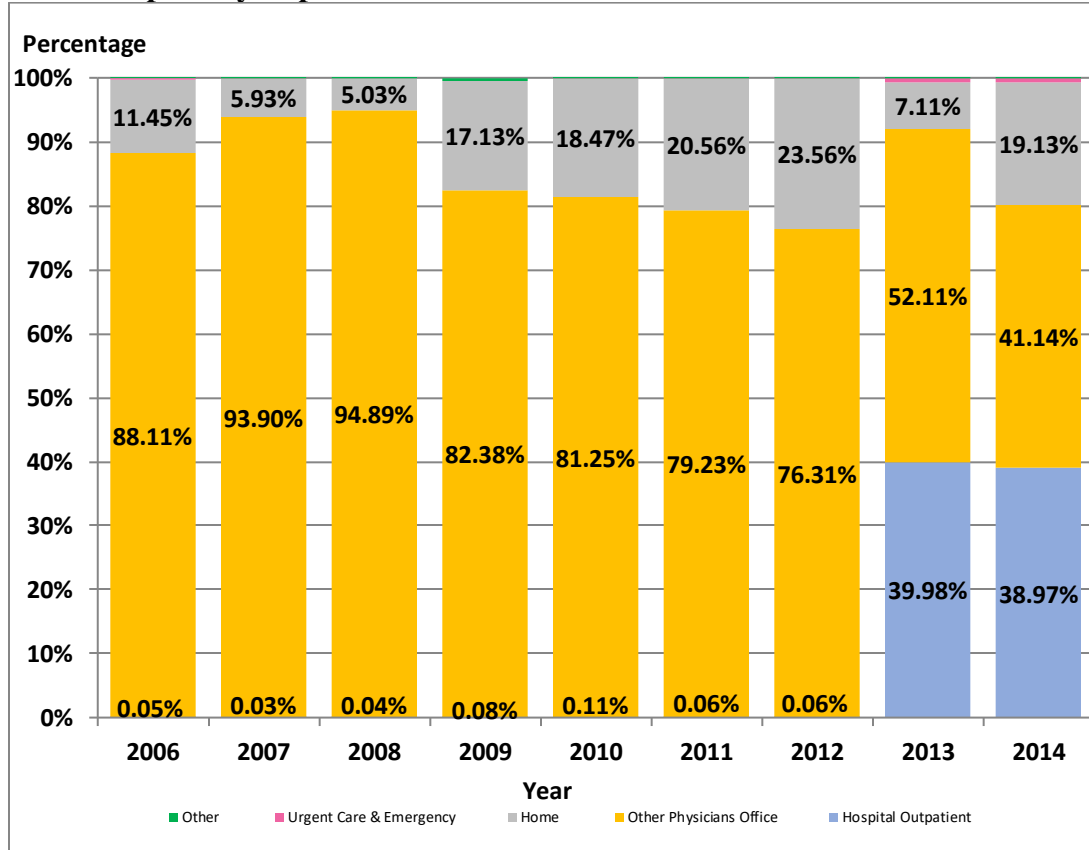
From 2006 to 2014 the greatest number of specialty claims and the greatest amount of specialty expenditures under the medical benefit were accounted for by drugs and drug-related products flowing through the physician's office, as shown in Figure 4.82 and Figure 4.83. Over time, however, the amount of claims and expenditures accounted for by drugs and drug-related products flowing through the physician's office went down. In 2006, 88 percent of total medical specialty drug and drug-related expenditures were accounted for by physician's office, and in 2014 it went down to 41 percent. A similar trend was observed for the flow of claims. In 2006, 75 percent of medical specialty drug and drug-related claims were flowing through the physician's office, and in 2014 this also went down, to 46 percent.

The trend observed for hospital outpatient settings is different than the trend observed for physician's offices. From 2006 to 2012 total medical specialty expenditures accounted for by drug and drug-related products flowing through hospital outpatient were less than 1 percent. Similarly, the total medical specialty claims accounted for by drug and drug-related products flowing through hospital outpatient was less than or equal to 1 percent. However, there was a significant jump in both claims and expenditures for hospital outpatient in 2013, followed by less than a 3 percent increase in both claims and expenditures in 2014, as observed in Figure 4.82 and Figure 4.83. In 2006, 0.5 percent of total medical specialty drug and drug-related expenditures were accounted for by hospital outpatient, and in 2014 it went up to 39 percent, a 72,383 percent increase. A similar trend was observed for the flow of claims. In 2006, 0.96 percent of medical specialty drug and drug-related claims were flowing through the physician's office, and in 2014 this also went up to 30 percent, a 6,849 percent increase.

From 2006 to 2014 medical specialty expenditures accounted for through the home site of care fluctuated between a low of 5 percent in 2008 to a high of 23 percent in 2013, as presented in Figure 4.82. The overall fluctuation of medical claims accounted for by the home site of care was similar to the fluctuation seen for the home site percent for expenditures. From 2006 to 2014 medical specialty claims accounted for by the home site of care fluctuated between a low of 13 percent in 2008 to a high of 30 percent in 2012, as noted in Figure 4.83.

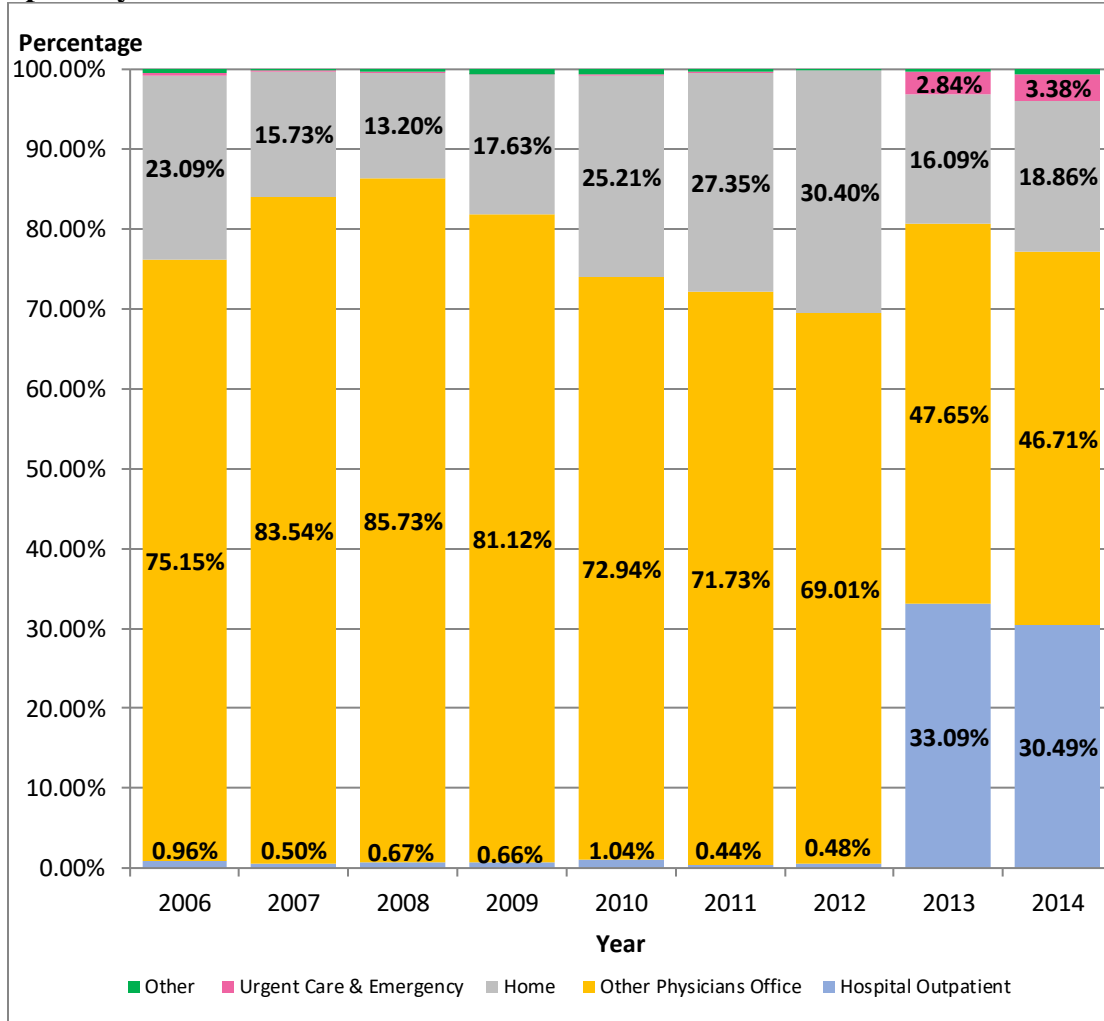
Both medical specialty claims and expenditures accounted for by Urgent Care & Emergency and other sites of care stayed consistently below 4 percent during the study period of 2006 to 2014.

**Figure 4.82: Specialty Medical Expenditures by Site of Care as a Percent of Total Medical Specialty Expenditures\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

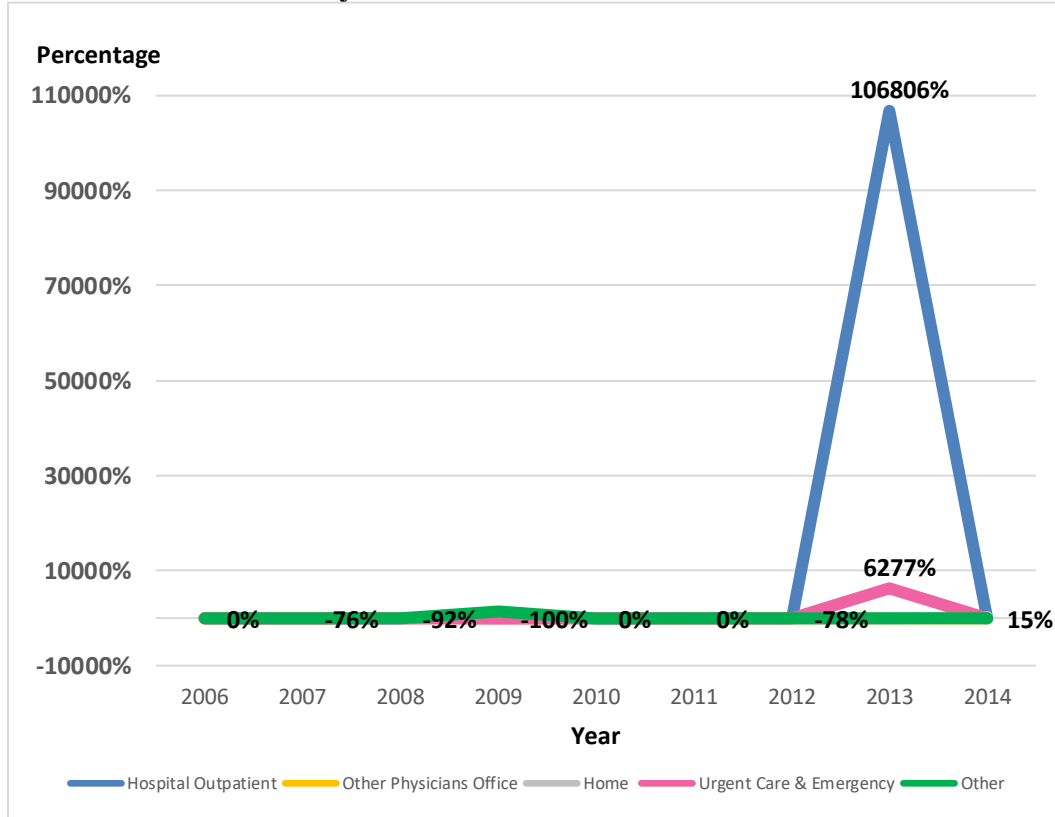
**Figure 4.83: Specialty Medical Claims by Site of Care as a Percent of Total Medical Specialty Claims\***



\*Total claims include total drug and drug-related claims under the medical benefit.

Figure 4.84 and Table 4.40 show that compared with growth observed in all sites of care, hospital outpatient expenditures had a significant outlier trend in 2013 at a growth of 106,806 percent from 2012. Similarly, but at a lower magnitude, urgent care and emergency had a growth in expenditures of 6,277 percent from 2012 to 2013. From 2008 to 2009 other sites of care had a growth of 1,406 percent, the third-highest percent increase in specialty expenditures by site of care.

**Figure 4.84: Percent Year to Year Change in Expenditures for Specialty Drugs under Medical Benefit by Site of Care: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

**Table 4.40: Percent Change in Average Specialty Expenditure by Site of Care under Medical Benefit: 2006 to 2014\***

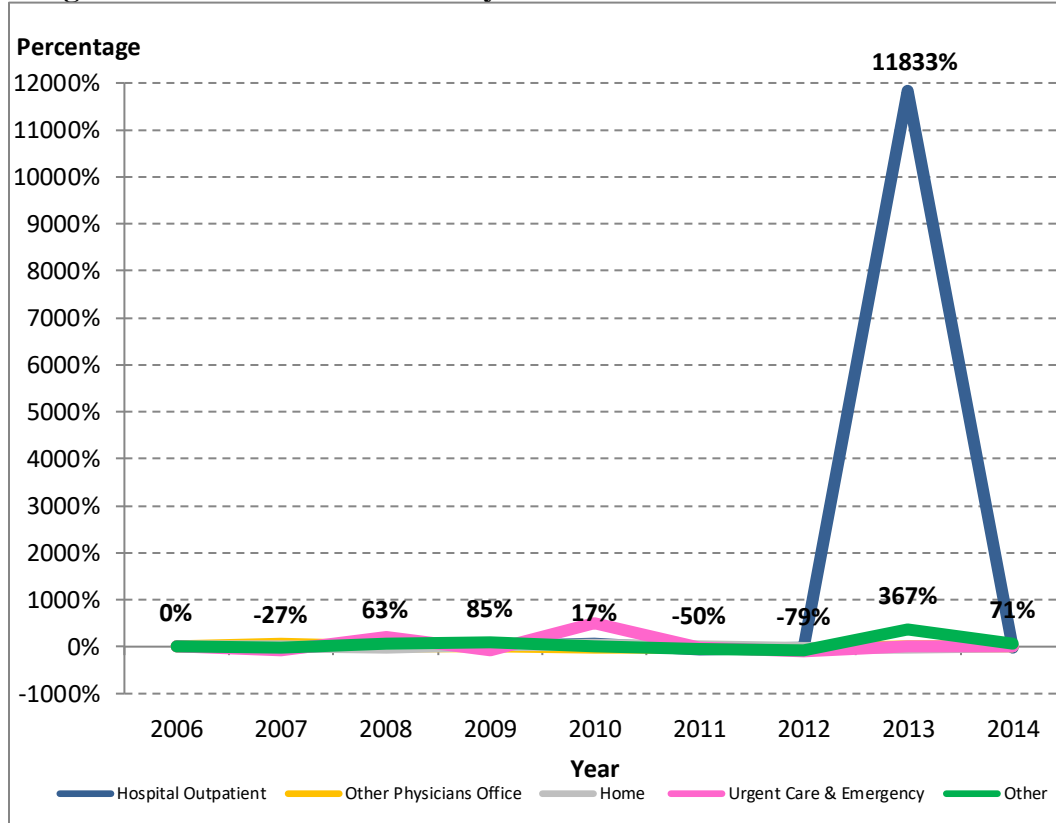
Year	Hospital Outpatient	Other Physicians Office	Home	Urgent Care & Emergency	Other
2006					
2007	-47%	0%	-51%	-76%	52%
2008	40%	8%	-9%	-92%	-24%
2009	170%	6%	315%	-100%	1406%
2010	23%	-4%	5%	0%	-78%
2011	-37%	3%	18%	0%	-27%
2012	-9%	1%	21%	-78%	-15%
2013	106,806%	1%	-56%	6,277%	55%
2014	20%	-3%	232%	15%	10%

\*Total expenditures include total drug and drug-related expenditures under the medical benefit.

As observed with the year-to-year change in expenditures we see a similar trend for the number of claims in the hospital outpatient setting on a year-to-year basis, as shown in Figure 4.85 and Table 4.40. From 2012 to 2013 there was an 11,833 percent growth in the number of claims flowing through the hospital outpatient setting. From 2012 to 2013 growth was noted for physician’s offices, and other sites of care, while no growth was noted for urgent care and emergency settings. A reduction of claims in the home care setting from 2012 to 2013 was noted. From 2013 to 2014 the number of claims went down by 8 percent for hospital outpatient, while physician’s office claims went down by 2 percent. For all other sites, growth was noted from 2013 to 2014.



**Figure 4.85: Percent Year to Year Change in Number of Claims for Specialty Drugs under the Medical Benefit by Site of Care: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

**Table 4.41: Percent Change in Number of Specialty Claims under the Medical Benefit by Site of Care: 2006 to 2014**

Year	Hospital Outpatient	Physician's Office	Home	Urgent Care & Emergency	Other
2006					
2007	-23%	62%	0%	-91%	-27%
2008	40%	7%	-12%	200%	63%
2009	0%	-3%	37%	-67%	85%
2010	54%	-12%	39%	500%	17%
2011	-60%	-8%	2%	-17%	-50%
2012	-29%	-38%	-28%	-100%	-79%
2013	11,833%	19%	-9%	0%	367%
2014	-8%	-2%	17%	19%	71%

\*Total claims include total drug and drug-related claims under the medical benefit.

#### **4.5 Aim four results**

Identify and assess utilization and expenditures of specialty drugs and drug-related products that are covered by both the pharmacy and the medical benefit from 2006 to 2014 for the University of Minnesota's UPlan.

##### **4.5.1 Question 4a results**

How many specialty drugs were distributed under both the pharmacy and the medical benefit each year?

A total of 35 drugs were found to be present as claims under both the pharmacy and the medical benefit. While some of these dual channel drugs were distributed somewhat equally across both the pharmacy and medical benefits, other drugs were either mainly under the pharmacy benefit or mainly under the medical benefit. Table 4.42 lists the dual channel drugs present under both the pharmacy and medical benefits.

#### **4.5.2 Question 4b results**

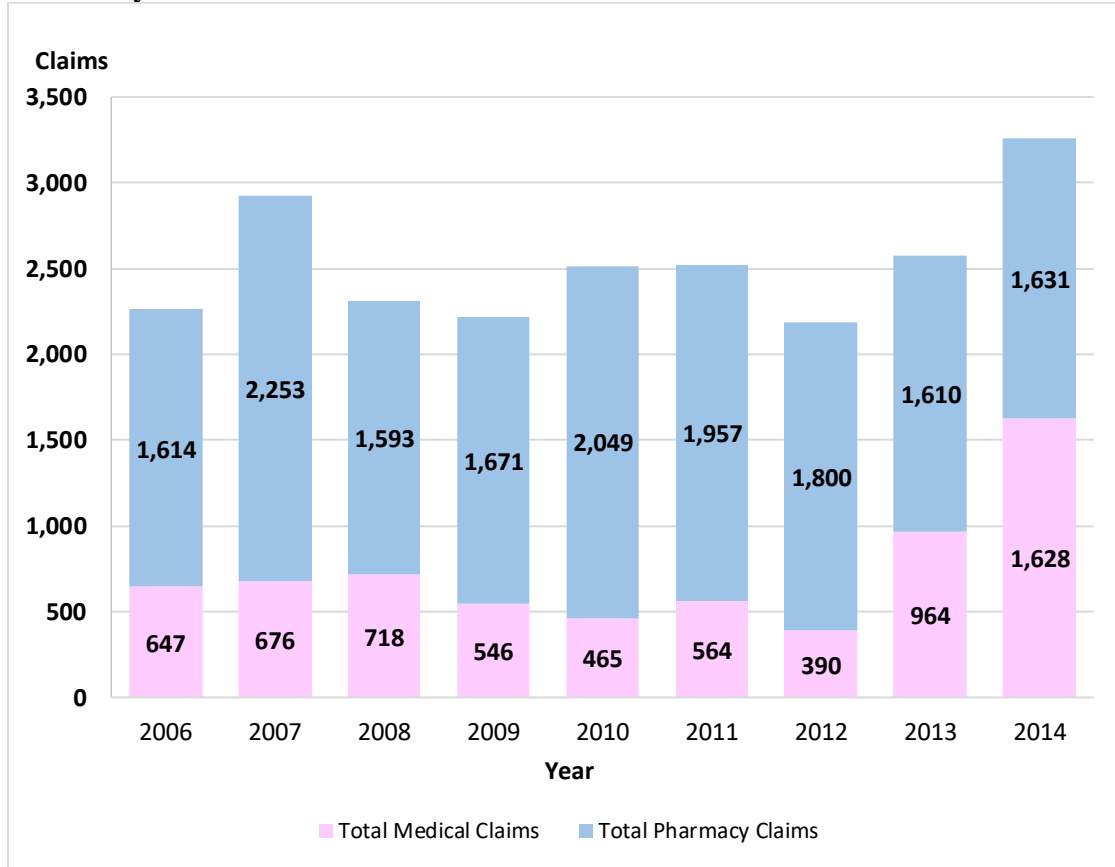
What specialty drugs are utilized under both the pharmacy and medical benefits?

Of the 35 drugs, 27 of the following drugs were present under both pharmacy and medical benefits across multiple years from 2006 to 2014. The dual channel drugs were: abatacept, aprepitant, chorionic gonadotropin, cyclophosphamide, cyclosporine, dalteparin, enoxaparin sodium, epoetin alfa, etoposide, filgrastim, fondaparinux sodium, histrelin acetate, infliximab, interferon alfa-2b, leucovorin calcium, leuprolide acetate, mesna, mycophenolate mofetil, naltrexone, octreotide acetate, omalizumab, pegfilgrastim, tacrolimus, tobramycin, urofollitropin, and ustekinumab. The remaining eight drugs present under both benefits were only present for one year in either the pharmacy or medical benefit.

