MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH BENEFITS

PREFERRED DRUG LIST AND SUPPLEMENTAL REBATE PROGRAM

ANNUAL PUBLIC REPORT – STATE FISCAL YEAR 2016

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DEDICATED TO GOVERNMENT HEALTH PROGRAMS

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Executive Summary

The North Carolina Department of Health and Human Services, Division of Health Benefits (Division), has engaged Myers and Stauffer to provide an annual public report related to the Division's Preferred Drug List (PDL) and Supplemental Rebate Program as required by their Medicaid state plan. This annual report reflects the fiscal impact of the program, as well as the program impact on related services other than pharmacy for state fiscal year (SFY) 2016 (July 1, 2015 through June 30, 2016). Within this report, Myers and Stauffer evaluated the following:

- *Estimated cost savings associated with the PDL program.*
- *Estimated cost savings associated with the State's participation in the National Medicaid Pooling Initiative (NMPI) supplemental rebate program.*
- *Whether the PDL program impacted beneficiaries' access to PDL program medications.*
- *Whether the PDL program resulted in changes in expenditures and/or utilization of medical services (such as emergency department visits, inpatient hospital admissions, physician office visits, outpatient visits) and laboratory services.*

Background

Beginning in March 2002, the Division implemented a prior authorization (PA) process for certain prescription drugs. The selected drugs were chosen by a panel of clinical and academic physicians and pharmacists based on their cost and high potential for overuse in an effort to encourage and promote clinically appropriate use. In an effort to improve quality of care and reduce costs, the Community Care of North Carolina (CCNC) Clinical Directors developed and published the Prescription Advantage List (PAL) in November 2002. The PAL was a voluntary list intended as a guide to prescribe more cost-effective medications when clinically appropriate. Based on the success of the PAL, the Division implemented an updated PAL in November 2003. Because savings realized by enhancing the utilization management of the PAL were insufficient, the Division was directed to establish and implement a PDL with supplemental rebates by the North Carolina General Assembly in 2009.

As a result of Session Law 2009-451, Sections 10.66(a)-(d) the Division established a PDL and joined the NMPI supplemental rebate purchasing pool in March 2010. The NMPI is a multi-state Medicaid pharmaceutical purchasing pool administered by Magellan Medicaid Administration, Inc. The intent of multi-state purchasing pool programs is to allow participating state Medicaid programs to combine their covered lives and increase their negotiating power to obtain greater supplemental rebates and lower net drug costs.

Based upon Session Law 2014-100, Sections 12H.9(a)-(c), the Division was required to make adjustments to the PDL to maximize supplemental rebates for mental health drugs. This legislation also gave authority to the Division to impose prior authorization, utilization review criteria and other restrictions for mental health drugs. Effective June 2015, the Division implemented PDL updates regarding oral antipsychotic medications. These updates included showing preferred and non-preferred oral antipsychotics on the PDL, as well as requiring trial and

failure of one preferred antipsychotic without a prior authorization to obtain a non-preferred medication. Additionally, the Division reinstated their Off Label Antipsychotic Safety Monitoring in Beneficiaries through Age 17 (A+KIDS) and Off Label Antipsychotic Safety (ASAP-adults) programs. These programs require prior authorization for any preferred or non-preferred antipsychotic medication for children 17 years of age and younger or off label use for adults 18 and older.

The Division initially established 88 PDL therapeutic drug categories, including preferred and non-preferred medications. Drugs on the PDL are indicated as "preferred" or "non-preferred" based on therapeutic effectiveness, safety and clinical outcomes. Generally, "preferred" drugs do not require prior authorization unless there are other clinical coverage criteria requirements or quantity limits. "Non-preferred" drugs are available through prior authorization. For therapeutic drug categories that do not appear on the PDL, prescribers can prescribe drugs in these classes as appropriate unless clinical coverage criteria requiring prior authorization exist. *Chart 1* below and *Chart 2* on the following page illustrate the spend and claim breakdowns for SFY 2016 based upon PDL designation after exclusion of claims as noted on page 24. The 102 therapeutic drug categories included in the PDL program represented 78 percent of total spend and 83 percent of total claims during the study period. As illustrated below, spend for preferred drugs represented 63 percent of total spend and 81 percent of spend for medications subject to the PDL. Additionally, preferred drug claims represented 79 percent of total claims and 95 percent of claims subject to the PDL.