**Table 4.42: Specialty Drugs Present under Both the Pharmacy Benefit and the Medical Benefit for the UPlan: 2006 to 2014**

Arimidex (anastrozole)
Arixtra (fondaparinux sodium)
Avonex and Rebif (Interferon Beta -1A)
Botulinum Toxin
Bravelle (urofollitropin)
Cellcept (mycophenolate mofetil)
Cytarabine
Cytosan (cyclophosphamide)
EMEND (aprepitant)
Epogen and Procrit (epoetin alfa)
Fragmin (dalteparin)
Intron (interferon alfa-2b)
leucovorin calcium
Lovenox (enoxaparin sodium)
Lupron Depot (leuprolide acetate)
Mesnex (mesna)
Neoral, Gengraf, and Sandimmune (cyclosporine)
Neulasta (pegfilgrastim)
Neupogen (filgrastim)
Novarel or Pregnyl (chorionic gonadotropin)
ORENCIA (abatacept)
Prograf (tacrolimus)
Prolia (denosumab)
Remicade (infliximab)
Sandostatin (octreotide acetate)
Stelara (ustekinumab)
Supprelin LA (histrelin acetate)
Temodar (temozolomide)
Tobi (tobramycin)
Toposar (etoposide)
Velcade (bortezomib)
Vivitrol (naltrexone)
Xeloda (capecitabine)
Xolair (omalizumab)
Zirgan (ganciclovir)

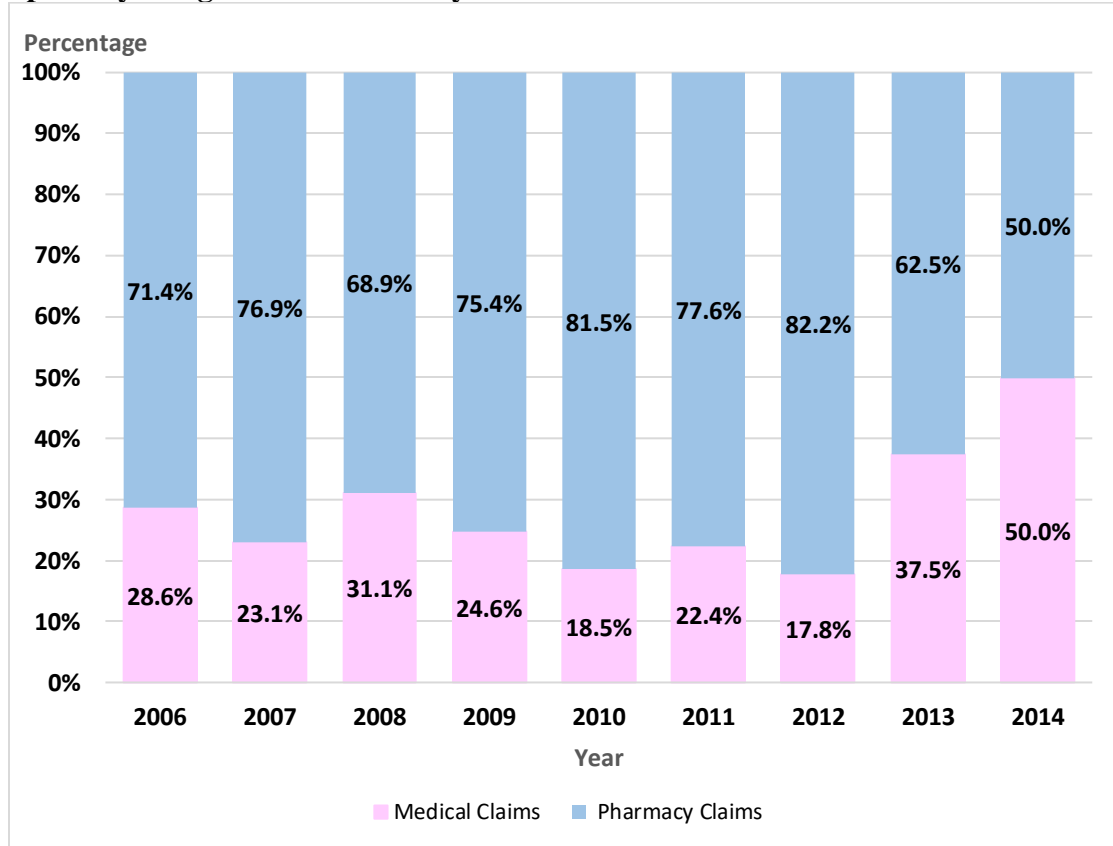
**Figure 4.86: Specialty Drug Claims for Specialty Drugs Found in Both the Pharmacy Benefit & the Medical Benefit: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical benefit.

Total claims for specialty drugs and drug-related products that were used across both pharmacy and medical benefits fluctuated from 2006 to 2014. Comparing 2006 to 2014 there is a visible growth in dual channel specialty drug claims flowing under the medical benefit especially in 2013 and 2014, as can be seen in Figure 4.86. However, the number of claims for dual channel specialty drugs under the pharmacy benefit, was relatively constant from 2006 compared 2014.

**Figure 4.87: Dual Channel Specialty Drug Claims as a Percent of Total Claims for Specialty Drugs across Pharmacy and Medical Benefits: 2006 to 2014\***



\*Total claims include total drug and drug-related claims under the medical and pharmacy benefits.

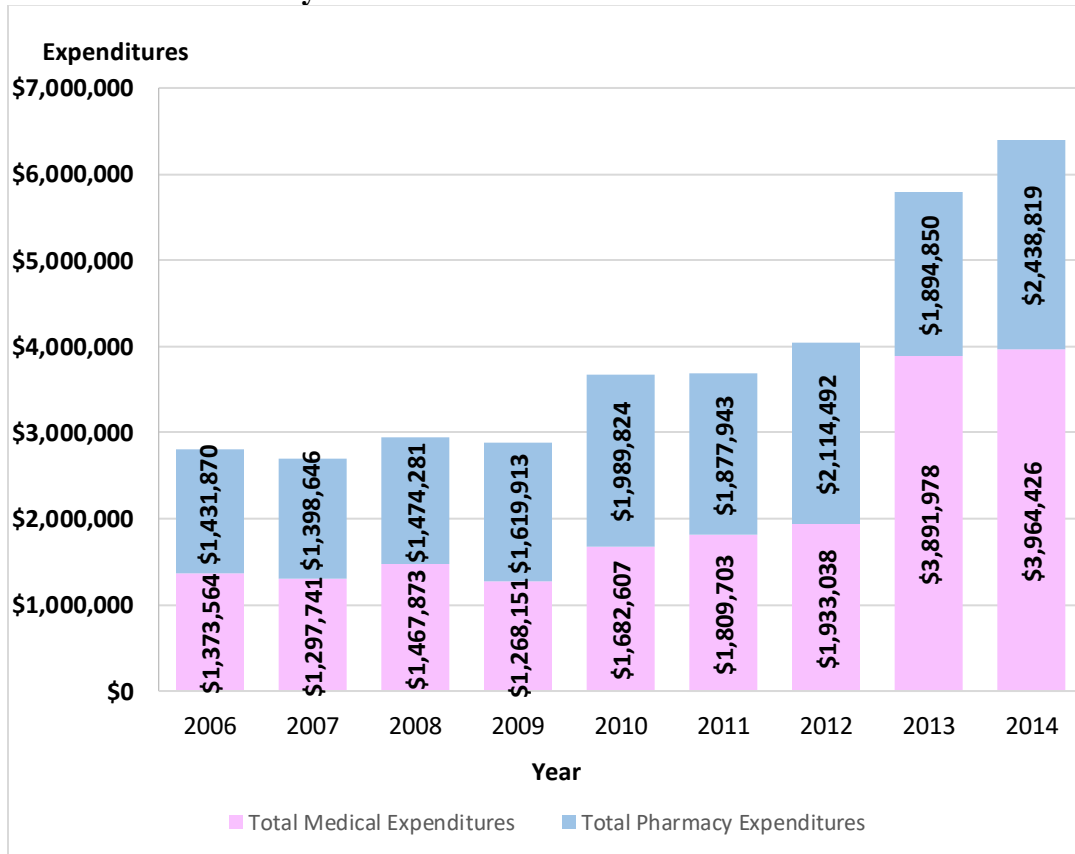
From 2006 to 2013 total claims under the pharmacy benefit accounted for a larger share of total claims for specialty drugs flowing under the pharmacy and medical benefits. As seen in figure 4.87 claims under the medical benefit accounted for 50% of total claims for specialty drugs flowing under the pharmacy and medical benefit in 2014.

#### 4.5.2 Question 4c results

What are the expenditures for specialty drugs and drug-related products that are used under both the pharmacy and medical benefits?

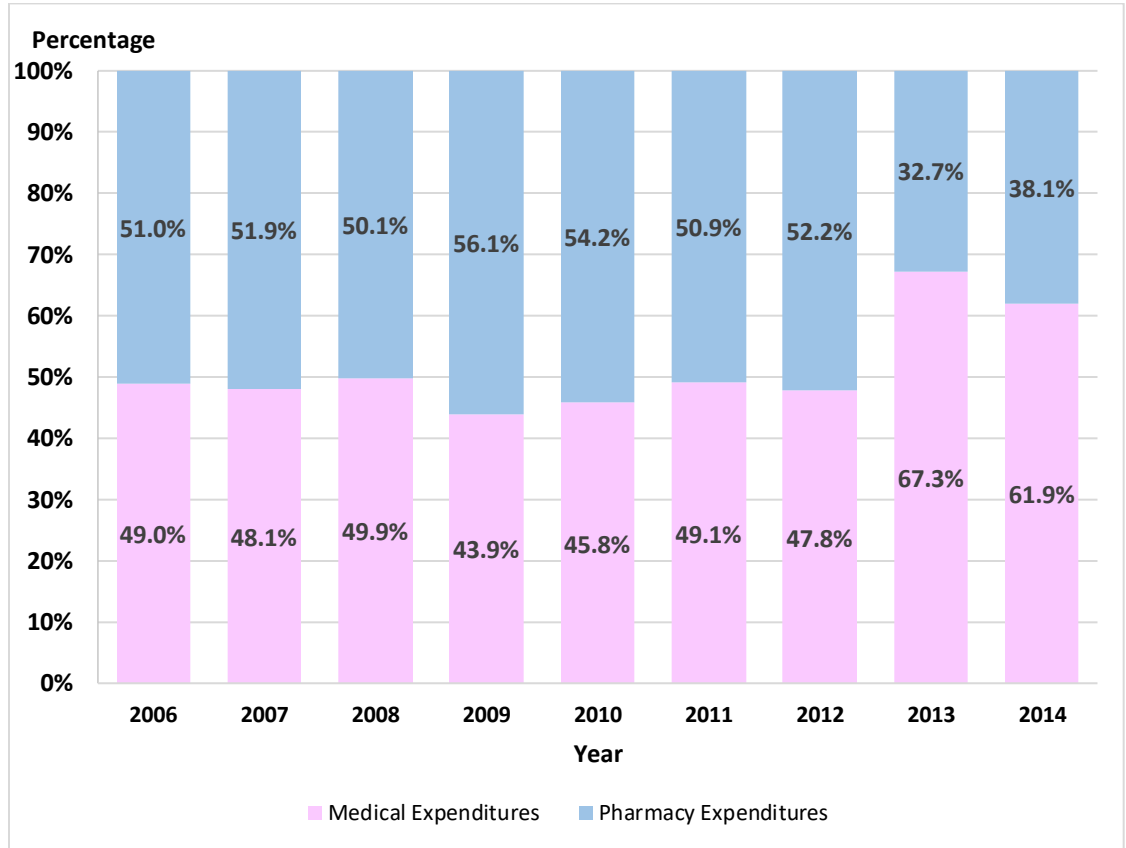
Total expenditures for specialty drugs and drug-related products that are used under both the pharmacy and medical benefits increased by 128 percent from 2006 to 2014. Dual channel drugs under the medical benefit had a greater expenditure growth than did expenditures under the pharmacy benefit from 2006 to 2014 with growth of 189 percent (\$2,590,861.92) for medical benefit claims vs. 70 percent (\$1,006,949.06) for pharmacy benefit claims.

**Figure 4.88: Expenditures for Dual Channel Specialty Products that were Used Under Both Pharmacy & Medical Benefits from 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical and pharmacy benefits.

**Figure 4.89: Dual Channel Specialty Drug Expenditures under Pharmacy and Medical Benefits as a Percent of Total Expenditures across Pharmacy and Medical Benefits from 2006 to 2014\***

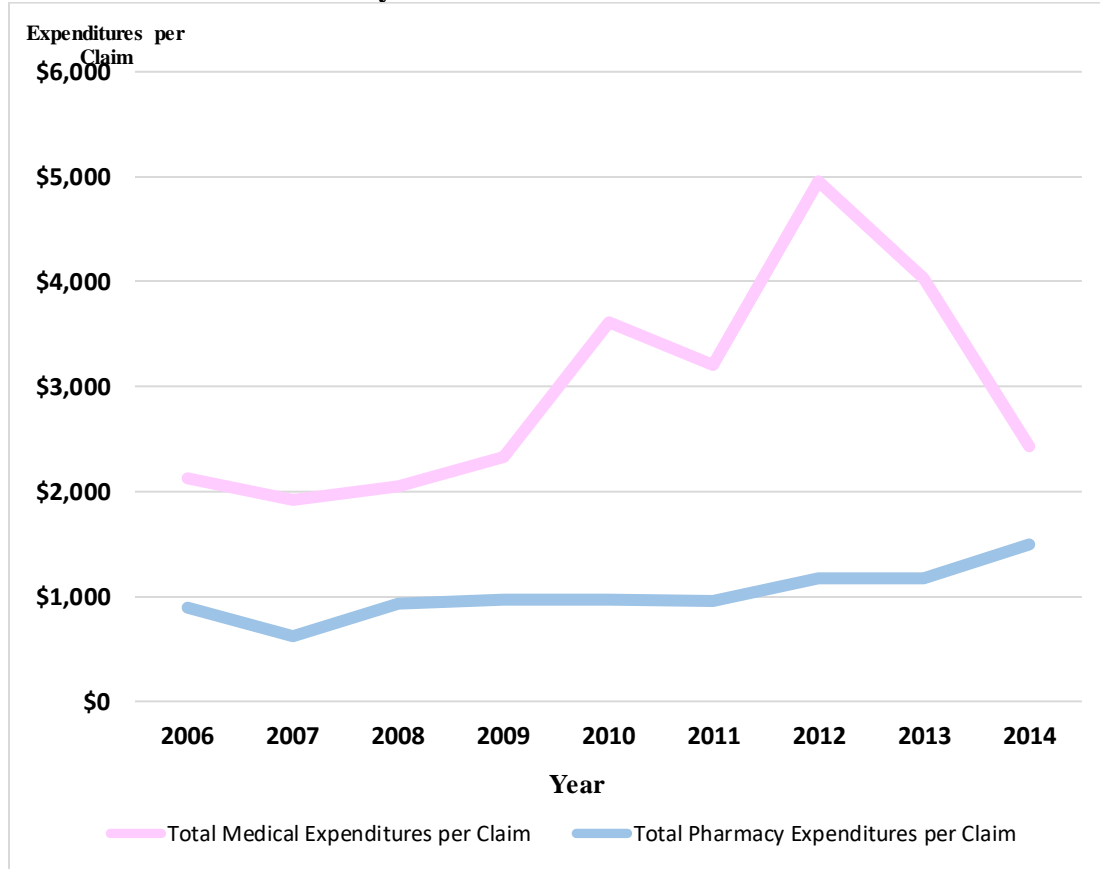


\*Total expenditures include total drug and drug-related expenditures under the medical and pharmacy benefits.

From 2006 to 2012 expenditures under the pharmacy benefit accounted for a larger share of total expenditures for dual channel specialty drugs than did the medical benefit. In 2013 and 2014, expenditures under the medical benefit accounted for a larger share of total expenditures for dual channel specialty drugs than did expenditures under the pharmacy benefit, as shown in Figure 4.89.



**Figure 4.90: Average Expenditures per Claim for Dual Channel Specialty Drugs Used Under Both Pharmacy & Medical Benefits: 2006 to 2014\***



\*Total expenditures include total drug and drug-related expenditures under the medical and pharmacy benefits.

From 2006 to 2014 the average expenditure per claim for dual channel specialty drugs used across both the pharmacy and medical benefits was higher under the medical benefit than under the pharmacy benefit. From 2006 to 2014 the average expenditure per claim under the medical benefit ranged from \$1,919.74 in 2007 to \$4,956.51 reaching the highest point in 2012. As observed in Figure 4.90 overall the average expenditure per claim under the medical benefit fluctuated, while it remained relatively steady with slow growth under the pharmacy benefit from 2006 to 2014.

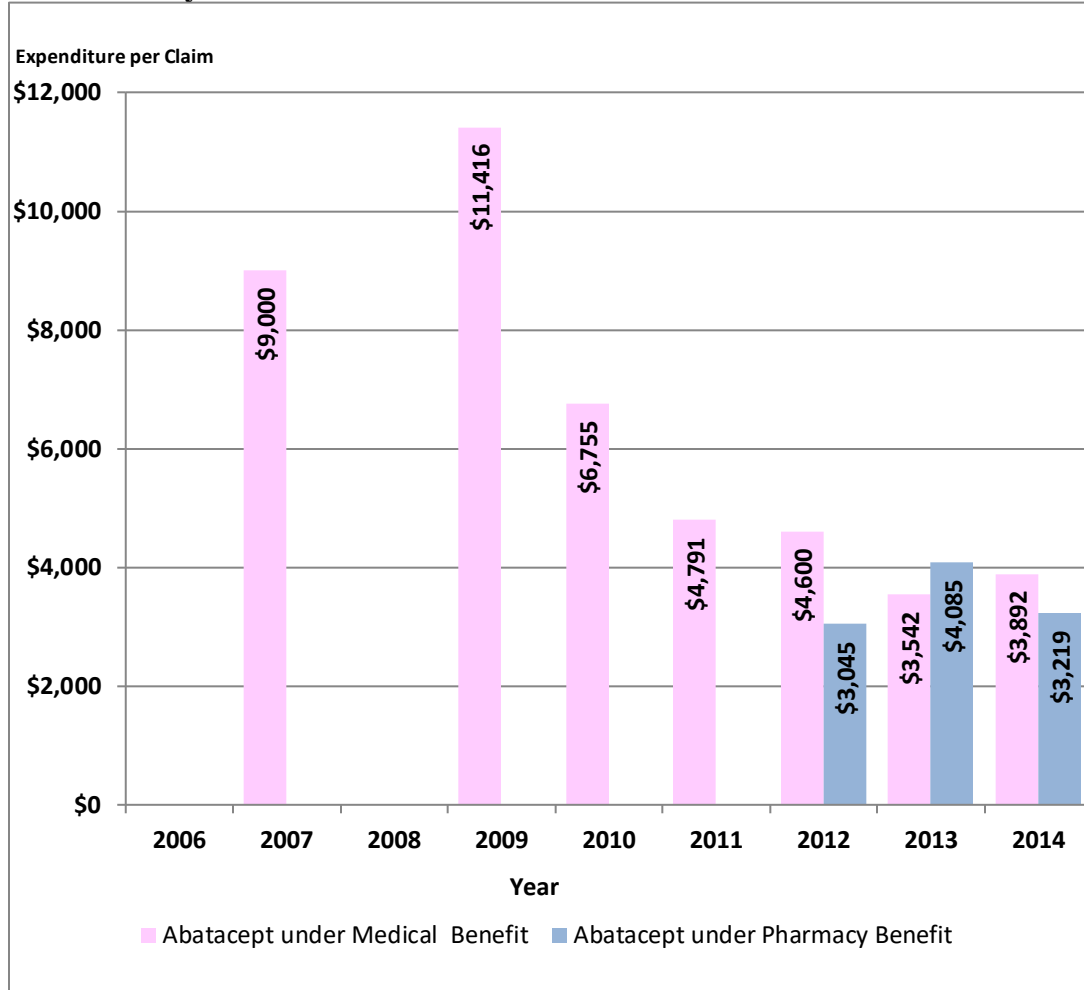
**Table 4.43: PMPY Expenditures for Dual Channel Specialty Drugs Used under the Pharmacy and Medical Benefit: 2006 to 2014\***

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
<b>2006</b>	\$ 41.34	\$ 43.09	\$ 84.43
<b>2007</b>	\$ 38.39	\$ 41.38	\$ 79.77
<b>2008</b>	\$ 41.86	\$ 42.04	\$ 83.90
<b>2009</b>	\$ 35.47	\$ 45.31	\$ 80.78
<b>2010</b>	\$ 45.28	\$ 53.55	\$ 98.84
<b>2011</b>	\$ 46.91	\$ 48.68	\$ 95.59
<b>2012</b>	\$ 49.48	\$ 54.13	\$ 103.61
<b>2013</b>	\$ 99.09	\$ 48.24	\$ 147.34
<b>2014</b>	\$ 102.31	\$ 62.94	\$ 165.25

\*Total expenditures include total drug and drug-related expenditures under the medical and pharmacy benefits.

Growth in PMPY expenditures for dual channel specialty drugs flowing under the pharmacy and medical benefits from 2006 to 2014 is shown in Table 4.43. In 2013 and 2014, a large jump in PMPY can be observed in the PMPY for dual channel specialty drugs covered under the medical benefit. The PMPY for dual channel specialty drug claims paid under the medical benefit grew from \$49.48 in 2012 to \$99.09 in 2013 and to \$102.31 in 2014. The Figures 4.91 to 4.105 and Table 4.44 to Table 4.58 describe the expenditures and PMPY for dual channel specialty drugs across both the pharmacy and medical benefits.