Chart 1: SFY 2016 Spend Breakdwon by PDL Designation

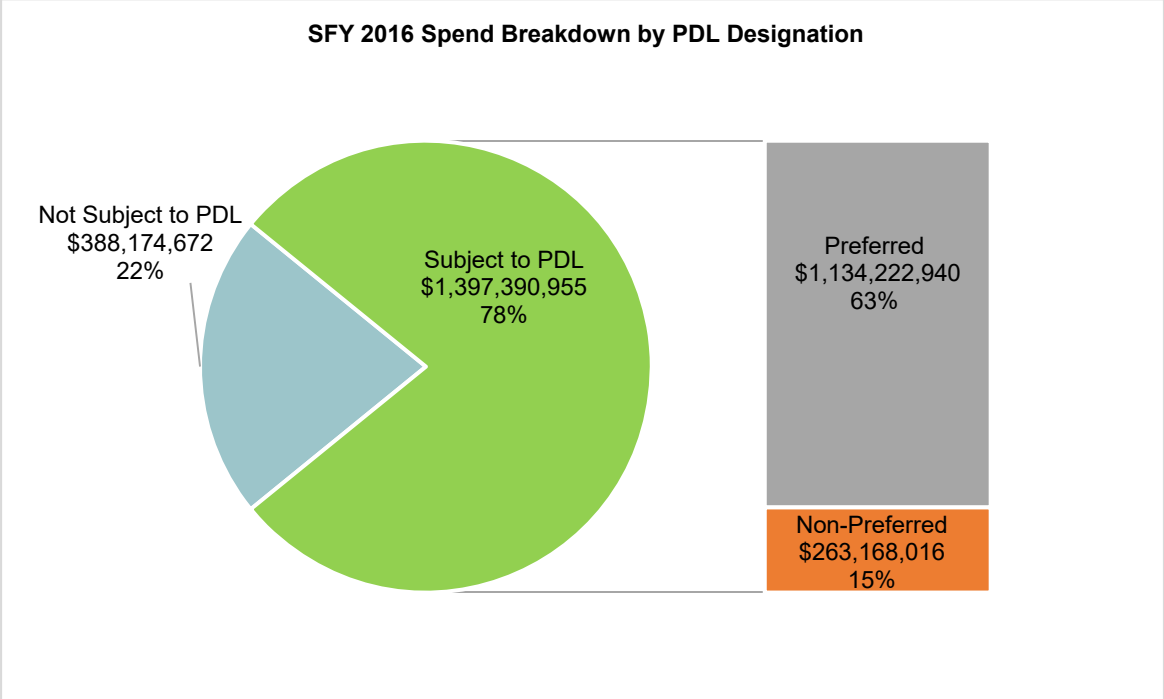
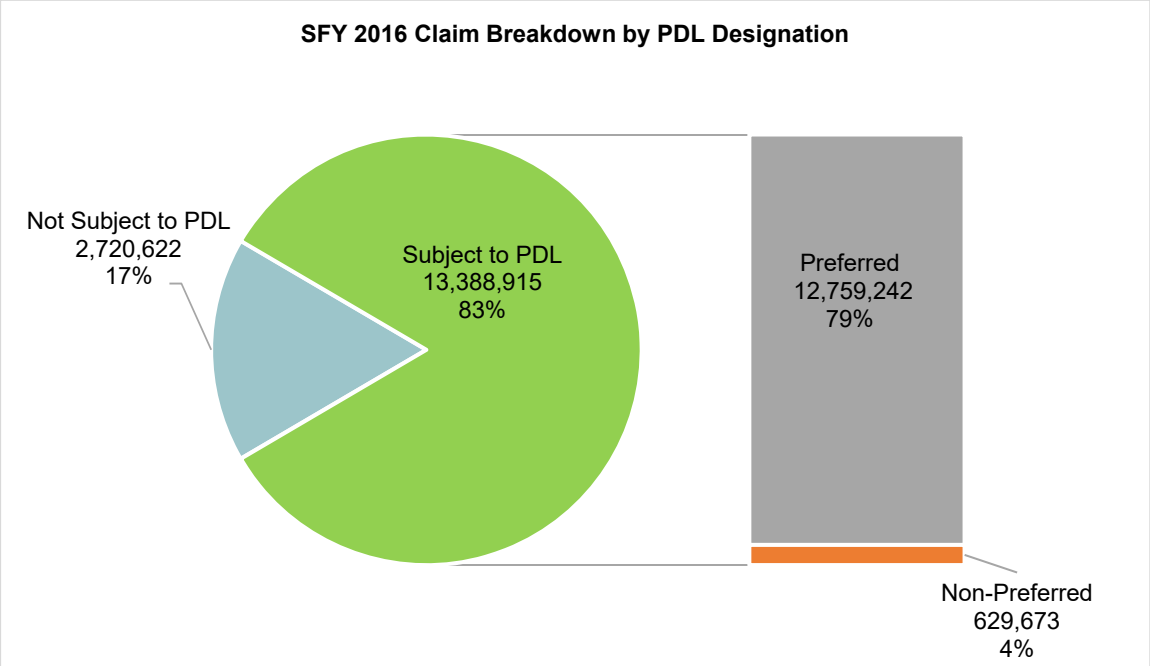