**Figure 4.91: Average Expenditure per Claim for Orenzia (abatacept) under the Pharmacy & Medical Benefits: 2006 to 2014\***



Orenzia (abatacept) is supplied as a subcutaneous solution and as an intravenous powder. The subcutaneous formulation of abatacept came onto the market in 2013, and this can be observed with the UPlan data, as expenditures for abatacept do not show under the pharmacy benefit until after 2013 as seen in Figure 4.91. Abatacept, which is an anti-rheumatic immune modulator, had FDA approved indications for juvenile idiopathic arthritis and rheumatoid arthritis. In general, the average cost of an abatacept claim was lower as a pharmacy claim than when it was paid for as a medical benefit claim. The

PMPY for Orendia is higher under the medical benefit as compared with the PMPY under the pharmacy benefit in 2013 and 2014.

**Table 4.44: PMPY Expenditures for Orendia (abatacept) under Pharmacy and Medical Benefit from 2006 to 2014\***

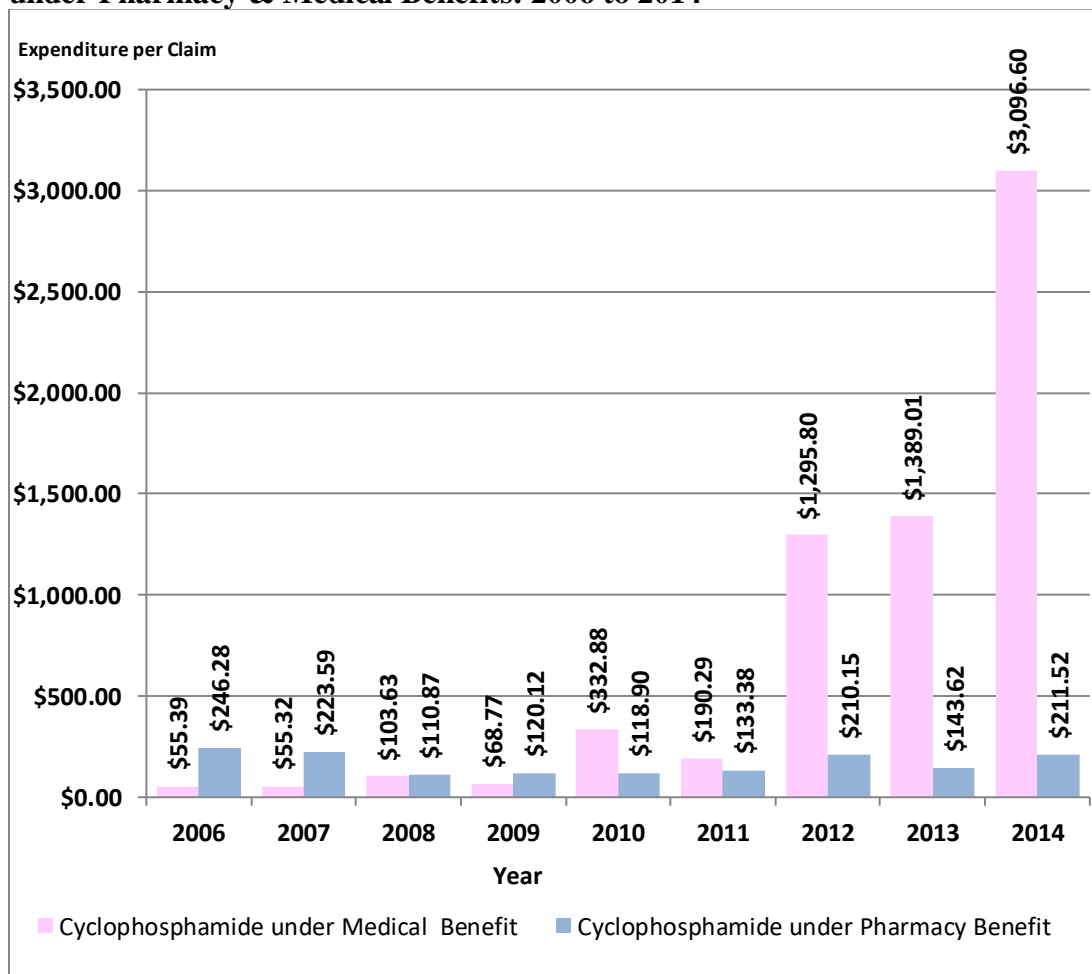
Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY under Medical and Pharmacy Benefit
2006	\$0.00	\$0.00	\$0.00
2007	\$0.25	\$0.00	\$0.25
2008	\$0.00	\$0.00	\$0.00
2009	\$1.18	\$0.00	\$1.18
2010	\$2.07	\$0.00	\$2.07
2011	\$3.54	\$0.00	\$3.54
2012	\$4.15	\$1.02	\$5.18
2013	\$6.51	\$1.06	\$7.57
2014	\$6.43	\$2.08	\$8.50

Cytosan (cyclophosphamide) is an antineoplastic agent with many FDA approved indications, utilized for many forms of cancer. Cyclophosphamide is available orally as well as intravenously. Figure 4.92 shows that the cost per claim for cyclophosphamide started out higher on the pharmacy side from 2006 to 2009. In 2010, the cost per claim on the medical side had a 384% increase over the 2009 cost per claim. The cost per claim under the medical benefit continued to go up all the way through 2014. From 2006 to 2014 the cost per claim for cyclophosphamide increased by 5,491 percent. On the other hand the cost per claim under the pharmacy benefit fluctuated over time ranging from a low of \$110.87 in 2008 to a high of \$246.28 in 2006. The cost per claim of cyclophosphamide under the pharmacy benefit was 14 percent lower in 2014 than it was in 2006.

The oral formulation of cyclophosphamide was the only version flowing through the pharmacy benefit providing one plausible explanation for the lower cost per claim

observed under the pharmacy benefit. The intravenous formulation of cyclophosphamide dominated the claims under the medical benefit. As discussed in Chapter 2, formulations that require provider administration tend to be associated with higher costs. In addition, the amount of product being infused per claim may be contributing to the much higher cost per claim observed under the medical benefit. The observation of Figure 4.92 is a good example of why detailed claim level data is critical to understanding what is driving the high per claim expenditures.

**Figure 4.92: Average Expenditure per Claim for Cytosxan (cyclophosphamide) under Pharmacy & Medical Benefits: 2006 to 2014\***



The PMPY of cyclophosphamide was \$0.23 or less from 2006 to 2012; however, when coverage under the medical benefit became more common, the overall PMPY for cyclophosphamide grew to \$0.69 in 2013 and \$2.02 in 2014.

**Table 4.45: PMPY Expenditures for Cytosan (cyclophosphamide) under Pharmacy & Medical Benefits from 2006 to 2014**

Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY Medical and Pharmacy Benefit
2006	\$0.07	\$0.16	\$0.23
2007	\$0.11	\$0.10	\$0.21
2008	\$0.09	\$0.02	\$0.11
2009	\$0.07	\$0.01	\$0.08
2010	\$0.07	\$0.06	\$0.13
2011	\$0.08	\$0.01	\$0.09
2012	\$0.17	\$0.02	\$0.19
2013	\$0.65	\$0.04	\$0.69
2014	\$1.92	\$0.10	\$2.02

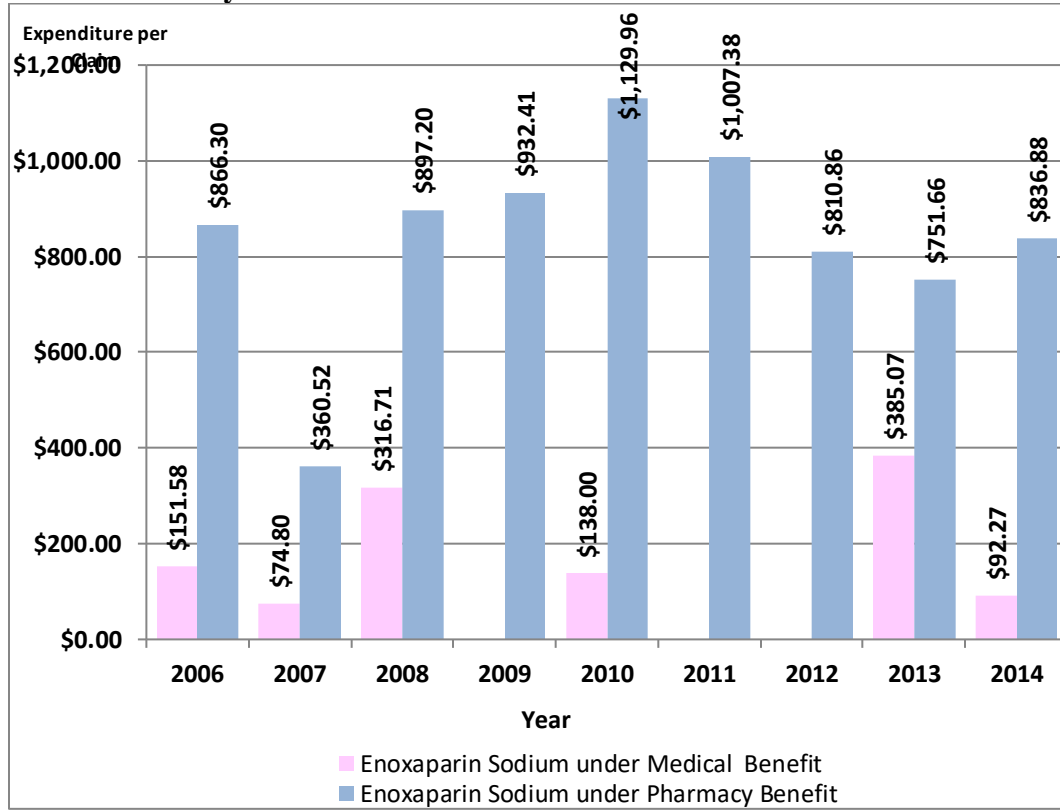
Lovenox (enoxaparin sodium) is a low molecular weight heparin anticoagulant blood modifier agent. This is one of those drugs that some consider specialty because of its cost, specialty administration, and monitoring requirements. However, some may consider it non-specialty, as it is commonly used and can be obtained through traditional pharmacies. Enoxaparin is most commonly used for deep venous thrombosis, but it has several other FDA approved indications.

Figure 4.93 shows that enoxaparin is present under the pharmacy benefit during the whole study period of 2006 to 2014. This is because it is a self-injectable product that does not require provider administration. The cost per claim for enoxaparin fluctuated from 2006 to 2014 under the pharmacy benefit and ranged from a low of \$360.52 in 2007 to a high of \$1,129.96 in 2010.

The PMPY for enoxaparin under the medical benefit remained \$0.16 and below as seen in Table 4.46 due to relatively low utilization rates under the medical benefit.

While under the pharmacy benefit, the PMPY for enoxaparin ranged from a low of \$3.85 to a high of \$10.50 over the study period from 2006 to 2014.

**Figure 4.93: Average Expenditure per Claim for Lovenox (enoxaparin sodium) under Pharmacy & Medical Benefit: 2006 to 2014**



**Table 4.46: PMPY Expenditures for Lovenox (enoxaparin sodium) under Pharmacy & Medical Benefit from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY Medical and Pharmacy Benefit</b>
2006	\$0.10	\$5.71	\$5.81
2007	\$0.01	\$3.84	\$3.85
2008	\$0.12	\$6.42	\$6.54
2009	\$0.00	\$7.28	\$7.28
2010	\$0.00	\$10.50	\$10.50
2011	\$0.00	\$7.62	\$7.62
2012	\$0.00	\$5.50	\$5.51
2013	\$0.12	\$4.88	\$5.00
2014	\$0.16	\$6.59	\$6.75

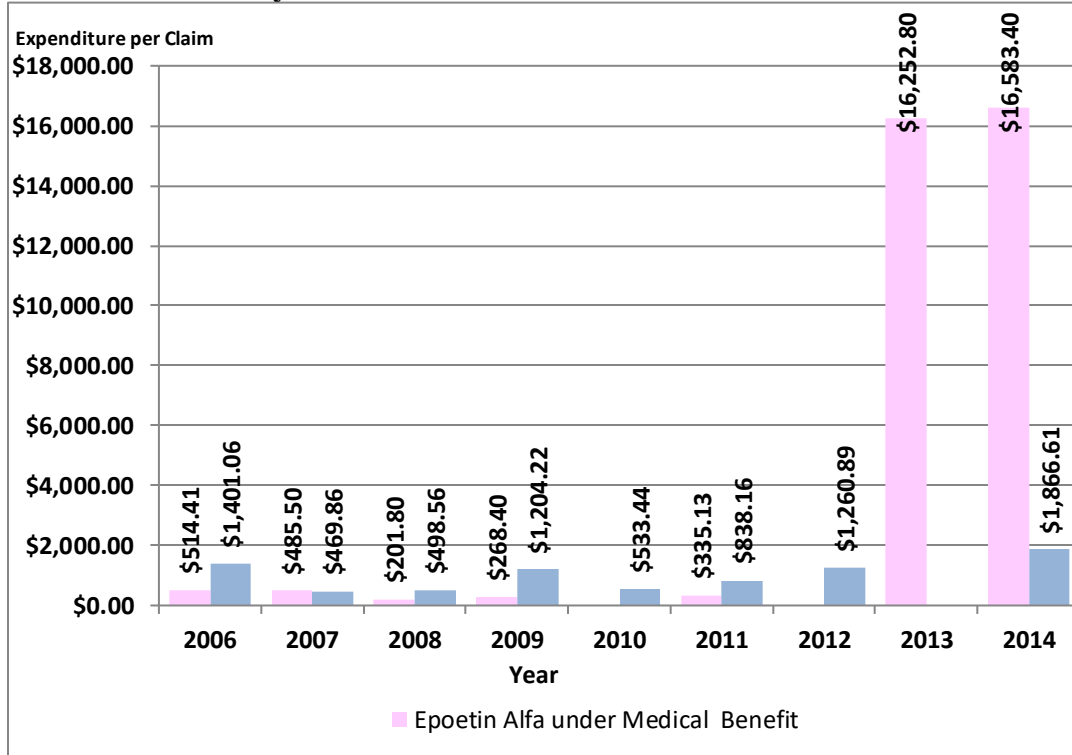
Epoetin Alfa is a biological hematopoietic blood modifier agent. Epoetin Alfa is used for anemia due to various other conditions, such as cancer or cancer-related treatments such as radiation. Epoetin Alfa is available on the market as two brand name products, Epogen and Procrit. Epogen and Procrit have the same dosage forms and strengths, although Procrit has one additional strength -- 40000 U/ML -- that is not available under the brand name Epogen. For most years the cost per claim for Epoetin Alfa appears to be lower on the medical side than on the pharmacy side. However, in 2013 the average cost per claim was \$16,252.80, a 4,750 percent change from 2011, the last time it was available under the medical benefit before 2013. The cost per claim went up slightly in 2014 to \$16,583.40. In 2013 and 2014 two HCPCS codes were used under the medical benefit. In 2013 The HCPCS code, Q4081 (INJ EPOETIN ALFA 100 UNITS FOR ESRD ON DIALYSIS), had 12 claims accounting for \$258,952.44 of the total Epoetin Alfa expenditures. And HCPCS code J0885 (INJECTION EPOETIN ALFAFOR NON-ESRD 1000 UNITS), had 4 claims accounting for \$1,092.38. In 2014



the HCPCS code, Q4081 (INJ EPOETIN ALFA 100 UNITS FOR ESRD ON DIALYSISs), had 12 claims accounting for \$214,224.66 of the total Epoetin Alfa expenditures. And HCPCS code, J0885 (INJECTION EPOETIN ALFAFOR NON-ESRD 1000 UNITS), had 1 claim accounting for \$1,359.57. The HCPCS code used from 2006 to 2012 was J0885. The use of Epoetin for End Stage Renal Disease (ESRD) may be contributing to the significant PMPY increase seen in 2013 and 2014 with HCPCS code Q4081.

All of the medical claims for Epoetin Alfa in 2013 and 2014 were from the hospital outpatient site of care, while in all other years, from 2006 to 2012, Epoetin Alfa products were administered in the physician's office site of care. A substantially higher cost was noted for hospital outpatient claims compared to physician's office claims for Epoetin Alfa. In addition, it may present a utilization management strategy employment. Under the pharmacy benefit from 2006 to 2012 both Epogen and Procrit were dispensed through specialty pharmacy. However, in 2014 both products were dispensed through retail pharmacies and none through the specialty pharmacy. This is another area of further investigation, as this product requires specialty handling, and should be dispensed through specialty pharmacies.

**Figure 4.94: Average Expenditure per Claim for Epogen & Procrit (epoetin alfa) under the Pharmacy & Medical Benefits: 2006 to 2014**



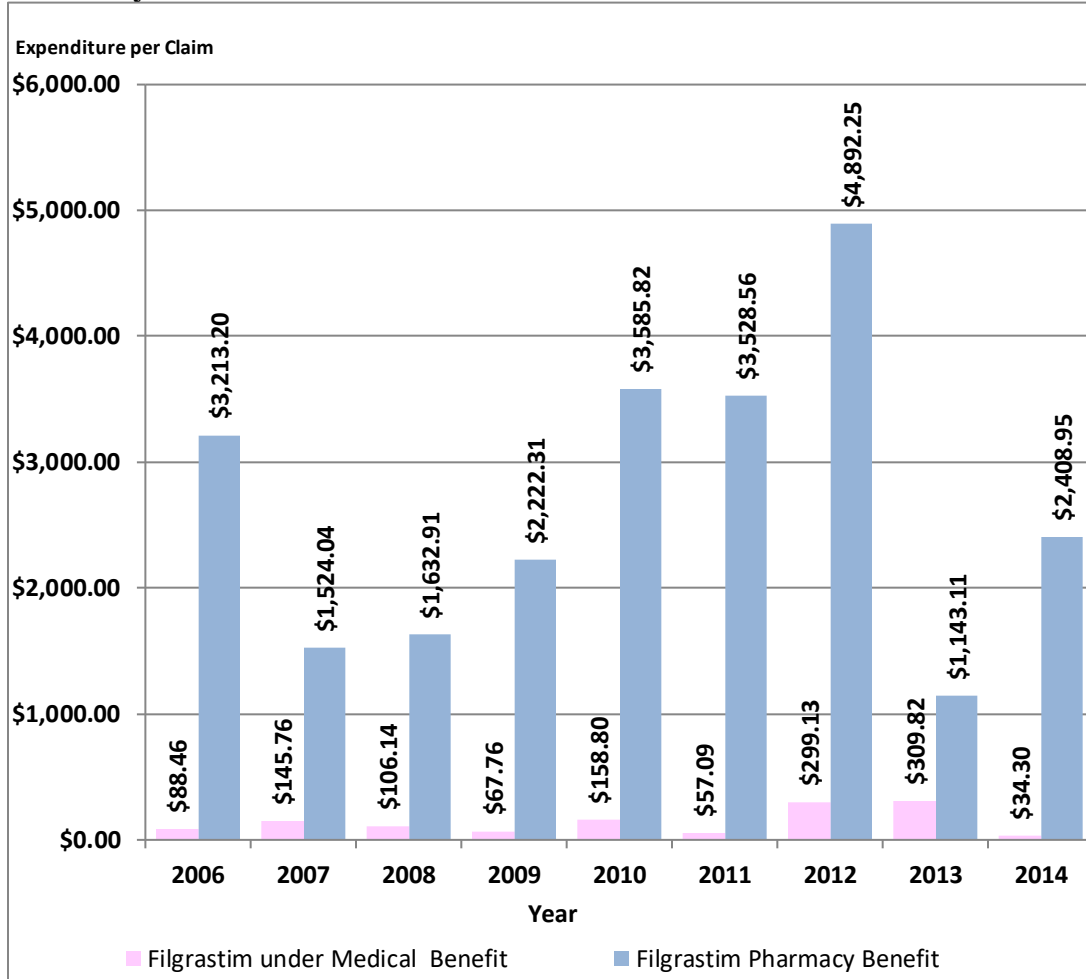
The PMPY for Epoetin Alfa was under \$1.00 in the pharmacy benefit during the period 2006 to 2014. Under the medical benefit, the PMPY was less than \$1.00 from 2007 to 2012, but it jumped dramatically in 2013 and 2014 with a PMPY of \$6.73 and \$5.56, respectively. The 2013 medical PMPY of \$6.73 was a 2,356 percent increase over 2012. The medical benefit PMPY in 2014 was lower than in 2013. However, at \$5.56, the 2014 medical PMPY was still a 55,500 percent increase over 2012.

**Table 4.47: PMPY Expenditures for Epogen & Procrit (Epoetin Alfa) under the Pharmacy & Medical Benefits from 2006 to 2014**

Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY under Medical & Pharmacy Benefit
2006	\$1.28	\$0.96	\$2.24
2007	\$0.33	\$0.11	\$0.43
2008	\$0.03	\$0.09	\$0.12
2009	\$0.03	\$0.53	\$0.57
2010	\$0.00	\$0.18	\$0.18
2011	\$0.07	\$0.17	\$0.24
2012	\$0.01	\$0.26	\$0.27
2013	\$6.73	\$0.00	\$6.73
2014	\$5.56	\$0.34	\$5.90

Neupogen (filgrastim) is a biological hematopoietic blood modifier agent that is FDA- indicated for febrile neutropenia, neutropenic disorder and hematopoietic sub-syndrome of acute radiation syndrome. Filgrastim can be administered subcutaneously or by intravenous infusion. Figure 4.95 shows that filgrastim was predominantly provided through the pharmacy benefit by the UPlan. Under the pharmacy benefit this drug flowed through both retail and specialty pharmacies from 2006 to 2014. The expenditure per claim remained around \$300 when provided through the medical benefit, while under the pharmacy benefit the expenditure per claim fluctuated from a low of \$1,143.11 in 2013 to a high of \$4,892.25 in 2012.

**Figure 4.95: Average Expenditure per Claim for Neupogen (filgrastim) under the Pharmacy & Medical Benefits: 2006 to 2014**



The PMPY for filgrastim remained at or below \$0.60 under the medical benefit from 2006 to 2014 with the exception of 2013—when the PMPY was \$1.07. Under the pharmacy benefit the PMPY, was less than \$1.00 in 4 years (2008, 2009, 2012 and 2013) and greater than \$1.00 PMPY in 2006, 2007, 2010, 2011 and 2014. In 2006 the overall PMPY was at its highest rate for the period at \$2.44.

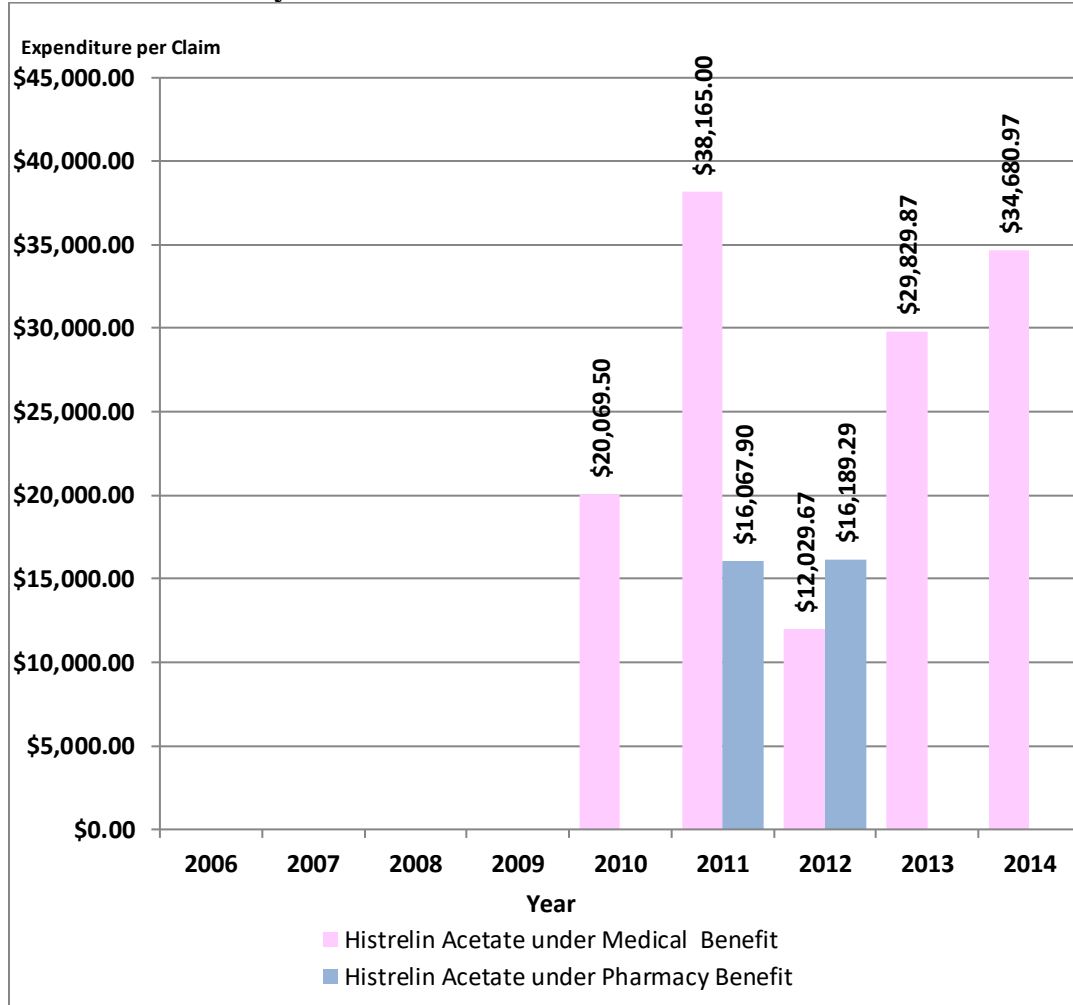
**Table 4.48: PMPY Expenditures for Neupogen (filgrastim) under Pharmacy & Medical Benefit from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$0.33	\$2.11	\$2.44
2007	\$0.54	\$1.24	\$1.78
2008	\$0.29	\$0.53	\$0.82
2009	\$0.06	\$0.69	\$0.75
2010	\$0.34	\$1.29	\$1.62
2011	\$0.07	\$1.89	\$1.95
2012	\$0.25	\$0.63	\$0.88
2013	\$1.07	\$0.24	\$1.31
2014	\$0.09	\$1.55	\$1.64

Supprelin LA (histrelin acetate) is an endocrine metabolic agent that is a gonadotropin-releasing hormone agonist. Histrelin acetate is FDA indicated for prostate cancer for central precocious puberty—an orphan indication. Histrelin is available on the market as two brand names, Supprelin LA and Vantas. For the UPlan only Supprelin LA was found in the claims under both the pharmacy and medical benefits. Histrelin is a subcutaneous implant.

In 2011, histrelin had a total expenditure of \$38,165 for four claim lines, even though the unique claim counts showed a count of zero. It is unclear why this is the case, although claim lines are sub-parts of an overall claim. Thus, the expenditures stated in the chart below for 2011 is the total expenditure in 2011. Figure 4.96 provides another example of why detailed claims level data is needed to provide insight and clarity to what is observed.

**Figure 4.96: Average Expenditure per Claim for Supprelin LA (histrelin acetate) under the Pharmacy & Medical Benefits: 2006 to 2014**



The PMPY under the pharmacy benefit was below \$1.00 in 2011 and 2012. The PMPY under the medical benefit was about \$1.00 for 2010 to 2012 and then jumped to \$3.86 and dropped back to \$1.79 in 2014.

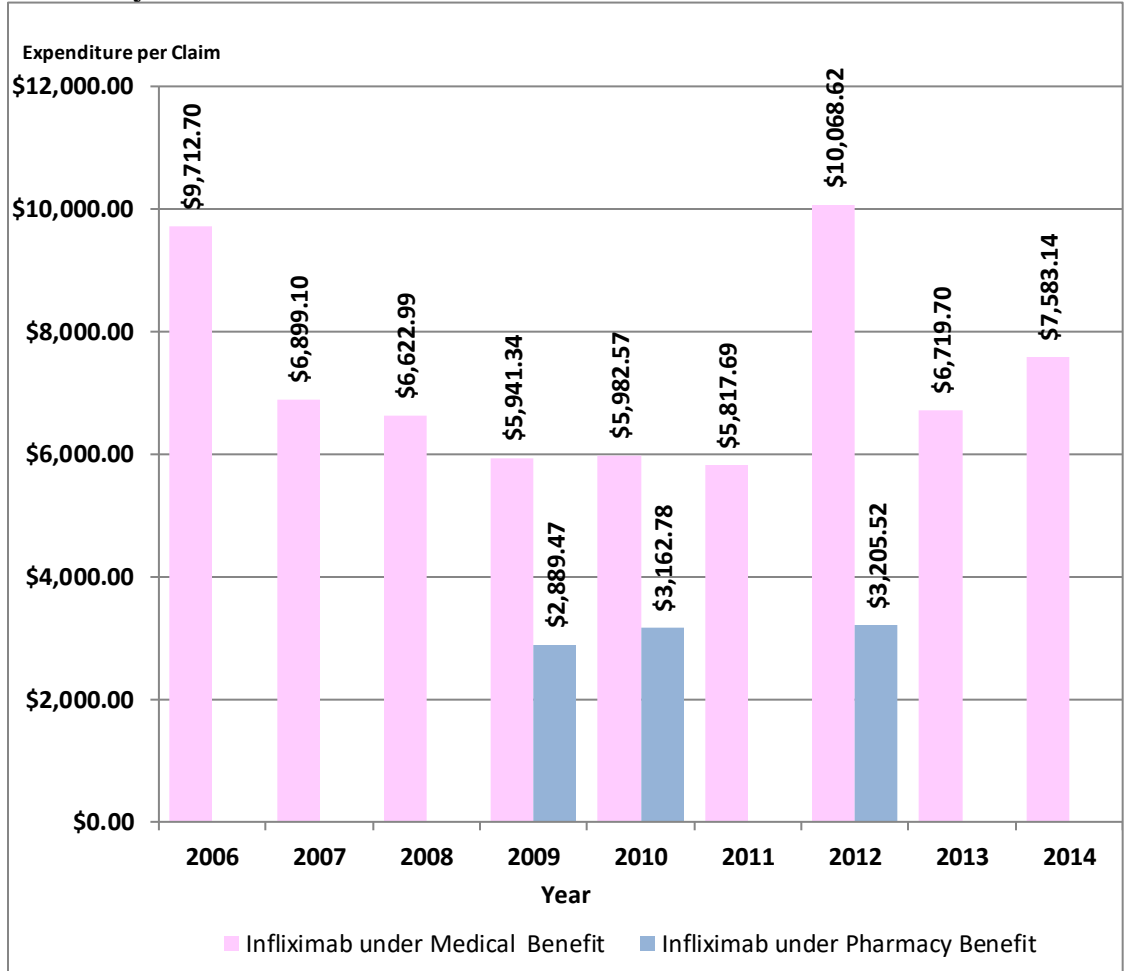
**Table 4.49: PMPY Expenditures for Supprelin LA (histrelin acetate) under Pharmacy & Medical Benefit from 2006 to 2014**

Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY under Medical & Pharmacy Benefit
2006	\$0.00	\$0.00	\$0.00
2007	\$0.00	\$0.00	\$0.00
2008	\$0.00	\$0.00	\$0.00
2009	\$0.00	\$0.00	\$0.00
2010	\$1.03	\$0.00	\$1.03
2011	\$0.97	\$0.82	\$1.79
2012	\$0.93	\$0.84	\$1.77
2013	\$3.86	\$0.00	\$3.86
2014	\$1.79	\$0.00	\$1.79

Remicade (infliximab) is a monoclonal antibody tumor necrosis factor inhibitor used to treat many autoimmune and inflammatory conditions. Infliximab is FDA indicated for Crohn’s disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis and ankylosing spondylitis. Infliximab is a biologic available as an intravenous powder for solution. Infliximab is a provider-administered drug and is expected to be predominantly administered under the medical benefit, as seen in Figure 4.97. The average expenditure per claim under the medical benefit remained above \$5,800 during the period from 2006 to 2014, with the highest cost per claim observed in 2012 at \$10,068.62. There were pharmacy claims observed for infliximab in 2009, 2010 and 2012. During those years the pharmacy expenditure per claim was much lower than what was observed under the medical benefit, ranging from a low of \$2,889.47 to a high of \$3,205.52. From 2006 to 2012 infliximab was predominantly administered in a home

care or physician’s office setting. However, in 2013 and 2014 all of the claims came from the hospital outpatient setting.

**Figure 4.97: Average Expenditure per Claim for Remicade (infiximab) under the Pharmacy & Medical Benefits: 2006 to 2014**



The PMPY for infiximab is one of the highest observed among the specialty drugs discussed thus far. There is a significant difference between the PMPY under the pharmacy benefit and the medical benefit. This is to be expected since the majority of infiximab utilization is under the medical benefit. Under the pharmacy benefit, the PMPY remained below \$0.25, while the PMPY under the medical benefit was \$18.56 in 2006 and increased to \$40.31 by 2014, a 217 percent growth during that time period.

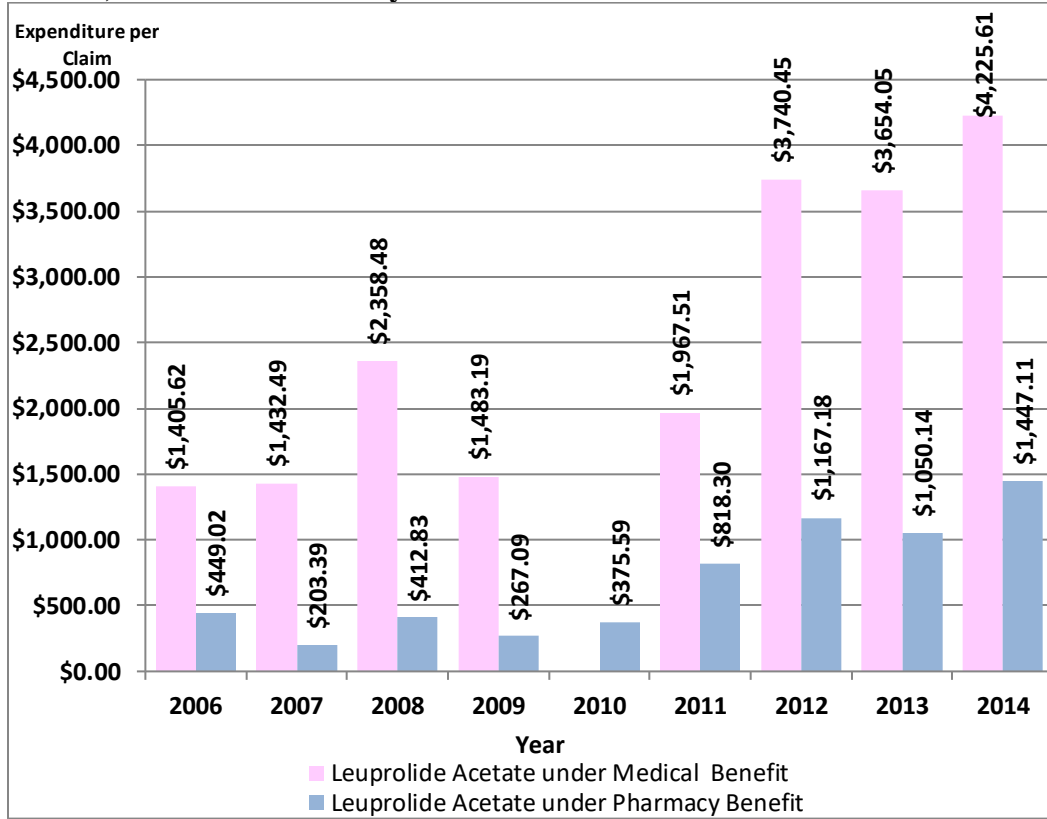


**Table 4.50: PMPY Expenditures for Remicade (infliximab) under the Pharmacy & Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$18.56	\$0.00	\$18.56
2007	\$18.72	\$0.00	\$18.72
2008	\$20.32	\$0.00	\$20.32
2009	\$20.18	\$0.22	\$20.40
2010	\$21.44	\$0.24	\$21.68
2011	\$22.66	\$0.00	\$22.66
2012	\$25.21	\$0.17	\$25.37
2013	\$40.35	\$0.00	\$40.35
2014	\$40.31	\$0.00	\$40.31

Lupron Depot (leuprolide acetate) is an endocrine-metabolic antineoplastic agent. Leuprolide is FDA approved for prostate cancer, endometriosis, central precocious puberty, and anemia-uterine leiomyoma. Leuprolide acetate is on the market as three different brands. Eligard, available on the market in 2015 and beyond, is a subcutaneous powder for suspension. Lupron Depot and Lupron Depot-Ped are intramuscular powders for suspension and were on the market for the entire period from 2006 to 2014. The expenditure per claim under the medical benefit was substantially higher than under the pharmacy benefit from 2006 to 2014. Under the medical benefit the expenditure per claim ranged from \$1,405.62 in 2006 to \$4,225.61 in 2014, a 201 percent growth during the 8-year period.

**Figure 4.98: Average Expenditure per Claim for Lupron Depot (leuprolide acetate) under the Pharmacy & Medical Benefits: 2006 to 2014**



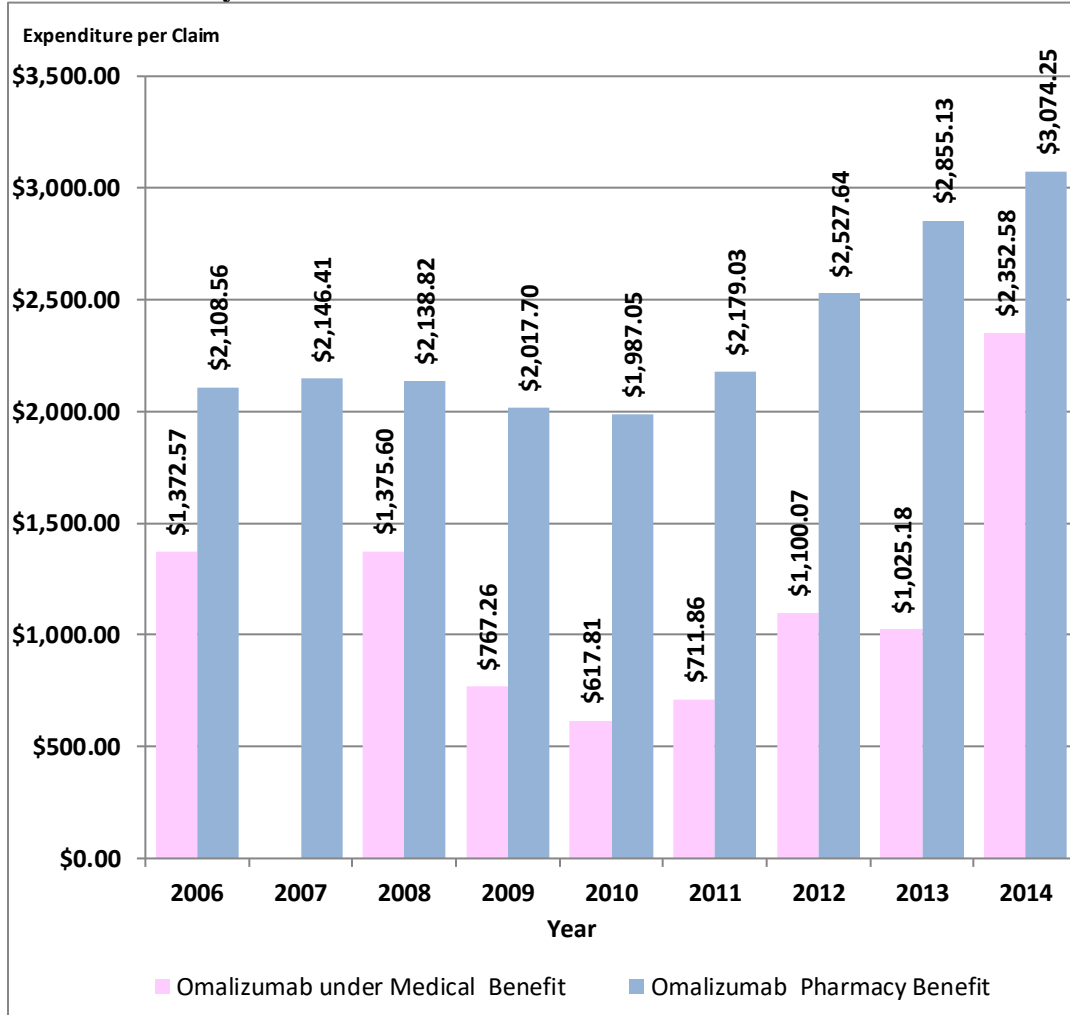
The PMPY under the medical benefit ranged from \$1.96 to \$3.25 between 2006 and 2014. The PMPY ranged from around \$0.42 to \$3.22 under the pharmacy benefit. The PMPY across both the pharmacy and medical benefit over the period 2006 to 2014 ranged from a low of \$2.57 in 2008 to a high of \$5.72 in 2013.

**Table 4.51: PMPY Expenditures for Leuprolide Acetate under the Pharmacy & Medical Benefits from 2006 to 2014**

Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY under Medical and Pharmacy Benefit
2006	\$2.45	\$0.59	\$3.03
2007	\$2.44	\$0.42	\$2.87
2008	\$2.09	\$0.48	\$2.57
2009	\$2.19	\$0.43	\$2.62
2010	\$2.47	\$0.48	\$2.95
2011	\$3.26	\$1.96	\$5.21
2012	\$2.12	\$3.22	\$5.35
2013	\$3.03	\$2.69	\$5.72
2014	\$1.96	\$2.02	\$3.98

Xolair (omalizumab) is a subcutaneous powder for solution that is FDA approved for idiopathic urticarial and IgE-mediated allergic asthma not controlled by inhaled corticosteroids. Omalizumab has been present under both the pharmacy and medical benefits for the UPlan from 2006 to 2014. Overall, the expenditure per claim for omalizumab under the pharmacy benefit was relatively constant at about \$2,000 per claim from 2006 to 2010. From 2010 to 2014, however, the expenditure per claim grew substantially from \$1,987 to \$3,074—an increase of 55 percent. On the other hand, the expenditure per claim under the medical benefit was consistently less than the amount per claim under the pharmacy benefit. For the medical benefit the amount per claim dropped from \$1,372.57 in 2006 to \$617.81 in 2010. From 2010, the amount per claim under the medical benefit grew from a low of \$617.81 to a high of \$2,352.58 in 2014. From 2006 to 2014 the expenditures per claim showed a growth of 46 percent under the pharmacy benefit and 71 percent under the medical benefit.