Chart 2: SFY 2016 Claim Breakdown by PDL Designation



The Division's PDL program has been in operation since 2010, consequentially the program and savings associated with it have remained relatively stable. Because the program is mature and stable, relatively few changes are made to the program each year. Prescribers' awareness of the program increases as the program ages which can impact prescribing habits. During SFY 2016, there were 102 therapeutic drug categories included on the PDL. PDL changes were made to a total of 63 therapeutic drug categories in November 2015, February 2016 and April 2016. The changes were minimal and only eight therapeutic drug categories had greater than five percent of claims shift based upon PDL changes. Due to this, the risk of impacting beneficiaries' access to PDL medications and utilization and/or expenditures on medical and laboratory services was low. The beta-blocker therapeutic drug category experienced the largest shift due to designating metoprolol succinate ER (generic Toprol XL®) as preferred and changing the brand drug to non-preferred. It is important to note that during this analysis, Myers and Stauffer can only determine association and not causality.

Summary of Results

Estimated Program Savings

For SFY 2016, Myers and Stauffer estimated the total net savings associated with the program components, as defined on page 7. The savings associated with the PDL, clinical PA and supplemental rebate programs were $225.5 million with a state share of $75.8 million. *Table 1* below illustrates the net PDL, clinical PA and supplemental rebate program savings by program component.

Table 1: SFY 2016 Savings by Program Component

Program Component	Total Savings	State Share
PDL Savings	$79,003,883.91	$26,742,814.70
Supplemental Rebate Collections	$83,795,574.19	$28,364,801.86
Market Shift Savings	$249,455.76	$84,440.77
Clinical PA Savings	$65,460,087.68	$22,158,239.68
Program Administrative Costs	$3,044,962.72	$1,522,481.36
Total Net PDL and Clinical PA Savings	**$225,464,038.81**	**$75,827,815.66**

After allocation of the program administrative costs, approximately $162.5 million, with a state share of $54.9 million, of the total net savings can be attributed to the Division's PDL and supplemental rebate programs and $62.9 million, with a state share of $20.9 million, can be attributed to the clinical PA program.

The top 10 therapeutic drug categories contributed to 67 percent of the total net savings associated with the PDL, clinical PA and supplemental rebate programs ($150.9 million with a state share of $51.1 million). *Table 2* highlights the top 10 therapeutic drug categories associated with the greatest overall program savings during the study period.