**Figure 4.99: Average Expenditure per Claim Xolair (Omalizumab injection) under Pharmacy & Medical Benefits: 2006 to 2014**



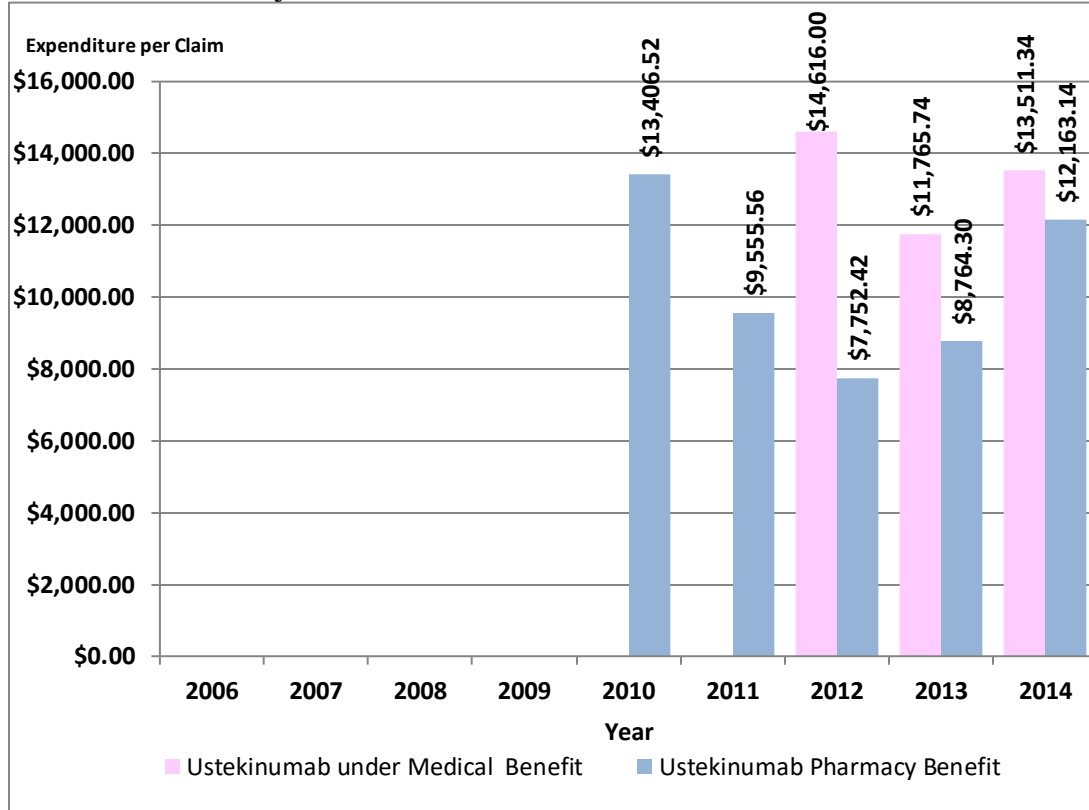
Omalizumab under the pharmacy benefit contributed more to the PMPY than under the medical benefit from 2006 to 2013 and in 2014 the medical benefit PMPY exceeded the pharmacy benefit. Under the medical benefit the PMPY ranged from \$0.27 in 2006 to \$5.52 in 2014. Under the pharmacy benefit the PMPY ranged from a low of \$3.03 in 2009 to a high of \$5.03 in 2013. The PMPY for omalizumab under the pharmacy benefit grew 36 percent from 2006 to 2014 and under the medical benefit PMPY grew more than 1,916 percent in the same period.

**Table 4.52 PMPY Expenditures for Xolair under Pharmacy & Medical Benefit from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical and Pharmacy Benefit</b>
2006	\$0.27	\$3.67	\$3.94
2007	\$0.00	\$4.14	\$4.14
2008	\$0.37	\$3.68	\$4.05
2009	\$1.51	\$3.03	\$4.55
2010	\$0.41	\$4.43	\$4.84
2011	\$1.01	\$4.11	\$5.12
2012	\$1.19	\$4.57	\$5.76
2013	\$1.88	\$5.03	\$6.91
2014	\$5.52	\$5.00	\$10.52

Stelara (ustekinumab) is a monoclonal antibody that is FDA indicated for plaque psoriasis and psoriatic arthritis. Ustekinumab comes as the brand name Stelara in two different dosage forms—an intravenous solution and a subcutaneous solution. Ustekinumab was FDA approved in 2009 and was first seen in the UPlan data under the pharmacy benefit in 2010 and under the medical benefit in 2013.

**Figure 4.100: Average Expenditure per Claim for Stelara (Ustekinumab injection) under the Pharmacy & Medical Benefits: 2006 to 2014**



The expenditure per claim for Stelara in the pharmacy benefit started at \$13,406 in 2010, then dropped to \$7,752 in 2012 and rose to \$12,163 in 2014. Under the medical benefit, the expenditure per claim for Stelara was always higher than under the pharmacy benefit and ranged from a high of \$14,616 in 2012 down to a low of \$11,765 in 2013. There are other drugs for plaque psoriasis and psoriatic arthritis such as Humira, Enbrel, and Remicade. In 2014, the expenditure per pharmacy claim for Humira was less than \$4,000, Enbrel was less than \$3,500 and Remicade was less than \$3,500 compared to expenditures per pharmacy claim of \$12,163 for Stelara in 2014. Comparing the expenditure per medical claim of Stelara and Remicade shows that the cost in 2014 were \$13,511 and less than \$10,000, respectively.

Examination of the PMPY for Stelara shows that it is higher under the pharmacy benefit than under the medical benefit driven both by higher utilization and higher cost. In 2014, for example, the PMPY for Stelara under the medical benefit was \$2.09, and it was \$10.04 under the pharmacy benefit. In 2014, the PMPY under the pharmacy benefit was 380 percent great than what was observed under the medical benefit.

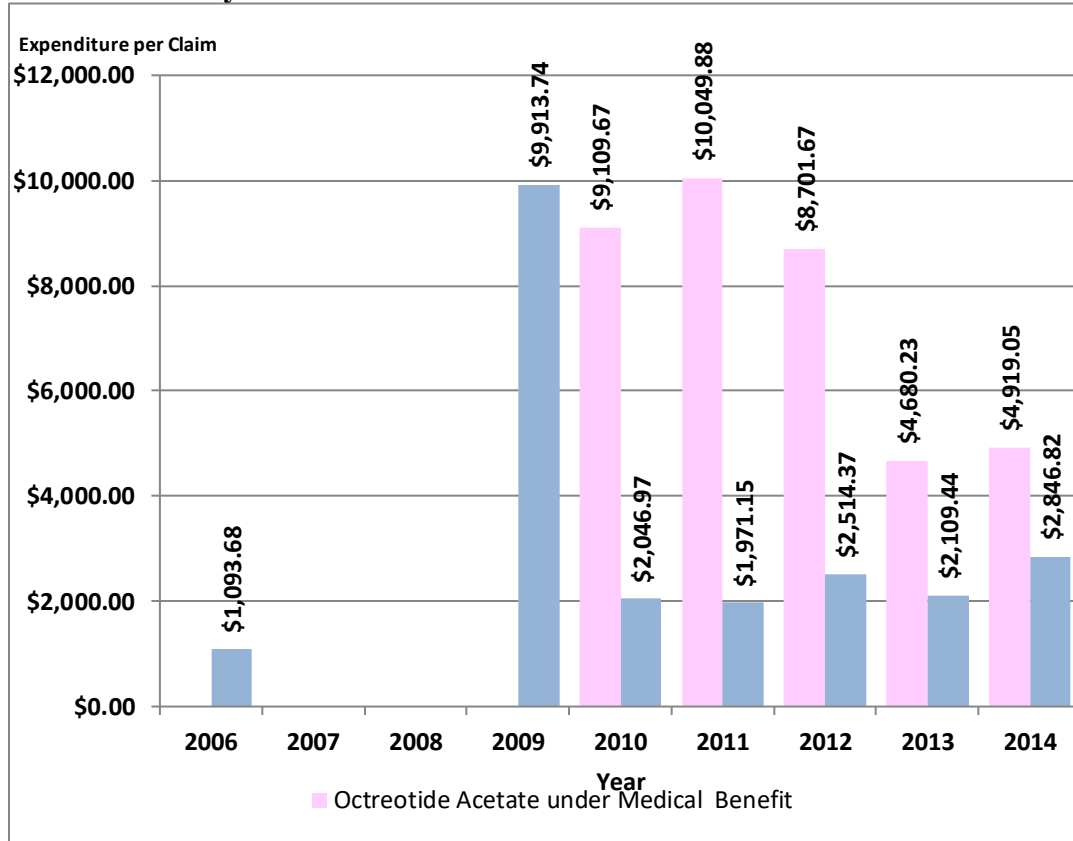
**Table 4.53: PMPY Expenditures for Stelara (Ustekinumab injection) under the Pharmacy and Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$0.00	\$0.00	\$0.00
2007	\$0.00	\$0.00	\$0.00
2008	\$0.00	\$0.00	\$0.00
2009	\$0.00	\$0.00	\$0.00
2010	\$0.00	\$0.69	\$0.69
2011	\$0.00	\$1.22	\$1.22
2012	\$1.13	\$3.80	\$4.93
2013	\$2.13	\$4.99	\$7.12
2014	\$2.09	\$10.04	\$12.14

Sandostatin (octreotide) is an endocrine-metabolic agent that is available as a brand and generic that comes as an injection solution, as well as an intramuscular powder for suspension. Octreotide is FDA indicated for three different indications, including Acromegaly, an orphan indication. The expenditure per pharmacy claim dropped dramatically from 2009 to 2010 as expected since octreotide had entry of generics in 2005. The per claim expenditure under the pharmacy benefit remained between \$2000 and \$3000 from 2010 to 2014 much lower than the cost under the medical benefit. From 2010 to 2014 the expenditure per claim under the medical benefit was higher than under the pharmacy benefit. Since the expenditure per claim for octreotide is lower under the

pharmacy benefit, the UPlan should examine whether octreotide claims should be covered only under the pharmacy benefit.

**Figure 4.101: Average Expenditure per Claim for Sandostatin (Octreotide inj) under Pharmacy & Medical Benefits: 2006 to 2014**



The PMPY for octreotide under the pharmacy benefit grew from \$0.16 in 2006 to \$2.14 in 2012 and then declined to \$0.87 in 2013 and \$0.95 in 2014. Under the medical benefit the octreotide PMPY ranged from \$1.35 to \$2.67 from 2010 to 2014. The highest PMPY under the pharmacy benefit was noted in 2012, at \$2.14. The PMPY under the medical benefit in 2010 was \$2.10 and grew to \$2.67 in 2014. The PMPY under the medical benefit has grown from 2010 to 2014, while the PMPY for the pharmacy benefit declined from 2010 to 2014.

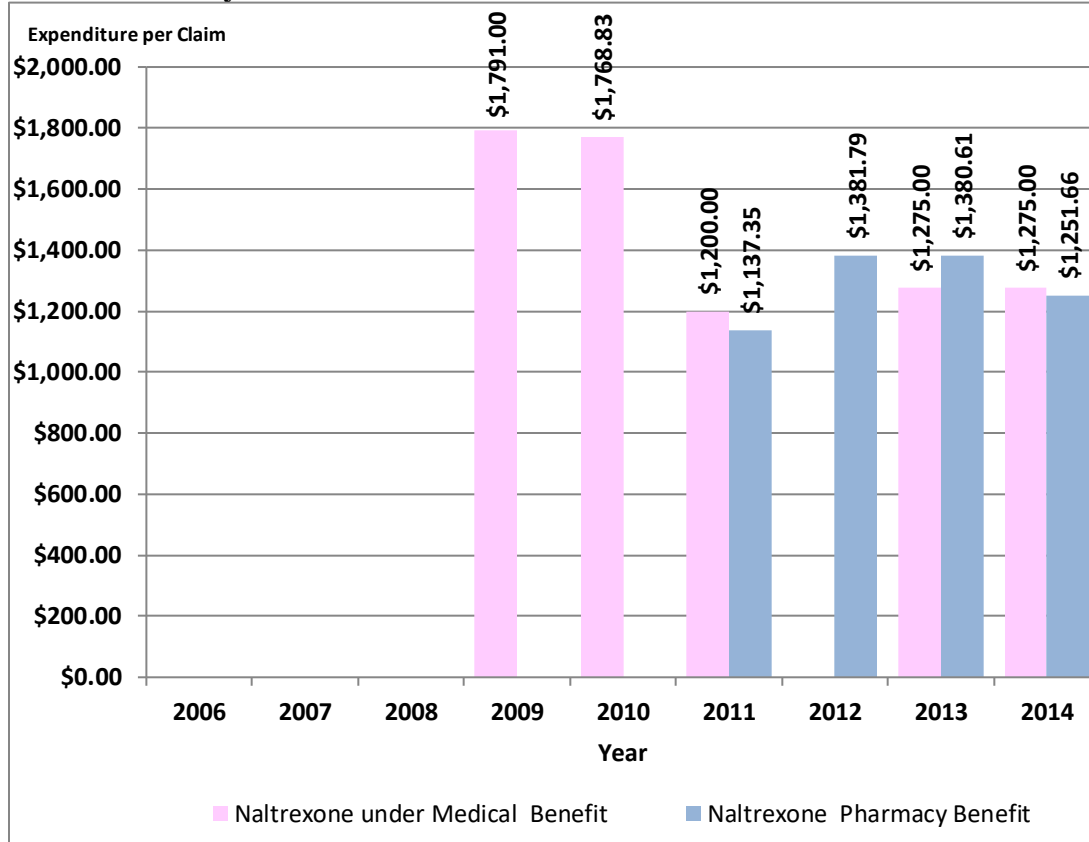


**Table 4.54: PMPY Expenditures for Sandostatin (Octreotide inj) under the Pharmacy & Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$0.00	\$0.16	\$0.16
2007	\$0.00	\$0.00	\$0.00
2008	\$0.00	\$0.00	\$0.00
2009	\$0.00	\$0.51	\$0.51
2010	\$2.10	\$1.31	\$3.41
2011	\$2.05	\$1.51	\$3.55
2012	\$1.35	\$2.14	\$3.49
2013	\$2.42	\$0.87	\$3.30
2014	\$2.67	\$0.95	\$3.62

Vivitrol (naltrexone) is an opioid antagonist that is FDA indicated for alcohol dependence and opioid dependence. Naltrexone is available as a powder for suspension and intramuscular injection. Naltrexone was initially FDA approved in 2006, and it was not seen in UPlan claims until 2009. From 2009 to 2010 naltrexone was observed only under the medical benefit at a cost of nearly \$1,800 per claim. In 2011, naltrexone had both pharmacy and medical claims with a cost of about \$1,200 per claim. In 2012 the expenditure per pharmacy claim rose from \$1,137 to \$1,382 per claim. In 2013, the per claim expenditure for naltrexone was higher under the pharmacy benefit than under the medical benefit, and by 2014 it was slightly higher under the medical benefit.

**Figure 4.102: Average Expenditure per Claim Vivitrol (naltrexone Injection) under Pharmacy & Medical: 2006 to 2014**



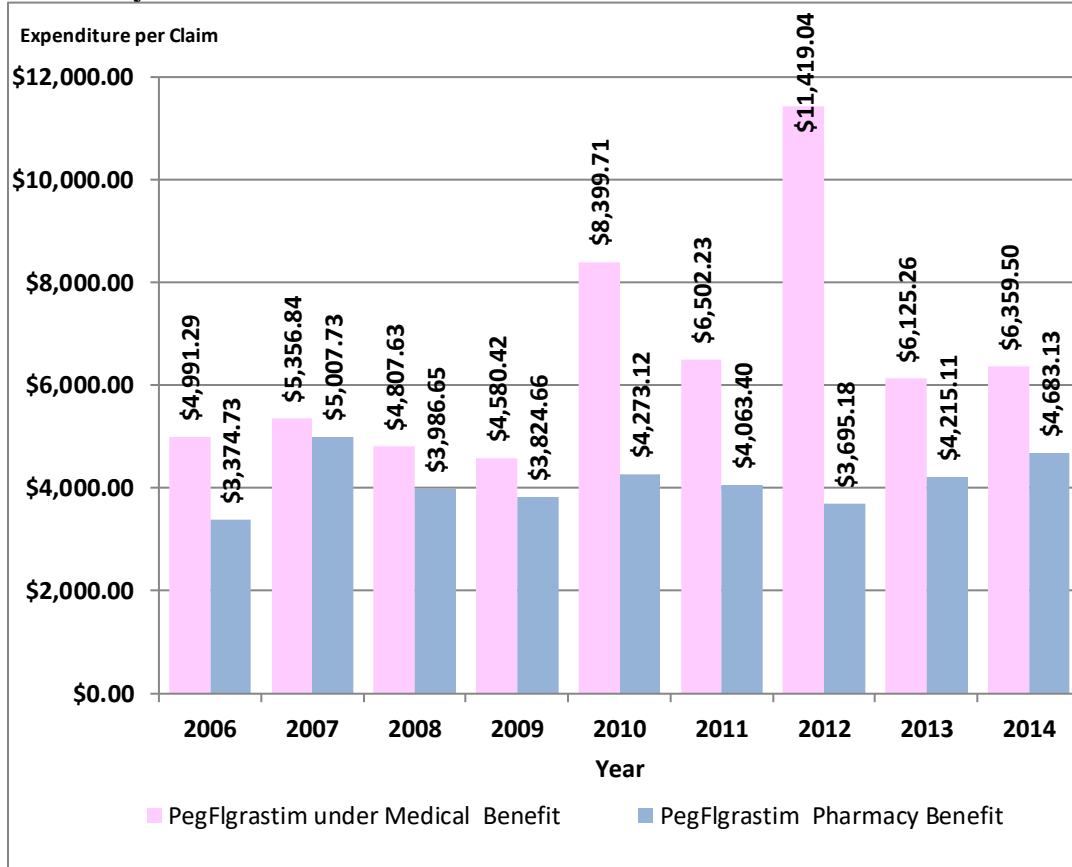
The PMPY for naltrexone under the pharmacy benefit has grown from 2011 to 2014 when the PMPY was \$0.52. The PMPY for naltrexone under the medical benefit was highest in 2010 at \$0.27 and has declined since then to a PMPY of \$0.10. The higher naltrexone PMPY under the pharmacy benefit compared to the medical benefit reflects the higher utilization of naltrexone under the pharmacy benefit.

**Table 4.55: PMPY Expenditures for Vivitrol under the Pharmacy and Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$0.00	\$0.00	\$0.00
2007	\$0.00	\$0.00	\$0.00
2008	\$0.00	\$0.00	\$0.00
2009	\$0.05	\$0.00	\$0.05
2010	\$0.27	\$0.00	\$0.27
2011	\$0.03	\$0.06	\$0.09
2012	\$0.00	\$0.14	\$0.14
2013	\$0.10	\$0.25	\$0.35
2014	\$0.10	\$0.52	\$0.62

Neulasta (pegfilgrastim) is a blood modifying colony stimulating factor that is FDA indicated for febrile neutropenia in patients with non-myeloid malignancies and radiation injury of bone marrow. Pegfilgrastim is supplied as a subcutaneous solution. For the UPlan, pegfilgrastim claims were present under the pharmacy and medical benefits for all the years of this study. Overall, the expenditure per claim for pegfilgrastim was always higher under the medical benefit than under the pharmacy benefit. The expenditure per medical claim ranged from a low of \$4,580.42 in 2009 to a high of \$11,419.04 in 2012. The expenditure per pharmacy claim ranged from a low \$3,374.73 in 2006 to a high of \$5,007.73 in 2007 and by 2014 the expenditure per claim was \$4,683.13.

**Figure 4.103: Average Expenditure per Claim Neulasta (Pegfilgrastim) under the Pharmacy & Medical Benefits: 2006 to 2014**



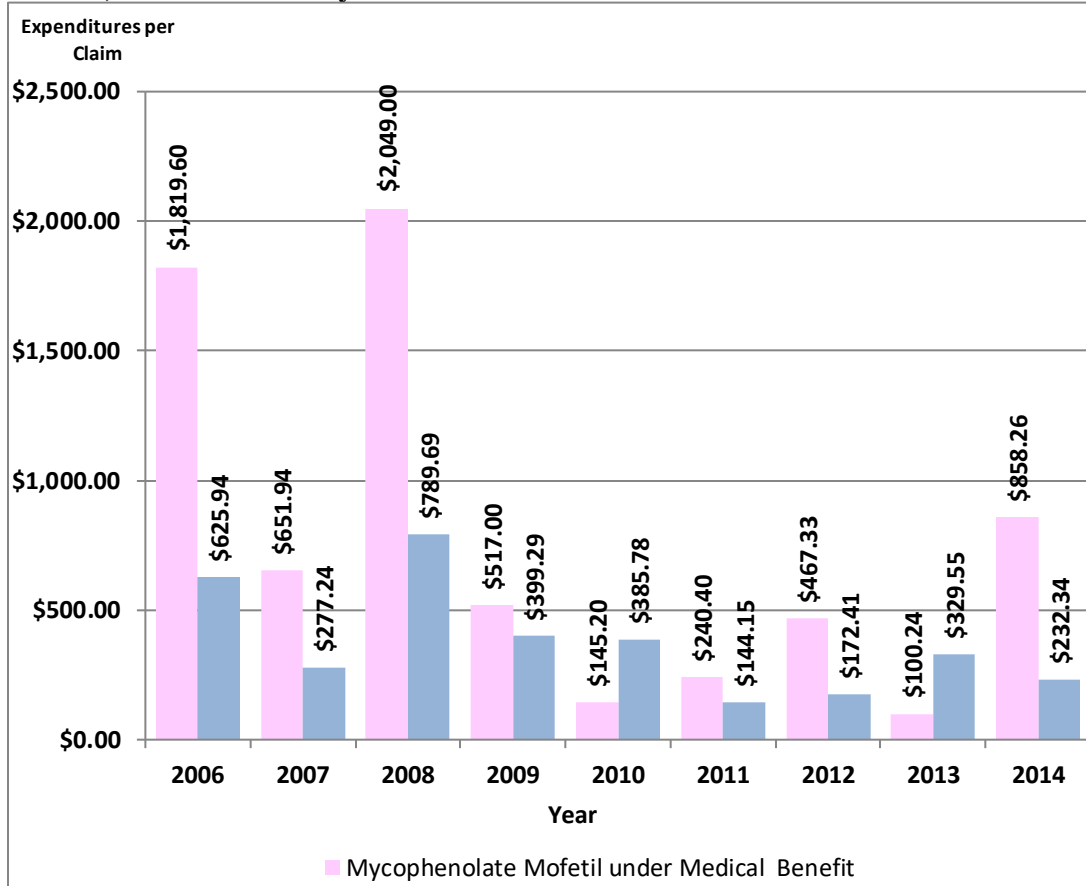
The PMPY for pegfilgrastim was higher under the medical benefit compared to the pharmacy benefit for every year from 2006 to 2014, except for 2009. This pattern largely reflects higher utilization on the medical benefit side. The PMPY under the medical benefit was 27 percent higher in 2014 than in 2006. The lowest PMPY under the medical benefit was noted in 2009 at \$3.09, and the highest PMPY was noted in 2014 at \$15.59. The PMPY observed under the pharmacy benefit was much lower than that of the medical benefit, ranging from a high of \$4.86 in 2009 to a low of \$0.33 in 2013.