Table 2: Top 10 Therapeutic Drug Categories – Overall Program Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Hepatitis C agents	$40.4	$13.7	18%
Stimulants and related agents	$33.8	$11.4	15%
Antipsychotics	$32.7	$11.1	15%
Growth hormone	$7.9	$2.7	3%
Epinephrine, self-injected	$7.4	$2.5	3%
Opiate dependence treatments	$6.9	$2.3	3%
NSAIDs	$6.2	$2.1	3%
Bronchodilators, beta agonist	$5.6	$1.9	2%
Glucocorticoids, inhaled	$5.4	$1.8	2%
Anticoagulants	$4.6	$1.6	2%
Top 10 Total Savings	**$150.9**	**$51.1**	**67%**
Remaining Category Savings	**$74.6**	**$24.7**	**33%**
Total Program Net Savings	**$225.5**	**$75.8**	**100%**

Beneficiary Access to PDL Program Medications

Myers and Stauffer evaluated the impact of the PDL on beneficiaries' access to PDL program medications. The results of this analysis demonstrated that 7.5 percent of unique continuously eligible beneficiaries (86,865 out of 1,154,134) experienced a denied non-preferred point-of-sale pharmacy claim related to a pharmacy point-of-sale PDL edit and did not receive a subsequent paid claim within the same therapeutic drug category. For all therapeutic drug categories, 2.4 percent of beneficiaries with a denied non-preferred claim did not receive a paid claim within the same therapeutic drug category. This percentage is comparable to past years. Additionally, there were a small number (0.3 percent) of beneficiaries who reverted back to a non-preferred medication after switching to a preferred medication due to the PDL program changes in SFY 2016.

PDL Program Impact on Medical and Laboratory Services

Myers and Stauffer examined the PDL impact on medical and laboratory services. For most of the therapeutic drug categories that had PDL changes during the study period, the sample sizes were too small to perform a statically valid analysis; therefore, no statistically conclusive results could be drawn. Myers and Stauffer examined graphically two therapeutic drug categories with the largest study group sample sizes where beneficiaries had switched from non-preferred to preferred medications during the study period. In conclusion, it is unclear if the minor changes in medication therapy were due to the PDL or clinical prescriber intervention and, therefore, resulting changes in expenditures and/or utilization of medical and laboratory services should not be relied upon to evaluate the PDL impact.

PDL and PA Program Savings

Myers and Stauffer, calculated the estimated savings across all therapeutic drug categories associated with the PDL program effective in SFY 2016. The estimated savings calculations account for:

- *PDL savings, which are the savings, net of federal rebates, associated with denied point-of-sale outpatient pharmacy claims for non-preferred PDL medications. The PDL savings include the offset in savings due to alternate drug therapies dispensed within the market basket.*
- *Supplemental rebates collected from manufacturers as reported by the Division's supplemental rebate vendor.*
- *Market shift savings, which are the savings, net of federal rebates, associated with beneficiaries switching from a non-preferred medication to a preferred medication without a point-of-sale outpatient pharmacy claim denial.*
- *Clinical PA savings, which are the savings, net of federal rebates, associated with denied point-of-sale outpatient pharmacy claims for clinical edit codes. These savings are independent of the supplemental rebate program. This program requires PA for certain medications to ensure that clinically appropriate criteria are followed.*
    - *If the denied claim contained both clinical PA and PDL edit codes, the savings were accounted for in the clinical PA savings and not the PDL savings.*
- *Administrative costs associated with the program.*

Estimated Net Savings

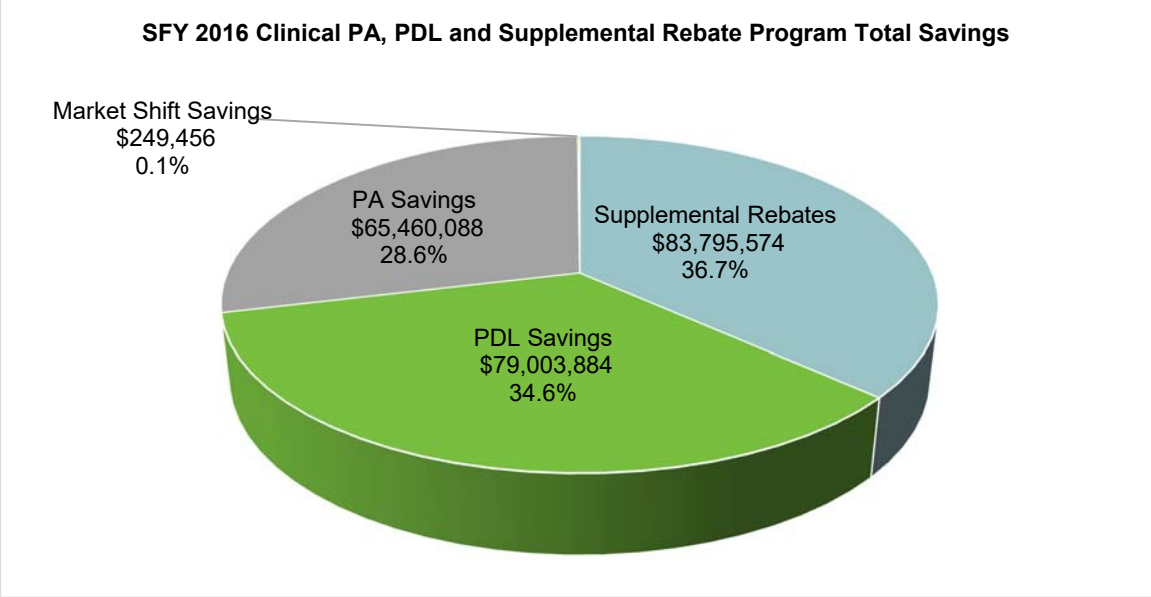
Myers and Stauffer estimated that the total net savings associated with the PDL, clinical PA and supplemental rebate programs were $225.5 million with a state share of $75.8 million. Of the total net savings, approximately $162.5 million, with a state share of $54.9 million, can be attributed to the Division's PDL and supplemental rebate programs and $62.9 million, with a state share of $20.9 million, can be attributed to the clinical PA program.

Table 3 and *Chart 3* on the following page illustrate the breakdown of savings, including both state and federal allocations.

Table 3: Clinical PA, PDL and Supplemental Rebate Program Savings

Program Component	Total	% of Total	Federal Share	State Share
PDL Savings	$79,003,883.91	N/A	$52,261,069.21	$26,742,814.70
Supplemental Rebate Collections	$83,795,574.19	N/A	$55,430,772.33	$28,364,801.86
PDL and Supplemental Rebate Administrative Costs	$521,742.50	N/A	$260,871.25	$260,871.25
Market Shift Savings	$249,455.76	N/A	$165,014.98	$84,440.77
Net PDL and Supplemental Rebate Savings	**$162,527,171.36**	**72%**	**$107,595,985.27**	**$54,931,186.09**
Clinical PA Savings	$65,460,087.68	N/A	$43,301,848.00	$22,158,239.68
Clinical PA Administrative Costs	$2,523,220.22	N/A	$1,261,610.11	$1,261,610.11
Net Clinical PA Savings	**$62,936,867.46**	**28%**	**$42,040,237.89**	**$20,896,629.57**
Total Net PDL and Clinical PA Savings	**$225,464,038.81**	**100%**	**$149,636,223.15**	**$75,827,815.66**

Chart 3: Distribution by Savings Component – SFY 2016 Total Savings



Preferred Drug List Savings

For SFY 2016, Myers and Stauffer estimated a total savings of $79.0 million net of federal rebates associated with the PDL as described above. The state share of the savings would be approximately $26.7 million, before accounting for administrative costs. *Table 4* on the following page highlights the top 10 therapeutic drug categories with the largest PDL associated savings during the study period.