**Table 4.56: PMPY Expenditures for Neulasta (pegfilgrastim) under the Pharmacy and Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$12.24	\$4.04	\$16.28
2007	\$11.09	\$3.08	\$14.17
2008	\$10.22	\$1.39	\$11.62
2009	\$3.09	\$4.86	\$7.95
2010	\$8.82	\$0.66	\$9.47
2011	\$7.28	\$2.07	\$9.35
2012	\$7.66	\$0.67	\$8.33
2013	\$14.90	\$0.33	\$15.23
2014	\$15.59	\$2.42	\$18.01

Cellcept (mycophenolate mofetil) is an immune suppressant, FDA approved for cardiac, liver and renal transplant rejection. It is available on the market as a brand and as a generic. It comes as an oral capsule, oral tablet and oral powder for suspension. Starting in 2009 the expenditure per claim is lower for both the pharmacy and medical benefits. This is because the generic version of the drug was available on the market starting in 2009. The expenditure per claim in the medical benefit was over \$1,800 per claim in 2006 and 2008. Since 2009, the expenditure per claim under both the pharmacy and medical benefit was lower than \$800 until 2014 when the expenditure per medical claim jumped to \$858.26.

**Figure 4.104: Average Expenditures per Claim for Cellcept (Mycophenolate mofetil) under Pharmacy and Medical Benefits: 2006 to 2014**



The PMPY for mycophenolate was higher under the pharmacy benefit than under the medical benefit reflecting more use under the pharmacy benefit than under the medical benefit. The PMPY remained about \$1.00 or lower under the medical benefit. Overall, the PMPY for mycophenolate dropped from a high in 2006 of \$4.79 to a low of \$1.26 in 2011 and then rose to \$2.55 in 2014. However, an analysis of this class of drugs is recommended, as more and more PBMs are requiring the flow of these drugs through specialty pharmacies. In addition, some PBMs are requiring the use of the brand name product over the generic, resulting in a higher cost per claim. While this is not the case

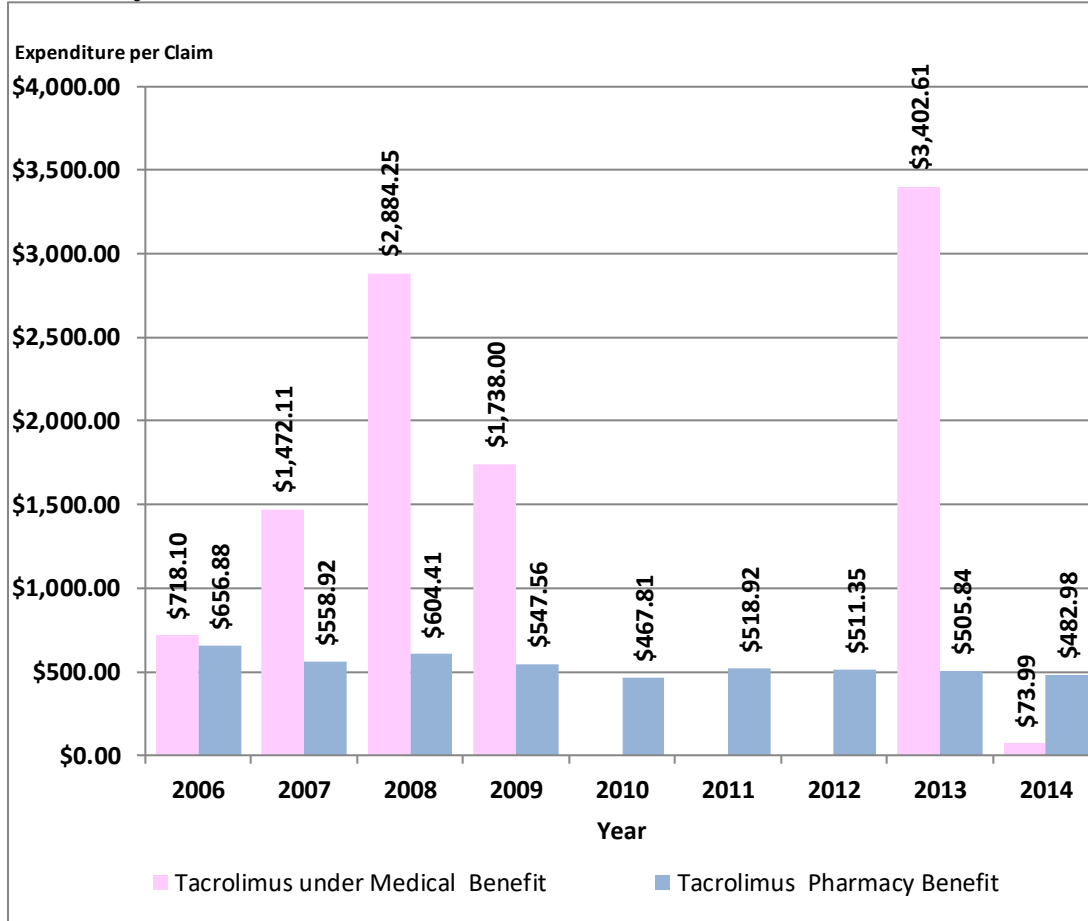
for the UPlan, it was an issue raised in the broader Minnesota market as a result of a new report about this type of PBM pricing and steering behavior.

**Table 4.57: PMPY Expenditures for Mycophenolate Mofetil under Pharmacy & Medical Benefits from 2006 to 2014**

Year	PMPY under Medical Benefit	PMPY under Pharmacy Benefit	PMPY under Medical and Pharmacy Benefit
2006	\$0.52	\$4.27	\$4.79
2007	\$0.33	\$4.44	\$4.77
2008	\$0.11	\$4.55	\$4.66
2009	\$0.04	\$2.00	\$2.04
2010	\$0.02	\$3.13	\$3.15
2011	\$0.03	\$1.23	\$1.26
2012	\$0.04	\$1.41	\$1.44
2013	\$0.00	\$2.48	\$2.48
2014	\$1.04	\$1.51	\$2.55

Prograf (tacrolimus) is an immune suppressant and immunological agent, FDA approved for cardiac, liver and renal transplant rejection. It is available on the market as a brand and as a generic. Tacrolimus comes as an oral capsule and an intravenous solution. From 2006 to 2014 both the brand and the generic version of the drug were on the market. Figure 4.105 shows that the expenditure per pharmacy claim was highest in 2006 at \$656.88 and was \$482.98 in 2014. The expenditure per medical claim ranged from a low of \$718.10 in 2006 to \$2,884.25 by 2008 and had a high of \$3,402.61 in 2014, a 96 percent growth from 2009. No medical claims were reported in 2010 to 2012. The trend data for tacrolimus shows clearly why we need detailed claims level data that includes quantity of drug product used, along with units of measure, and price per claim. Without the detailed level of information, we are unable to discern what is causing significant variations in expenditure per claim and PMPY. This concern is an issue for all of the drugs present under both the pharmacy and medical benefits.

**Figure 4.105: Average Expenditure per Claim for Prograf (tacrolimus) under the Pharmacy & Medical Benefits: 2006 to 2014**



The overall PMPY for tacrolimus was \$3.28 in 2006 and dropped to a low of \$2.09 in 2009. The PMPY for tacrolimus then rose to a high of \$2.75 in 2014. While tacrolimus claims under the medical benefit were higher than under the pharmacy benefit, the major reason for the higher PMPY under the pharmacy benefit was the higher utilization rate for tacrolimus as a pharmacy benefit.



**Table 4.58: PMPY Expenditures for Prograf (tacrolimus) under the Pharmacy & Medical Benefits from 2006 to 2014**

<b>Year</b>	<b>PMPY under Medical Benefit</b>	<b>PMPY under Pharmacy Benefit</b>	<b>PMPY under Medical &amp; Pharmacy Benefit</b>
2006	\$0.20	\$3.07	\$3.28
2007	\$0.37	\$2.50	\$2.87
2008	\$0.31	\$1.95	\$2.26
2009	\$0.14	\$1.96	\$2.09
2010	\$0.00	\$2.73	\$2.73
2011	\$0.00	\$2.79	\$2.79
2012	\$0.00	\$2.19	\$2.19
2013	\$0.18	\$2.20	\$2.38
2014	\$0.71	\$2.03	\$2.75

## **CHAPTER 5:**

### **DISCUSSION AND CONCLUSION**

#### **5 Introduction**

This chapter has seven sections. The first section provides discussion of the general trends for drug expenditures observed for the UPlan over time. The second section discusses findings from Aims 1 and 2 focusing on specialty trends observed for the UPlan. The third section discusses findings from Aim 2 focusing on specialty drug utilization and expenditures by therapeutic category. The fourth section examines findings from Aim 3 focusing on specialty drug utilization and expenditures by site of services under the medical benefit. The fifth section discusses findings from Aim 4 focusing on specialty drugs used in both the pharmacy and medical benefits. Section six presents limitations of this study. Finally, section seven outlines the implications and conclusions from this study.

#### **5.1 UPlan general trends**

Overall drug and drug-related expenditures for the University of Minnesota UPlan went up from 2006 to 2014 for drugs under the pharmacy and medical benefits, as observed within the pharmaceutical marketplace and noted in Chapter 2. As expected, from 2006 to 2014 drug expenditures and utilization as measured by number of claims under pharmacy benefit were greater than what was observed under the medical benefit. The percentage of total drug and drug-related expenditures accounted for by the pharmacy benefit went down from 2006 to 2014. Conversely, the percent of total drug and drug-related expenditures accounted for by the medical benefit grew from 2006 to 2014. These findings are in line with what is observed in the marketplace. In addition,

these findings are similar to what was observed by a study completed by the Minnesota Department of Health on the MN All Payer Claims Database (APCD); which found that spending on drugs flowing through medical benefits increased nearly three-fold from 2009 to 2013, as noted in Chapter 2.

Comparing the percentage of total claims and total expenditures accounted for by the medical benefit, the findings show that medical expenditures accounted for a greater percentage of total expenditures than did medical claims as a percentage of total claims. For total drug and drug-related expenditures under the medical benefit, the key drivers are drugs, drug administration, immunization and immunization administration, and durable medical equipment (DME). For total drug and drug-related expenditures under the pharmacy benefit, the key driver was drugs which accounted for 97 percent to 98 percent of total pharmacy drug and drug-related claims and expenditures.

The overall PMPY expenditures for all drug and drug-related products were greater under the pharmacy benefit than under the medical benefit from 2006 to 2014. In general, the PMPY growth rate for total drug and drug-related expenditures fluctuated for both the pharmacy and medical benefits. However, in 2013, there was a notable growth (71 percent) in the PMPY expenditure under the medical benefit that was much greater than what was observed under the pharmacy benefit. For the pharmacy benefit, the highest growth was noted from 2010 to 2011. Overall, from 2006 to 2014 expenditures under the medical benefit had a greater growth rate than observed under the pharmacy benefit. This observation is in line with the trends as observed in the market.

Average expenditures per claim under the medical benefit were greater than those under the pharmacy benefit during the study period. Average expenditure per

claim under the pharmacy benefit demonstrated a slow but steady growth from 2006 to 2014. Expenditures per claim under the medical benefit demonstrated a clear fluctuation throughout 2006 to 2014. The fluctuation observed for the average expenditure per claim under the medical benefit can partly be explained by the impact of seasonal immunizations as observed in Figures 4.22 and 4.23. The percentage change in expenditures per claim under the pharmacy benefit shows slow and steady growth over time. Percentage change in per claim expenditures under the medical benefit varied from 2006 to 2014, with an upward growth observed from 2009 to 2012.

The general trends observed show that drug and drug-related expenditures are going up. The data clearly shows that a growing percentage of drug expenditures are accounted for under the medical benefit. Thus, employers like the UPlan have to have strategies to manage this growing trend not just on the pharmacy side of the benefit, but on the medical side of the benefit as well. In addition, when considering total drug expenditures it is important to also account for the drug-related expenditures on the medical side of the benefit, similar to the way drug-related expenditures are currently accounted for under the pharmacy benefit.

An active engagement by employers is necessary to identify what specific products are driving the trends on each side of the benefit. Once the trend drivers are identified, it is important to develop strategies to manage drug and drug-related products that will ensure the wise use of employers' funds. The key is for employers to identify general trends first, and then drill down to identify specific drivers, which calls for access to both pharmacy and medical claims data. Without access to the data with enough details

on drug and drug-related claims, employers are limited in their ability to identify what their current status is for total drug utilization and spending.

## **5.2 UPlan specialty drug trends (Aim 1 and Aim 2)**

A look at utilization and expenditures for specialty drug and drug-related products vs. traditional drug and drug-related products shows that specialty drug and drug-related product expenditures are growing as a share of total drug expenditures. However, they account for a small share of total drug claims. As discussed regarding market trends in Chapter 2, specialty drug and drug-related expenditures grew from 2006 to 2014. However, expenditures for traditional drugs accounted for a greater portion of the total drug expenditures than did specialty drugs from 2006 to 2014. That being the case, the growth in specialty drug and specialty drug-related expenditures was notably greater than what was observed for traditional drugs from 2006 to 2014.

In 2014, specialty drug and drug-related expenditures represented 42 percent of total drug expenditures, but only represented 3 percent of total drug and drug-related claims. This finding is in line with industry trends noted in the background section of this study. While specialty drug and drug-related claims account for a small portion of total drug and drug-related claims, they represent a much greater percentage of total drug and drug-related expenditures. The percentage of total drug and drug-related expenditures accounted for by specialty drug and drug-related expenditures grew from 26 percent to 42 percent from 2006 to 2014. Traditional drug and drug-related expenditures as a percentage of total drug and drug-related expenditures went down from 74 percent to 58 percent, a 17 percent decline from 2006 to 2014. Over that time the percentage of total

drug and drug-related claims accounted for by specialty drugs remained low and consistently below 3 percent from 2006 to 2014. In contrast, the percentage of total drug and drug-related claims accounted for by traditional drugs remained high and consistently over 97 percent from 2006 to 2014.

During the study period from 2006 to 2014, the PMPY for traditional drug and drug-related products was greater than the PMPY for specialty drug and drug-related products. The PMPY for traditional drug and drug-related products ranged from a low of \$792.62 to a high of \$985.17. While the PMPY for specialty drug and drug-related products ranged from a low of \$271.46 to a high of \$713.98. In addition, a greater growth is observed for specialty PMPY expenditures as compared to traditional PMPY expenditures. A similar trend is observed for total drug and drug-related expenditures, including both traditional and specialty with the PMPY. Over time the PMPY expenditure for specialty drugs is growing and taking a larger portion of the total drug and drug-related PMPY across pharmacy and medical benefits. The year-to-year growth in PMPY expenditures fluctuated for both specialty and traditional drug and drug-related expenditures. However, the percentage growth year to year was higher for specialty drugs than for traditional drug and drug-related products from 2008 to 2014. The greatest year-to-year percentage growth in PMPY expenditures was observed from 2012 to 2013 for both specialty and traditional drug and drug-related products.

The UPlan findings regarding trends for specialty and traditional drug and drug-related products are in line with observations in the industry. The findings show that expenditures for specialty is growing over time, and that it is growing at a greater rate than what is observed for traditional drug and drug-related products. Employers such as

the UPlan need to employ strategies specific to traditional and specialty drugs. As discussed in Chapter 2, different strategies are employed for specialty vs. traditional drugs. For both traditional and specialty drug and drug-related products, an active management approach is critical. Active management such as a clinically-driven benefit design and formulary along with utilization management efforts like quantity limits, step therapy and prior authorization are critical under both sides of the benefit. In addition, for specialty drugs, it is critical that additional active management strategies be deployed, such as appropriate definition of specialty drugs, distribution channel and site-of-care management, patient engagement, and provider engagement.

### **5.2.1 Specialty drug utilization vs expenditures**

A clear growth in total specialty expenditures is observed from 2006 to 2014. Growth in specialty expenditures from 2006 to 2014 under the pharmacy benefit was greater than what is observed under the medical benefit. Utilization for specialty and drug-related products is proportionally a small percent of total claims, but takes a large percentage of expenditures under both the pharmacy and medical benefits. Pharmacy claims accounted for greater than 53 percent of total specialty claims from 2006 to 2014. Both pharmacy and medical claims fluctuated in the percentage of claims contributing to total specialty claims across the benefits.

Claims for specialty drugs and drug-related products under the medical benefit remained below 11 percent as a percentage of total claims throughout the study period. Alternatively, the 11 percent of total specialty claims accounted for by the medical benefit represent greater than 48 percent of total medical drug expenditures. A study published in 2016 on the share of specialty drugs in commercial plans found that under pharmacy benefits, specialty drugs accounted for 0.6 percent of fills in 2003 and 1.8 percent of fills in 2014.<sup>2</sup> However, expenditures for specialty drugs for 2003 and 2014 accounted for 11.0 percent and 43.2 percent, respectively, of total specialty drug expenditures under the pharmacy benefit.<sup>3</sup> A similar trend is seen for the UPlan, as in 2006 specialty claims under the pharmacy benefit accounted for 1 percent of total pharmacy claims and in 2014 accounted for 2 percent of total pharmacy claims. However, expenditures for specialty drugs accounted for 15 percent of total pharmacy expenditures in 2006 and 36 percent in 2014.

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<sup>2</sup>Dusetzina SB. Share of specialty drugs in commercial plan nearly quadrupled, 2003-14. Health Affairs. 2016. 35(7):1241-11247



The drug and drug-related specialty PMPY expenditure flowing through pharmacy and medical benefits grew from 2006 to 2014. However, the PMPY expenditure growth rate observed was higher under the pharmacy benefit than under the medical benefit. The average specialty drug and drug-related expenditure per claim was higher for claims under the medical benefit than they were under the pharmacy benefit from 2006 to 2014.

The number of drugs accounting for by 50 percent, 75 percent and 90 percent of the total specialty expenditures grew from 2006 to 2014. This is because the total number of unique specialty drugs across the pharmacy and medical benefits also grew from 2006 to 2014. For example, in 2006, 17 drugs accounted for 50 percent of total specialty drug expenditures across the pharmacy and medical benefits. However, by 2014, 22 drugs accounted for 50 percent of total specialty drug expenditures across pharmacy and medical benefits. The total number (520) of specialty drug and drug-related products in 2014 across the pharmacy and medical benefits were 42 percent more than they were in 2006.

### **5.2.2 Growth of specialty drug expenditures**

The growing impact of specialty drugs on total drug expenditures that was observed in the market was also observed for The University of Minnesota UPlan. According to the report by Schumock et al., expenditures for specialty drugs were one-third of total drug expenditures in 2014.<sup>4</sup> For the UPlan, specialty drug and drug-related

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<sup>3</sup> Dusetzina SB. Share of specialty drugs in commercial plan nearly quadrupled, 2003-14. *Health Affairs*. 2016. 35(7):1241-11247

<sup>4</sup> Schumock GT, Li EC, Suda KJ, Wiest MD, Stubbings J, Matusiak LM, et al. National trends in prescription drug expenditures and projects for 2015. *Am J Health-Syst Pharm*. 2015. 72:(e19-238). Retrieved on: 8/27/2015. Retrieved from: <http://www.ashpmedia.org/AJHP/05-01-Special-Feature-Schumock-14-0849-AOP.pdf>

expenditures accounted for more than one-third of total drug expenditures from 2008 to 2014. As noted by trends from Prime Therapeutics in 2014, there was a greater increase in the percentage of total expenditures accounted for by specialty drugs vs. traditional drugs.<sup>5</sup> For the UPlan the percentage of specialty drugs accounting for total drug and drug-related expenditures went up from 2013 to 2014, while expenditures accounted for by traditional drugs and drug-related products decreased for the same period. In 2006 and 2007 and from 2010 to 2012, the percentage change in the average specialty expenditure per claim under the pharmacy benefit is higher than what is observed under the medical benefit. However, in 2009 and 2013, the percentage change in average specialty expenditures per claim was higher under the medical benefit.

In the more recent years the specialty drug and drug-related expenditure growth is higher under the medical benefit than the pharmacy benefit both in dollars and as a percent increase in dollars. This trend is expected to continue as more and more drugs are being approved that require provider administration. With the exception of 2007 and 2010, the year-to-year change in specialty expenditures for drug and drug-related products flowing through both pharmacy and medical benefits was higher than the change in the CPI All. In 2007 and 2010, the increase in the CPI All was higher than the increase in specialty drug and drug-related expenditures under the medical benefits.

The growth of specialty drug and drug-related expenditures under both pharmacy and medical benefits continue to reinforce the need for management of drug and drug-related products across both the pharmacy and medical benefits. In more recent years following the study period, the UPlan has started to work closely with the medical benefit

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<sup>5</sup> Prime Therapeutics. Defining dynamics:2014 prescription drug cost report. Prime Therapeutics. 8/19/2015. Retrieved on: 8/27/2015. Retrieved from: [http://issuu.com/prime\\_creative/docs/5476k\\_rxdrugcostreport\\_2014\\_15\\_?e=11661593/1470199](http://issuu.com/prime_creative/docs/5476k_rxdrugcostreport_2014_15_?e=11661593/1470199).

vendor to develop and implement a more active and proactive approach for managing drugs on the medical side of the benefit, as the UPlan does on the pharmacy side of the benefit. This includes employing the management strategies discussed in Chapter 2.

### **5.2.3 Top specialty drugs contributing to trend**

The top 10 specialty drugs under the medical benefit accounted for a greater percentage of total specialty expenditures than did the top 10 specialty drugs under the pharmacy benefit from 2006 to 2010, and in 2014. From 2011 to 2013 the top 10 specialty drugs under the pharmacy benefit accounted for a greater percentage of total specialty expenditures than did the top 10 specialty drugs under the medical benefit.