Table 4: Top 10 Therapeutic Drug Categories – PDL Program Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Stimulants and related agents	$14.3	$4.9	18%
Hepatitis C agents	$12.1	$4.1	15%
Antipsychotics	$10.2	$3.4	13%
Acne agents, topical	$4.1	$1.4	5%
Hypoglycemics, insulin and related agents	$2.8	$0.9	4%
Intranasal rhinitis agents	$2.5	$0.8	3%
NSAIDs	$2.3	$0.8	3%
Skeletal muscle relaxants	$2.2	$0.8	3%
Bronchodilators, beta agonist	$2.2	$0.7	3%
Hypoglycemics, metformins	$2.1	$0.7	3%
Top 10 Total Savings	**$54.8**	**$18.6**	**69%**
Remaining Category Savings	**$24.2**	**$8.1**	**31%**
Total PDL Savings	**$79.0**	**$26.7**	**100%**

The top 10 therapeutic drug categories comprised 69 percent of the overall savings associated with the PDL program ($54.8 million with a state share of $18.6 million) while the top five therapeutic drug categories accounted for 55 percent of the PDL program savings ($43.5 million with a state share of $14.7 million).

Supplemental Rebate Collections

In SFY 2016, the total of supplemental rebates collected from pharmaceutical manufacturers was approximately $83.8 million with a state share of $28.4 million. Rebates collected for the top 10 therapeutic drug categories were $69.4 million and represented 83 percent of total supplemental rebates collected. The top 10 therapeutic drug categories with the largest supplemental rebate associated savings during the study period included:

- *Stimulants and related agents*
- *Antipsychotics*
- *Epinephrine, self-injected*
- *Growth hormone*
- *Hepatitis C agents*
- *Opiate dependence treatments*
- *Anticoagulants*
- *Progestational agents*
- *Cephalosporins and related antibiotics*
- *Ophthalmics for allergic conjunctivitis*

Market Shift Savings

For SFY 2016, Myers and Stauffer estimated the market shift savings based on the number of days between the paid non-preferred claim and the paid preferred claim (7 days, 30 days and 60 days). To be included in this savings analysis, beneficiaries must have had a paid outpatient pharmacy claim for a non-preferred medication and a subsequent paid claim for a preferred medication within the same therapeutic drug category without a point-of-sale denial between the two claims. Because claims for seizure medications for beneficiaries with a seizure diagnosis are not subject to the PDL and prior authorization criteria, market shift savings were not calculated for these claims. *Table 5* illustrates the market shift savings using variable days between paid claims.

Table 5: Market Shift Savings by Days Between Paid Claims

Days Between Paid Claims	Number of Beneficiaries	Total Savings	State Share
7	1,106	$53,340	$18,056
30	2,970	$146,845	$49,707
60	3,892	$214,732	$72,687

Table 6 highlights the top 10 therapeutic drug categories with the largest market shift savings during the study period within 60 days between paid non-preferred and paid preferred claims.

Table 6: Top 10 Therapeutic Drug Categories – Market Shift Savings

Therapeutic Drug Category	Number of Beneficiaries	Total Savings	State Share
Anticonvulsants	154	$48,257.70	$16,335.23
Hypoglycemics, metformins	91	$35,288.45	$11,945.14
Glucocorticoids, oral	183	$25,057.25	$8,481.88
Analgesics, narcotics short	385	$22,803.47	$7,718.98
Stimulants and related agents	1,098	$18,143.45	$6,141.56
Antidepressants, other	174	$15,522.06	$5,254.22
Neuropathic pain	1,363	$14,994.39	$5,075.60
Antidepressants, SSRIs	66	$12,444.03	$4,212.31
Analgesics, narcotics long	239	$11,435.10	$3,870.78
Sedative hypnotics	139	$10,785.99	$3,651.06

Clinical PA Savings

For SFY 2016, Myers and Stauffer estimated a total of $65.5 million net of federal rebates associated with the clinical PA program as described above. The state share of the savings would be approximately $22.2 million. *Table 7* on the following page highlights the top 10 therapeutic drug categories with the largest clinical PA associated savings during the study period.

Table 7: Top 10 Therapeutic Drug Categories – Clinical PA Savings

Therapeutic Drug Category	Total Savings (in millions)	State Share (in millions)	% of Total Savings
Hepatitis C agents	$23.2	$7.8	35%
Antipsychotics	$11.8	$4.0	18%
Glucocorticoids, inhaled	$4.6	$1.6	7%
Proton pump inhibitors	$3.7	$1.2	6%
Bronchodilators, beta agonist	$3.4	$1.2	5%
NSAIDS	$2.7	$0.9	4%
Neuropathic pain	$2.4	$0.8	4%
Opiate dependence treatments	$1.6	$0.5	2%
Hypoglycemics, incretin mimetics/enhancers	$1.5	$0.5	2%
Anticonvulsants	$1.4	$0.5	2%
Top 10 Total Savings	**$56.3**	**$19.1**	**86%**
Remaining Category Savings	**$9.2**	**$3.1**	**14%**
Total Clinical PA Savings	**$65.5**	**$22.2**	**100%**

The top 10 therapeutic drug categories comprised 86 percent of the overall savings associated with the clinical PA program ($56.3 million with a state share of $19.1 million) while the top five therapeutic drug categories accounted for 71 percent of the clinical PA program savings ($46.7 million with a state share of $15.8 million).

Administrative Costs

The Division works collaboratively with its fiscal agent, GDIT, to manage the PDL, clinical PA and supplemental rebate programs. For SFY 2016, the Division paid GDIT a fixed monthly rate of $52,174.25 beginning in September 2016 to operate the PDL and supplemental rebate programs. The cost of the PA program varies month over month based upon the number of PAs reviewed. The rate per PA is variable and decreases with higher PA review volume. *Table 8* illustrates the administrative costs by program.

Table 8: Administrative Cost by Program

Program	SFY 2016 Cost	State Share
PDL and Supplement Rebate Program	$521,742.50	$260,871.25
Clinical PA Program	$2,523,220.22	$1,261,610.11
Total	$3,044,962.72	$1,522,481.36

It would be assumed that administrative costs related to operation of the PDL, clinical PA and supplemental rebate programs would be categorized as administrative expenses subject to a FMAP of 50 percent

Beneficiary Access to PDL Program Medications

A potential concern with implementation and administration of a PDL program is that beneficiaries may be negatively impacted due to delays in initiation of drug therapy or "restricting access" to certain non-preferred medications. Upon a point-of-sale denial of a non-preferred medication, the pharmacist must contact the prescriber for a resolution. The prescriber may 1) authorize the pharmacist to dispense a preferred medication, 2) submit a PA request to GDIT or 3) could determine the medication is not medically necessary. Prescribers may submit PA requests via fax, phone or through the secure NCTracks provider portal. If the pharmacist cannot contact the prescriber and bring resolution to the denied claim rather quickly, the beneficiary may leave the pharmacy without the prescribed medication. When a beneficiary leaves the pharmacy without the prescribed medication, they may eventually receive the medication after a delay, or they may choose not to follow-up and either discontinue or never begin therapy. To reduce the occurrence of beneficiaries leaving without any medication, the Division encourages pharmacy providers to use the 72-hour emergency supply allowed for medications requiring prior authorization. Use of this emergency supply ensures access to medically necessary medications.

All delays associated with non-preferred medications cannot be attributed directly to the PDL program. Delays in therapy can occur for a number of reasons. The beneficiary could have requested an early refill, the physician may have chosen to discontinue therapy and not pursue a prior authorization for the medication or the beneficiary's Medicaid eligibility may have ended. Furthermore, delays identified within this analysis, time between paid claims, does not necessarily indicate delays in therapy. Beneficiaries could have received samples or an emergency fill to cover the delay between paid claims. For purposes of this analysis, identified delays are quantified whereas it would be inappropriate to associate any causality to delay in therapy.