Top disease states observed in the market and the UPlan as specialty expenditure drivers were also noted. Top categories such as multiple sclerosis, oncology, hepatitis C, and inflammatory conditions were observed as being trend drivers in the market.<sup>6,7</sup> These categories also played a key role in driving trend for the UPlan in 2013 and 2014. These categories accounted for an estimated 58 percent and 59 percent of total specialty expenditures in 2013 and 2014, respectively. Immune modulators, while considered trend drivers in industry, only accounted for total specialty expenditures of less than 3 percent, or less for the UPlan in 2013 and 2014.

From 2006 to 2014, the therapeutic categories with the largest PMPY across the pharmacy and medical benefits were antineoplastic agents, analgesics and anesthetics

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<sup>6</sup> Prime Therapeutics. Defining dynamics:2014 prescription drug cost report. Prime Therapeutics. 8/19/2015. Retrieved on: 8/27/2015. Retrieved from: [http://issuu.com/prime\\_creative/docs/5476k\\_rxdrugcostreport\\_2014\\_15\\_?e=11661593/1470199](http://issuu.com/prime_creative/docs/5476k_rxdrugcostreport_2014_15_?e=11661593/1470199).

<sup>7</sup> Express Scripts Lab. The 2014 drug trend report. March 2015. Express Scripts. Retrieved on:8/27/2015 Retrieved from: <http://lab.express-scripts.com/drug-trend-report/>

(including drugs for inflammatory conditions such as Humira and Enbrel), and endocrine and metabolic agents.

### **5.2.3.1 Top specialty drug under pharmacy benefit**

The top drugs contributing to the growth of specialty drug expenditures observed in industry were also observed in the UPlan data. A study published in 2016 on the share of specialty drugs in commercial plans published in Health Affairs notes that Sovaldi had the highest reimbursement per fill, at \$28,083 in 2014.<sup>8</sup> A similar trend was also seen for the UPlan, as Sovaldi had the second highest expenditure per claim under the pharmacy benefit in 2014. Under the pharmacy benefit, Harvoni was the No. 1 drug in 2014. Sovaldi and Harvoni are near-cure therapy for hepatitis C, approved by FDA in 2013 and 2014, respectively. Another drug for hepatitis C is the fourth on the list — Olysio — under the pharmacy benefit. Drugs for multiple sclerosis, such as Copaxone and Rebif, were also noted as being major trend drivers for the UPlan. Evaluation of total expenditures by drug shows that drugs for inflammatory conditions such as Humira and Enbrel were specialty expenditure drivers for the UPlan, also seen in industry.<sup>9</sup>

During the initial entry to market of drugs for hepatitis C, many employers and drug benefit managers raised concerns regarding the pricing of these drugs. However, one justification used for the high price tag associated with these drugs at the time was their ability to essentially cure the disease. With such a high price tag there were a lot of management strategies that employers such as the UPlan needed to consider, such as

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<sup>8</sup> Dusetzina SB. Share of specialty drugs in commercial plan nearly quadrupled, 2003-14. Health Affairs. 2016. 35(7):1241-11247

<sup>9</sup> Dusetzina SB. Share of specialty drugs in commercial plan nearly quadrupled, 2003-14. Health Affairs. 2016. 35(7):1241-11247

ensuring that patients are clinically eligible to take the drugs and are able to be adherent. Adherence is a critical part of the use of these drugs, which is one of the key focus points of the University's specialty pharmacy. With more specialty drugs coming to the market with similar pricing, it is important that employers deploy a variety of management strategies for specialty drugs as discussed in Chapter 2.

### **5.2.3.2 Top specialty drugs under the medical benefit**

For specialty drugs flowing through the medical benefit, the top three therapeutic categories with the highest PMPM in 2006 were antineoplastic agents, hematological agents, and gastrointestinal agents. In 2014, the top three categories included antineoplastic agents, endocrine and metabolic drugs, and gastrointestinal agents. Drugs under the medical benefit such as infliximab and rituximab are known to have contributed to the increase in specialty drug expenditures on the medical side in the market place.<sup>9</sup> These drugs were also observed within the UPlan data. Infliximab and rituximab were among the top 10 drugs with the highest expenditure per claim under the medical benefit for the UPlan. Ipilimumab, an antineoplastic agent used to treat melanoma, was the agent with the highest per claim expenditure in 2014. This is in line with antineoplastic agents being among the top three categories both in 2006 and 2014. Injection galsulfase, an enzyme endocrine metabolic agent, was among the top 10 highest expenditure per claim under the medical benefit in 2014. Injection galsulfase was not a drug commonly noted in industry reports or trends. This is because injection galsulfase is indicated for an orphan condition called mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome). Since orphan conditions impact a small percent of the general population, it is possible

that this condition may not be observed in the disease state trends. However, this is a good example of how an employer's population of covered lives and utilizers may impact their trends differently than what is observed industry wide.

### **5.3 Specialty drug utilization and expenditures by therapeutic category (Aim 2)**

Evaluating drugs by therapeutic category provides a look into trends based on different disease states and categories of conditions. This approach is important as it provides an employer, such as the UPlan, a view into what trends may be present for specific conditions and how they compare with what is happening nationally. In addition, it allows an employer to develop management strategies focused on specific patient populations. It also shows which type of the benefit, either pharmacy, medical, or both, needs to have a focused strategy to better manage costs.

Evaluating the utilization and expenditure trends of therapeutic categories for the UPlan, a similar trend that is observed in the overall specialty drug trend is observed with individual therapeutic categories. That is, the overall specialty drug trend shows the total number of specialty drug claims remain relatively low and consistent over time. On the other hand, expenditures for specialty drugs are relatively high and continue grow faster than expenditures for traditional drugs.

Both in 2006 and 2014, while the following categories - antineoplastic agents, biologicals, gastrointestinal agents, psychotherapeutic and neurological agents, and analgesic and anesthetics accounted for a lower percentage of total specialty claims, they accounted for a much higher percentage of total specialty expenditures.

Antineoplastic (oncology) agents accounted for the greatest percent of total specialty expenditures across the pharmacy and medical benefits from 2006 to 2014. However, over the study period, even though oncology expenditures increased the share of total specialty expenditures accounted for by antineoplastic agents went decreased. Breaking down specialty drugs by the top conditions they treat, we found similar trends as observed by industry for 2013 and 2014. For the UPlan, oncology agents, hepatitis C, multiple sclerosis, autoimmune agents, and immunomodulatory/immune serums accounted for greater than 50 percent of total specialty expenditures both in 2013 and 2014. Similarly, a study by EMD Serono based on data from 70 commercial health plans in the U.S. representing more than 100 million covered lives, found that Prime Therapeutics and ESI had similar specialty drug expenditures by therapeutic category.<sup>59</sup>

Hepatitis C had very low expenditures in 2013 as new agents were just entering the market towards the end of 2013. However, uptake of Hepatitis C agents for the UPlan can be seen as expenditures go up from 2013 to 2014, with a similar market trend observed in the EMD Serono study.

Specialty drugs for oncology and autoimmune conditions had the highest percentage of total specialty expenditures across the pharmacy and medical benefits. These findings are in line with what is observed in the market as trend driver drugs, as discussed in Chapter 2 as well as Chapter 4. Drugs for oncology were flowing under both the pharmacy and medical benefits. However, over a third of the total specialty oncology expenditures were under the medical benefit.

The presence of trend driver therapeutic categories is observed across pharmacy and medical benefits for the UPlan. Thus, the need for drug management strategies across pharmacy and medical benefits is clear. The breakdown of trends by therapeutic categories provides insight into the complete picture of the expenditures at the population level as it relates to drugs, enabling an employer like the UPlan to manage specialty drugs not just at the drug level but at the condition level.

#### **5.4 Specialty drug utilization and expenditures by site of services under medical benefit (Aim 3)**

Industry trends during the study period demonstrated the top sites of services for specialty drug administration were hospital outpatient, physician's office, and home health. The trends for sites of services observed in the industry were also observed for the UPlan. The top site of services for the UPlan for drugs flowing under the medical benefit were the physician's office, hospital outpatient, patient's home, and urgent care & emergency. Over the study period, drug expenditures through physician's offices were the highest and stayed at the top over time. From 2006 to 2012 patient's home had the second highest expenditures for specialty drugs. In 2013, hospital outpatient rose to be



the second highest site of expenditures and that was maintained in 2014.

From 2006 to 2012, there was minimal specialty drug administration under hospital outpatient for the UPlan. That is from 2006 to 2012, less than one percent of total medical specialty claims were accounted for by hospital outpatient. However, in 2013 and 2014, there was a significant jump in total specialty drug claims flowing through the hospital outpatient setting to 33 percent (2013), and 30 percent (2014). Similar to the claims experience, specialty drug expenditures accounted for by the hospital outpatient setting were less than one percent from 2006 to 2012, while in 2013 and 2014 hospital outpatient specialty expenditures accounted for 40 percent (2013) and 39 percent (2014) of total medical specialty expenditures.

Of the most common site of services for specialty drug administration, hospital outpatient tends to be the most expensive as discussed in chapter 2. While the UPlan trends for 2006 to 2012 are not in line with what is observed in the industry, by 2013 and 2014 they are in line. The 2013 and 2014 data for the UPlan shows that hospital outpatient had the highest cost per specialty claim.

This observation from the UPlan leads to several questions. First, what market place or contractual changes occurred between the UPlan health plan (medical benefit vendor) and health systems and provider groups between 2012 and 2013 that resulted in such a huge shift of drugs being administered under hospital outpatient? Second, what specific hospital outpatient sites from health systems and provider groups saw an increase in the flow of patients for specialty drug administration after 2013? Third, what is the role of a health plan (medical benefit vendor) in informing a client like the UPlan about such a significant shift in site of services? Fourth, what type of reporting and strategies

should be presented to a client like the UPlan regarding site of service issues.

First, based on the data available for this study, it is unclear what market place or contractual changes occurred between the health plan for the UPlan and health systems. However, given the dramatic shift of claims and expenditures from 2012 to 2013 something changed. Or a number of physician's office clinics could have been purchased by hospitals, and reclassified as hospital outpatient settings. But, with aggregated data at the HCPCS level with no claim line detail, it is not possible to identify specifically what took place. Second, if detailed claims data was available at the claim line level, it would be possible to identify which providers and health systems saw an uptake of patients in their hospital outpatient facilities for specialty drug administration in 2013. Third, given that more and more drugs are flowing through the medical benefit, it is important for health plans that manage the medical benefit to keep clients like the UPlan in the loop concerning these types of changes and trends. Fourth, a client like the UPlan should expect in-depth reporting quarterly and as requested as to what drugs are flowing through what sites of services as well as other trends that are being observed, such as a massive shift from one site of service to another. As employers like the UPlan expect reporting from their PBMs regarding drug trends, employers should expect a similar level of reporting from their health plans regarding drugs that are flowing under the medical benefit. This reporting should not just be at the aggregated HCPCS level, but it should also be available at the detailed claim line level. That way an employer like the UPlan gets a high level of information on trends observed, and can have the option to dig deeper to identify specific issues that should be addressed.

Evaluating medical specialty drug trends by site of care is important. Differences observed in the cost per claim by site of service demonstrate that employers should have management strategies that addresses site of service differences. A variety of approaches to site of service management are available for employers. One strategy is a restrictive strategy where the plan restricts or limits where a patient can get a drug administered under the medical benefit. Usually, in this scenario, patients get restricted to the physician's office or patient's home sites of service, rather than the hospital outpatient setting. However, there is a risk associated with such a strategy because first, prices at the physician's office and patient's home can go up. Secondly, what has been observed in the marketplace is an increased acquisition of physician's practices by hospital outpatient facilities. When these acquisitions happen, it limits the number of options patients have within a community to have their drugs administered. An alternative to limiting access to a particular site of service is known as site of service parity. In this approach, employers can place a limit on how much they will pay for a particular drug and its administration, and any site of service that is willing to accept that amount would be able to administer the drug. While appealing, the site of service parity concept has not yet taken off. Currently, the most common strategy being deployed focuses on restriction of site of service or moving patients from one site of service to another. Employers like the UPlan can work with their health plan to identify the best approach to managing site of services issues.

## **5.5 Specialty drugs used across pharmacy and medical benefits (Aim 4)**

An evaluation of drug and drug-related products flowing through both the pharmacy and medical benefit shows that there is variation in the expenditures per claim for the same drugs, as well as in PMPY. A key observation of drugs used for autoimmune disorders is that there are multiple drugs available that may be used under both the pharmacy and medical benefit. Many of the 35 drugs found flowing through the pharmacy and medical benefits show that the expenditure per claim tends to be higher under the medical benefit in most cases. For example, drugs for autoimmune conditions demonstrate variation in the per claim expenditure and PMPY for drugs such as Remicade (infliximab), Stelara (ustekinumab) and Orencia (abatacept). The differences found under both the pharmacy and medical benefits lead to some key questions.

Should drug management across pharmacy and medical benefits be at the drug level or at the disease state level? This is an important question, because if the drug management strategy is at the drug level then the big picture of the disease specific management may be lost. This is because there may be multiple drugs that can be used across benefit types for the one disease state. However, if drug management strategies were based on disease specific indications, then the number and types of drugs to manage that disease across the benefits can be selected and monitored. That way all of the drugs that can possibly be identified for that disease state can be evaluated and selected. For example, take into account the disease indications of plaque psoriasis and psoriatic arthritis. These two indications can be treated with some of the top expenditure drugs, such as Remicade, Stelara, Humira and Enbrel. Humira and Enbrel are under the

pharmacy benefit while Remicade is observed under the medical benefit, and Stelara is available across both the pharmacy and medical benefits. While all of these drugs may be used to treat the same indications, a clear variation in the PMPY and per claim expenditure for these drugs is observed, as was discussed in Chapter 4. As discussed in Chapter 2, this difference in distribution across channels may require development of strategies for both the pharmacy and medical benefits. With recent moves by major PBMs and health plans to combine their efforts through mergers and acquisitions, the management of drugs across benefits channels continues to gain attention and traction.

The average per claim expenditure under the pharmacy benefit may vary for the same drug within the pharmacy benefit, and under the medical benefit, the average per claim expenditure under the medical benefit may have a range, too. This variation in the per claim expenditures of the same product across and within the benefit types raises some key questions:

1. Should the specialty drug be reimbursed under the pharmacy benefit or the medical benefit or both for the UPlan?
2. Should the specialty drug be reimbursed at the same rate under the pharmacy benefit and the medical benefit for the UPlan? If not, why different rates?
3. Are specific medical providers and pharmacies billing for the same drug at a different rate than other providers? Why, and is it justified?
4. Are the expenditure per claim differences between pharmacy and medical benefits driven by differences in units of reporting, by differences in acquisition cost, or by other factors?

If pharmacy identification variables such as NPI and NCPDP were provided on specific claims, determination of specific pharmacies with higher per claim expenditures would have been possible. For claims under the medical benefit, if the number of units along with unit of measure used were provided, then an evaluation could have shown the expenditure per unit, thus allowing comparison of the per unit difference between the pharmacy and medical benefit. For example, for oral drugs it is possible that under the medical benefit individuals are only getting one or two doses or units of a drug, while under the pharmacy benefit, claims may represent a month's supply or more.

## **5.6 Study limitation**

The key limitation for this study is the use of aggregated administrative claims data vs. detailed claim line administrative claims for both pharmacy and medical benefits. A detailed discussion of the study limitations for both pharmacy and medical claims data is provided in Chapter 3, section 3.7. For employers to identify meaningful and actionable issues, it is critical to have detailed claims level data. Additionally, achieving as much consistency as possible between the type of data provided under the medical benefit and the pharmacy benefit is important. For example, each claim under the pharmacy benefit is for a specific drug product identified at the NDC level, while NDCs are not traditionally reported for the drugs listed on a medical benefit claim. It is important that employers demand and require reporting of NDC codes and number of units on individual drug claims under the medical benefit. Having consistency between the pharmacy and medical benefits when it comes to key fields such as product identifiers (e.g., NDCs) or units of administration, makes it easier to evaluate and manage drug utilization and expenditures across the pharmacy and medical benefits. For this study,

HCPCS were used to identify drugs under the medical benefit while NDCs were used under the pharmacy benefit. The use of HCPCS codes, while somewhat useful, does not provide the same level of detail about each drug product as does the NDC code. For example, the HCPCS code cannot distinguish whether a brand or generic version of the drug was used, while the NDC code is for a specific drug manufacturer and can make this distinction.

## **5.7 Study implications and conclusions**

This study provides key findings with practical and important implications for the UPlan and decision makers. First, it shows that any of the specialty drug and drug-related product utilization and expenditure trends observed in aggregate by the industry across pharmacy and medical benefits are also observed under the UPlan. This confirms the need and importance of specialty drug management strategies across the pharmacy and medical benefits by the UPlan.

Second, a key implication of this study is that it shows the UPlan the share and rate of growth for specialty drug expenditures under the medical benefit. Like other self-insured employers, the UPlan is just beginning to understand the role and impact of drugs under the medical benefit on total drug and drug-related expenditures. That being the case, among its peers in the Minnesota employer market, the UPlan is making substantial progress in addressing drug management under the medical benefit. This study confirms the need for the same attention in drug management under the medical benefit as under the pharmacy benefit, as drugs flowing through the medical benefit continue to take a growing share of total drug expenditures, both for specialty and non-specialty drugs.

Third, this study highlights the presence of variation in cost per claim for the same drug in the same time period across and among providers under the pharmacy benefit and the medical benefit. This has huge implications in that it shows the importance of evaluating claims across sites of care, and also from provider to provider to identify why variation in expenditure for the same product exists. An important note for this effort is the need for detailed claims level data, and not aggregated data such as was provided for this study. While it is important to do this for both pharmacy and medical claims, it is especially critical under the medical benefit. A process for management of drugs under the medical benefit is under continuing development for the UPlan. Variation in expenditures for the same product shows the need for a more involved drug management strategy under the medical benefit, as discussed in Chapter 2.

Fourth, this study raises the question of drug management across pharmacy and medical benefits based at the disease state level. This approach is not widely practiced in the industry, in general. However, a coordinated strategy may prove to be an efficient drug management approach, especially for common conditions that have multiple drugs flowing through both pharmacy and medical benefits. With major health plans and PBMs now merging together (e.g., Aetna and Caremark CVS), this type of management approach becomes more feasible, as the administrative burden of coordinating across benefits may be lessened within one organization rather than two separate organizations.

This study demonstrates to UPlan decision-makers the importance of having key data elements collected and available for analysis. Without the right data elements available, proper comparison and evaluations cannot be made. This limits the full scope of understanding of the trends that may be present within pharmacy and medical claims



data. Not only does this study bring value to the UPlan, but other stakeholders concerned with the management of specialty drugs may also benefit. Specifically, this study provides a well-rounded picture of specialty drug distribution and utilization trends over time for the employer-sponsored health plans. In addition, it provides insights into possible approaches to better manage both the distribution and the safe and appropriate use of specialty drugs. This study identifies where the pharmacy benefit and the medical benefit overlap in terms of specialty drug coverage and distribution for a self-funded employer.

In conclusion, for effective data analysis of drug and drug-related utilization and expenditures across the pharmacy and medical benefits, detailed claim level access and analysis is critical. Without detailed claim level data and analysis, critical details are missing and appropriate comparisons cannot be made. Overall, drug and drug-related expenditures have grown substantially from 2006 to 2014. The percentage of total drug expenditures accounted for by the medical benefit is growing overtime while from 2007 to 2014 it has been going down under pharmacy benefit. There is a notable growth in expenditures for specialty drugs under both the pharmacy and medical benefits. Both traditional and specialty drug and drug-related management strategies need to be applied across the pharmacy benefit and the medical benefit. Developing disease specific drug management policies may be an efficient management strategy for drugs that flow through both the pharmacy benefit and the medical benefit. Specialty drugs generally account for a very small percentage of the total drug claims, but they account for a disproportionately higher percentage of the growing total drug expenditures. A small number of therapeutic categories account for greater than 50 percent of total specialty

drug expenditures. Management strategies should start by focusing on drugs that belong to the top therapeutic categories that are driving specialty expenditure trends across both the pharmacy benefit and the medical benefit.

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**APPENDICES**

**Appendix 1**

<b>Pharmacy Claim Data Elements</b>			
<b>Data Element Type</b>	<b>Short Name</b>	<b>Long Name</b>	<b>Description</b>
Benefit Design	Frmly Tier	Formulary Tier	Formulary tier of claim; 1 = tier 1 (generic plus); 2 = tier 2 (formulary brand) 4 = tier 3 (non-formulary brand); 5 = 0 = not covered
Benefit Design	STInd	Step Therapy Indicator	Indicates claim required step therapy process
Benefit Design	PAInd	Prior Authorization Indicator	Indicates claim required prior authorization process
Benefit Design	PA Reason	Prior Authorization Reason	Reason prior authorization is required
Benefit Design	PA Eff Date	Prior Authorization Effective date	Date that prior authorization approval begins
Benefit Design	PA End Date	Prior Authorization End Date	Date that prior authorization approval ends
Benefit Design	FrmlyInd	Formulary Indicator	Formulary status of claim (1= on formulary; 0= not on formulary)
Claim descriptor	Claim ID	Claim ID	Unique claim ID number added by the claim processor (PBM)
Claim descriptor	Rx Nmbr	Prescription Number	Unique prescription number assigned by the pharmacy
Claim descriptor	Refill #	Refill Number	Indicates the number of refills remaining
Clinical	%DAW	% of Rx's as DAW	Percent of claims with DAW code > 0
Clinical	DAW	Dispense as Written	Dispensed as written code (0-9)
Clinical	MTMInd	Drug Therapy Management Indicator	Indicates whether an MTM service was delivered to this patient for this prescription

Data	Yr Mo	Year Month	Code indicating the year and month of the claim (i.e., 2017 01)
Date	DateSub	Date Submitted	Indicates the date the claim was submitted
Date	Date Svc	Date of service	Indicates the date the prescription claim was filled
Distribution channel	Spec Ind	Specialty Indicator	Indicates prescription was processed through specialty pharmacy
Distribution channel	Mail Order Ind	Mail Order Indicator	Indicates prescription was processed through mail order pharmacy
Distribution channel	Spec Ind	Specialty Indicator	Indicates if the drug was processed through specialty pharmacy
Distribution channel	Retail Ind	Retail Indicator	Indicates if the drug was processed through a Retail pharmacy
Distribution channel	Mail Order Ind	Mail Order Indicator	Indicates if the drug was processed through a mail order pharmacy
Distribution channel	PhrNet	Pharmacy Network	Indicates drug was processed by a pharmacy network pharmacy
Distribution channel	NCPDP #	National Council for Prescription Drug Programs Number	Pharmacy ID; a number that uniquely identifies each pharmacy (National Council for Prescription Drug Programs (NCPDP) code)
Distribution channel	Phrm Name	Pharmacy Name	Pharmacy name or DBA name
Distribution channel	PhrmType	Pharmacy Type	Pharmacy Type based on NCPDP categories
Distribution channel	Phrm City	Pharmacy City	City of pharmacy location
Distribution channel	Phrm State	Pharmacy State	State of pharmacy location
Distribution channel	Phrm Zip Code	Pharmacy Zip Code	Zip code of pharmacy location
Distribution channel (Place of service)	ClamType	Claim type	Claim type indicating source of claim
Distribution channel (Place of service)	ClamType	Claim type	S=Specialty pharmacy M=Mail order MR=Mail at Retail R=Retail
Financial	Total\$	Total paid	Total amount paid (plan paid amount plus member paid amount)

Financial	Plan Pd	Plan paid	Plan amount paid per claim
Financial	Mbr Pd	Member Paid	Member amount paid per claim
Financial	Ing Cost	Ingredient cost	The drug product ingredient cost allowed for the claim
Financial	Disp Fee	Dispensing Fee	Fee allowed for dispensing
Financial	Sales Tax	Sales tax	Sales Tax (if any) for a given state; in MN this is the MN Wholesale Drug Tax (~2% of the actual ingredient cost)
Financial	Inc Fee	Incentive fee	Incentive fee amount paid per claim, if any, paid to the pharmacy such as \$0.50 per generic prescription.
Financial	COB	Coordination of Benefits	Amount paid by other third party payers for this claim
Financial	PrfSvcFee	Professional Service Fee	Prof. service fee paid amount per claim; fee for special services such as \$15.00 for vaccine administration
Financial	Copay	Copay	Copay amount paid per prescription claim
Financial	U&C\$	Usual & Customary Price	Pharmacy's usual & customary price per claim
Member identifier	MemberID	Member identification	Member ID # (actual or de-identified)
Member identifier	Mbrage	Member Age	Member age in years
Member identifier	Gender	Gender	M=male; F=female
Plan identifier	Account ID	Account Identification	Code that identifies the specific plan type
Plan identifier	AccountDescr	Account Description	Text description of the plan type
Plan identifier	Group ID	Group Identification	Code that identifies a specific group member category
Plan identifier	GroupDescr	Group Description	Text description of a specific group member category
Plan identifier	Carrier ID	Carrier Identification	Code that identifies the insurance carrier
Plan identifier	CarrierDscr	Carrier Description	Text description of the insurance carrier
Product Identifier	Label Name	Brand Name	Official brand name of a drug product (if any).



Product Identifier	GPI Generic Name	Generic Product Indicator name	MediSpan's GPI (generic product indicator) generic name
Product Identifier	Package Qty	Package Quantity Dispensed	How many packages were dispensed
Product Identifier	Prod Pkg Size	Product Package Size	Package Size represents the total number of units per package. [Oral suspensions for reconstitution use the quantity per package after reconstitution
Product Identifier	SzUM	Package Standard Unit of Measure (SUM)	Package Standard Unit of Measure (SUM) is the unit of measure for the package size amount reported; i.e., ea, or ml for liquids..
Product Identifier	RteAdm	Route of Administration	The route by which the drug is administered (i.e. Oral, Injectable, Infusion)
Product Identifier	SpecRx	Specialty Prescription	Indicates the drug product is considered to be a specialty
Product Identifier	NDC	National Drug Code	NDCs are an 11-digit code uniquely identifying the drug product. When there is no NDC code this field may contain a UPC or an HRI code. These codes are converted to 11-character codes according to NCPDP standards.
Provider identifier	Prscr ID Type	Prescriber Type	Prescriber type (physician, dentist, nurse practitioner, etc)
Provider identifier	Prscr Name	Prescriber name	Last Name, First name, M.I.
Provider identifier	PrscrSpecialty	Prescriber Specialty	Prescriber specialty description
Provider identifier	PrscrCity	Prescriber City	City of prescriber's practice
Provider identifier	PrscrState	Prescriber State	State of prescriber's practice
Provider identifier	Prscr Zip Code	Prescriber Zip Code	Zip code for prescriber's practice
Provider identifier	Prescriber ID	Prescriber Identification	Prescriber ID (either NPI # or DEA #)
Utilization	#Utilizers	Number of Utilizers	Number of Utilizers per Claim (should be 1)
Utilization	#Claims	Number of Claims	Number of Claims per Line (should be 1)
Utilization	Qty	Quantity	Amount of drug dispensed per claim
Utilization	Days	Day supply	Days supply dispensed per claim

Utilization	ESN	Extended Supply Network	Indicates drug was processed by a pharmacy in the Extended Supply Network (ESN)
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## Appendix 2

<b>Appendix 2. CMS Place of Service Code Set for Facility Based Claims<sup>1011</sup></b>		
<b>Place of Service Code(s)</b>	<b>Place of Service Name</b>	<b>Place of Service Description</b>
<b>21</b>	Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions
<b>22</b>	Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
<b>23</b>	Emergency Room Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.
<b>24</b>	Ambulatory Surgical Center	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis
<b>26</b>	Military Treatment Facility	A medical facility operated by one or more of the Uniformed Services, Military Treatment Facility (MTF) also refers to certain former U.S. Public Health Service (USPHS) facilities now designated as Uniformed Service Treatment Facilities (USTF).
<b>31</b>	Skilled Nursing Facility	A facility which primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services but does not provide the level of care or treatment available in a hospital.
<b>34</b>	Hospice	A facility, other than a patient's home, in which palliative and supportive care for terminally ill patients and their families are provided
<b>41</b>	Ambulance Land	A land vehicle specifically designed, equipped and staffed for lifesaving and transporting the sick or injured.
<b>42</b>	Ambulance Air or Water	An air or water vehicle specifically designed, equipped and staffed for lifesaving and transporting the sick or injured.
<b>51</b>	Inpatient Psychiatric Facility	A facility that provides inpatient psychiatric services for the diagnosis and treatment of mental illness on a 24 hour basis, by or under the supervision of a physician.
<b>52</b>	Psychiatric Facility Partial Hospitalization	A facility for the diagnosis and treatment of mental illness that provides a planned therapeutic program for patients who do not require full time hospitalization, but who need broader programs than are possible from outpatient visits to a hospital based or hospital affiliated facility

<sup>10</sup> Centers for Medicare and Medicaid Services. Medicare Fee-For Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File: A Methodological Overview. Updated 9/14/2015. Retrieved on 1/8/2016. Retrieved from: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicare-provider-charge-data/downloads/medicare-physician-and-other-supplier-puf-methodology.pdf>

<sup>11</sup> Medical Claims Processing Manual: Chapter 26-Completing and Processing Form CMS-1500 Data Set. Updated:8/6/2015. Retrieved on 1/21/2016. Retrieved from: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

53	Community Mental Health Center	A facility that provides the following services: outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health services area who have been discharged from inpatient treatment at mental health facility; 24 hour a day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission; and consultation and education services.
56	Psychiatric Residential Treatment Center	A facility or distinct part of a facility for psychiatric care which provides a total 24 hour therapeutically planned and professionally staffed group living and learning environment.
61	Comprehensive Inpatient Rehabilitation Facility	A facility that provides comprehensive rehabilitation services under the supervision of a physician to inpatients with physical disabilities. Services include physical therapy, occupational therapy, speech pathology, social or psychological services, and orthotics and prosthetics services.

### Appendix 3

<b>CMS Place of Service Code Set for Professional Based Claims<sup>12</sup></b>		
<b>Place of Service Code(s)</b>	<b>Place of Service Name</b>	<b>Place of Service Description</b>
<b>01</b>	Pharmacy **	A facility or location where drugs and other medically related items and services are sold, dispensed, or otherwise provided directly to patients. (Effective October 1, 2003)
<b>02</b>	Unassigned	N/A
<b>03</b>	School	A facility whose primary purpose is education.(Effective January 1, 2003)
<b>04</b>	Homeless Shelter	A facility or location whose primary purpose is to provide temporary housing to homeless individuals (e.g., emergency shelters, individual or family shelters). (Effective January 1, 2003)
<b>05</b>	Indian Health Service Free-standing Facility	A facility or location, owned and operated by the Indian Health Service, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to American Indians and Alaska Natives who do not require hospitalization. (Effective January 1, 2003)
<b>06</b>	Indian Health Service Provider-based Facility	A facility or location, owned and operated by the Indian Health Service, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services rendered by, or under the supervision of, physicians to American Indians and Alaska Natives admitted as inpatients or outpatients. (Effective January 1, 2003)
<b>07</b>	Tribal 638 Free-standing Facility	A facility or location owned and operated by a federally recognized American Indian or Alaska Native tribe or tribal organization under a 638 agreement, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to tribal members who do not require hospitalization. (Effective January 1, 2003)
<b>08</b>	Tribal 638 Provider-based Facility	A facility or location owned and operated by a federally recognized American Indian or Alaska Native tribe or tribal organization under a 638 agreement, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to tribal members admitted as inpatients or outpatients. (Effective January 1, 2003)

<sup>12</sup> Centers for Medicare and Medicaid Service. Place of Service Codes for Professional Claims. Retrieved from [https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place\\_of\\_Service\\_Code\\_Set.html](https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html)

<b>09</b>	Prison/ Correctional Facility	A prison, jail, reformatory, work farm, detention center, or any other similar facility maintained by either Federal, State or local authorities for the purpose of confinement or rehabilitation of adult or juvenile criminal offenders. (Effective July 1, 2006)
<b>10</b>	Unassigned	
<b>11</b>	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
<b>12</b>	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.
<b>13</b>	Assisted Living Facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hours a day, 7 days a week, with the capacity to deliver or arrange for services including some health care and other services. (Effective October 1, 2003)
<b>14</b>	Group Home *	A residence, with shared living areas, where clients receive supervision and other services such as social and/or behavioral services, custodial service, and minimal services (e.g., drug administration). (Effective October 1, 2003)
<b>15</b>	Mobile Unit	A facility/unit that moves from place-to-place equipped to provide preventive, screening, diagnostic, and/or treatment services.(Effective January 1, 2003)
<b>16</b>	Temporary Lodging	A short term accommodation such as a hotel, camp ground, hostel, cruise ship or resort where the patient receives care, and which is not identified by any other POS code.(Effective January 1, 2008)
<b>17</b>	Walk-in Retail Health Clinic	A walk-in health clinic, other than an office, urgent care facility, pharmacy or independent clinic and not described by any other Place of Service code, that is located within a retail operation and provides, on an ambulatory basis, preventive and primary care services. (This code is available for use immediately with a final effective date of May 1, 2010)
<b>18</b>	Place of Employment- Worksite	A location, not described by any other POS code, owned or operated by a public or private entity where the patient is employed, and where a health professional provides on-going or episodic occupational medical, therapeutic or rehabilitative services to the individual. (This code is available for use effective January 1, 2013 but no later than May 1, 2013)
<b>19</b>	Off Campus- Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick

		or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
20	Urgent Care Facility	Location, distinct from a hospital emergency room, an office, or a clinic, whose purpose is to diagnose and treat illness or injury for unscheduled, ambulatory patients seeking immediate medical attention. (Effective January 1, 2003)
21	Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22	On Campus-Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)
23	Emergency Room – Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.
24	Ambulatory Surgical Center	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.
25	Birthing Center	A facility, other than a hospital's maternity facilities or a physician's office, which provides a setting for labor, delivery, and immediate post-partum care as well as immediate care of new born infants.
26	Military Treatment Facility	A medical facility operated by one or more of the Uniformed Services. Military Treatment Facility (MTF) also refers to certain former U.S. Public Health Service (USPHS) facilities now designated as Uniformed Service Treatment Facilities (USTF).
27-30	Unassigned	N/A
31	Skilled Nursing Facility	A facility which primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services but does not provide the level of care or treatment available in a hospital.
32	Nursing Facility	A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than mentally retarded individuals.

33	Custodial Care Facility	A facility which provides room, board and other personal assistance services, generally on a long-term basis, and which does not include a medical component.
34	Hospice	A facility, other than a patient's home, in which palliative and supportive care for terminally ill patients and their families are provided.
35-40	Unassigned	N/A
41	Ambulance - Land	A land vehicle specifically designed, equipped and staffed for lifesaving and transporting the sick or injured.
42	Ambulance - Air or Water	An air or water vehicle specifically designed, equipped and staffed for lifesaving and transporting the sick or injured.
43-48	Unassigned	N/A
49	Independent Clinic	A location, not part of a hospital and not described by any other Place of Service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only. (Effective October 1, 2003)
50	Federally Qualified Health Center	A facility located in a medically underserved area that provides Medicare beneficiaries preventive primary medical care under the general direction of a physician.
51	Inpatient Psychiatric Facility	A facility that provides inpatient psychiatric services for the diagnosis and treatment of mental illness on a 24-hour basis, by or under the supervision of a physician.
52	Psychiatric Facility- Partial Hospitalization	A facility for the diagnosis and treatment of mental illness that provides a planned therapeutic program for patients who do not require full time hospitalization, but who need broader programs than are possible from outpatient visits to a hospital-based or hospital-affiliated facility.
53	Community Mental Health Center	A facility that provides the following services: outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health services area who have been discharged from inpatient treatment at a mental health facility; 24 hour a day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission; and consultation and education services.
54	Intermediate Care Facility/ Individuals with	A facility which primarily provides health-related care and services above the level of custodial care to individuals but does not provide the level of care or treatment available in a hospital or SNF.



	Intellectual Disabilities	
55	Residential Substance Abuse Treatment Facility	A facility which provides treatment for substance (alcohol and drug) abuse to live-in residents who do not require acute medical care. Services include individual and group therapy and counseling, family counseling, laboratory tests, drugs and supplies, psychological testing, and room and board.
56	Psychiatric Residential Treatment Center	A facility or distinct part of a facility for psychiatric care which provides a total 24-hour therapeutically planned and professionally staffed group living and learning environment.
57	Non-residential Substance Abuse Treatment Facility	A location which provides treatment for substance (alcohol and drug) abuse on an ambulatory basis. Services include individual and group therapy and counseling, family counseling, laboratory tests, drugs and supplies, and psychological testing. (Effective October 1, 2003)
58-59	Unassigned	N/A
60	Mass Immunization Center	A location where providers administer pneumococcal pneumonia and influenza virus vaccinations and submit these services as electronic media claims, paper claims, or using the roster billing method. This generally takes place in a mass immunization setting, such as, a public health center, pharmacy, or mall but may include a physician office setting.
61	Comprehensive Inpatient Rehabilitation Facility	A facility that provides comprehensive rehabilitation services under the supervision of a physician to inpatients with physical disabilities. Services include physical therapy, occupational therapy, speech pathology, social or psychological services, and orthotics and prosthetics services.
62	Comprehensive Outpatient Rehabilitation Facility	A facility that provides comprehensive rehabilitation services under the supervision of a physician to outpatients with physical disabilities. Services include physical therapy, occupational therapy, and speech pathology services.
63-64	Unassigned	N/A
65	End-Stage Renal Disease Treatment Facility	A facility other than a hospital, which provides dialysis treatment, maintenance, and/or training to patients or caregivers on an ambulatory or home-care basis.
66-70	Unassigned	N/A

<b>71</b>	Public Health Clinic	A facility maintained by either State or local health departments that provides ambulatory primary medical care under the general direction of a physician.
<b>72</b>	Rural Health Clinic	A certified facility which is located in a rural medically underserved area that provides ambulatory primary medical care under the general direction of a physician.
<b>73-80</b>	Unassigned	N/A
<b>81</b>	Independent Laboratory	A laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a physician's office.
<b>82-98</b>	Unassigned	N/A
<b>99</b>	Other Place of Service	Other place of service not identified above.

## Appendix 4

Primary Dispenser Type Code	
Code	Code value
0	No longer allowed for new provider entries. Existing value "00" entries will be converted over time by NCPDP.
1	<b><u>Community/Retail Pharmacy</u></b> defined as a pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes. Associated taxonomy code is "3336C0003X".
2	No longer used. Value "02" converted to "01" by NCPDP.
3	No longer used. Value "03" converted to "01" by NCPDP.
4	<b><u>Long Term Care Pharmacy</u></b> defined as a pharmacy that dispenses medicinal preparations delivered to patients residing within an intermediate or skilled nursing facility, including intermediate care facilities for mentally retarded, hospice, assisted living facilities, group homes, and other forms of congregate living arrangements. Associated with taxonomy code "3336L0003X".
5	<b><u>Mail order pharmacy</u></b> defined as a pharmacy where pharmacists compound or dispense prescriptions or other drugs in accordance with federal and state law, using common carriers to deliver the drugs to patient or their caregivers. Mail order pharmacies counsel patients and caregivers (sometimes independent of the dispensing process) through telephone or email contact and provide other professional services associated with pharmaceutical care appropriate to the setting. Mail order pharmacies are licensed as a Mail Order Pharmacy in the state where they are located and may also be licensed or registered as nonresident pharmacies in other states. Associated with taxonomy code "3336M0002X".
6	<b><u>Home Infusion Therapy Provider</u></b> defined as a pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance. Associated with taxonomy code "3336H0001X".
7	<b><u>Non-pharmacy dispensing site</u></b> defined as a site other than a pharmacy that dispenses medicinal preparations under the supervision of a physician to patients for self-administration. (e.g. physician offices, ER, Urgent Care Centers, Rural Health Facilities, etc.) Associated with taxonomy code "332900000X".

8	<p><b><u>Indian Health Service/Tribal/Urban Indian Health (I/T/U) Pharmacy</u></b> defined as a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in Section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603. Associated with taxonomy code "332800000X".</p>
9	<p><b><u>Department of Veterans Affairs (VA) Pharmacy</u></b> defined as any place under VA jurisdiction where drugs are dispensed and Pharmaceutical Care is provided to enrolled Veterans, by licensed pharmacists. The Pharmacy is reviewed by JCAHO, utilizes the VA hospital's DEA number, and has a designated NCPDP number. VA facility pharmacies include Inpatient (Institutional), Outpatient, Consolidated Mail Outpatient Pharmacies, Research, Addiction Treatment Centers, Long Term Care and Community Based Outpatient Clinics Pharmacies. The VA Pharmacy Benefits Management – Strategic Healthcare Group has oversight for professional and practice activities of VA Pharmacies. Each pharmacy is under the direct supervision of a U.S. or U.S. territory licensed pharmacist, and has staffing to meet its designated scope of service. Associated with taxonomy code "332100000X".</p>
10	<p>No longer used. Value "10" converted to "11" by NCPDP.</p>
11	<p><b><u>Institutional pharmacy defined</u></b> as a pharmacy in a hospital (inpatient) or institution used by pharmacists for the compounding and delivery of medicinal preparations to be administered to the patient by nursing or other authorized personnel. Institutional Pharmacies also counsel patients and caregivers; administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes. Associated with taxonomy code "3336I0012X"</p>
12	<p><b><u>Managed Care Organization (MCO) Pharmacy</u></b> defined as a pharmacy owned by an MCO used by pharmacists for the compounding and dispensing of medicinal preparations to that MCO's covered members only. Associated with taxonomy code "3336M0003X".</p>
13	<p><b><u>Durable Medical Equipment (DME) Provider</u></b> defined as a supplier of medical equipment such as respirators, wheelchairs, home dialysis systems, or monitoring systems, that are prescribed by a physician for a patient's use. Associated with taxonomy code "332B00000X".</p>
14	<p><b><u>Clinic Pharmacy</u></b> defined as a pharmacy in a clinic, emergency room or hospital (outpatient) that dispenses drugs to patients for self-administration under the supervision of a pharmacist. Associated with taxonomy code "3336C0002X".</p>
15	<p><b><u>Specialty Pharmacy</u></b> defined as a pharmacy that dispenses generally low volume and high cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex and potentially life threatening. Often these therapies require specialized delivery and administration. Associated with taxonomy code "3336S0011X".</p>
16	<p><b><u>Nuclear Pharmacy</u></b> defined as a pharmacy dedicated to the compounding and dispensing of radioactive materials for use in nuclear imaging and nuclear medical procedures. Associated with taxonomy code "3336N0007X".</p>

17	<p><b><u>Military/US Coast Guard Pharmacy</u></b> defined as a Department of Defense (DoD) or U.S. Coast Guard entity whose primary function is to store, prepare and dispense pharmaceuticals and other associated items to Uniformed Services beneficiaries. These pharmacies may be associated with a DoD or U.S. Coast Guard clinic, DoD Hospital or freestanding. Usually associated with outpatient services. Associated with taxonomy code "332000000X".</p>
18	<p><b><u>Compounding Pharmacy</u></b> defined as a pharmacy that specializes in the preparation of components into a drug preparation as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/Patient/Pharmacist relationship in the course of professional practice. A compounding pharmacy utilizes specialized equipment and specially designed facilities necessary to meet the legal and quality requirements of its scope of compounding practice. Associated with taxonomy code "3336C0004X".</p>