Myers and Stauffer evaluated the impact the PDL program had on beneficiaries' access to PDL program medications. To monitor this impact the following were evaluated:

- *The number of beneficiaries who experienced a denied non-preferred point-of-sale claim at the pharmacy and the subsequent outcome from that denied claim. The outcomes included a paid non-preferred claim, a paid preferred claim or no subsequent paid claim within the same therapeutic drug category.*
- *The percentage of beneficiaries who had a paid non-preferred claim with a subsequent paid preferred claim and reverted back to a non-preferred medication within the same therapeutic drug category.*
- *Prior Authorizations.*

Beneficiaries with a Denied Non-Preferred Claim

Myers and Stauffer evaluated the number of continuously eligible beneficiaries who experienced a denied non-preferred point-of-sale claim at the pharmacy and the subsequent outcome from that denied claim. The beneficiaries were divided into three groups based on the outcome after the initial denied non-preferred claim within the same therapeutic drug category. The outcome groups consisted of a subsequent paid preferred claim, a subsequent paid non-preferred claim and no subsequent paid claim. *Table 9* illustrates the total count of beneficiaries and associated percent of total within each group for all therapeutic drug categories.

Table 9: Impact and Outcome of Beneficiaries Experiencing a Denied Non-Preferred Claim

Outcome	Total Beneficiaries	Impacted Beneficiaries	% of Total
Paid Preferred	1,154,134	147,927	12.8%
Paid Non-Preferred		41,774	3.6%
No Subsequent Claim		86,865	7.5%
Total		276,566	24.0%

Of the 102 therapeutic drug categories, changes were implemented in 63 categories during the study period. Overall, 7.5 percent (86,865) of unique continuously eligible beneficiaries (1,154,134) had a denied non-preferred claim with no subsequent paid claim within the same therapeutic drug category.

The top 10 therapeutic drug categories by beneficiary count who had a denied claim with no subsequent paid claim within the therapeutic class are presented in *Table 10.* Beneficiaries in *Table 10* could be counted more than once in the total if they are on medications in multiple therapeutic drug categories.

Table 10: Top 10 Therapeutic Drug Categories by Beneficiary Count Who Had a Denied Claim and No Subsequent Paid Claim Within the Therapeutic Drug Category
Ordered by Beneficiaries with No Subsequent Paid Claim Descending

Therapeutic Drug Category	Total Beneficiaries	Beneficiaries with No Subsequent Paid Claim	% of Total
NSAIDs	232,132	13,414	5.8%
Neuropathic pain	68,180	7,514	11.0%
Bronchodilators, beta agonist	223,910	4,812	2.1%
Acne agents, topical	35,513	4,441	12.5%
Skeletal muscle relaxants	86,216	4,070	4.7%
Proton pump inhibitors	101,351	3,872	3.8%
Intranasal rhinitis agents	145,285	3,133	2.2%
Angiotensin modulators	65,863	2,929	4.4%
Lipotropics, other	8,873	2,662	30.0%
Glucocorticoids, inhaled	88,855	2,361	2.7%
Total for Top 10	**1,056,178**	**49,208**	**4.7%**
Total for All	**4,240,525**	**100,138**	**2.4%**

Table 11 below highlights the top 10 therapeutic drug categories by percent of beneficiaries who had a denied non-preferred claim and did not have a subsequent paid claim within the therapeutic drug category.

Table 11: Top 10 Therapeutic Drug Categories by Percent of Total Who Had a Denied Claim and No Subsequent Paid Claim Within the Therapeutic Drug Category
Ordered by % of Total Descending

Therapeutic Drug Category	Total Beneficiaries	Beneficiaries With No Subsequent Paid Claim	% of Total
Hepatitis C agents	1,388	487	35.1%
Lipotropics, other	8,873	2,662	30.0%
Hepatitis B agents	72	16	22.2%
Phosphate binders	1,202	247	20.5%
Ulcerative colitis agents	1,337	261	19.5%
Immunomodulators, topical	2,863	549	19.2%
Angiotensin modulator combinations	2,942	510	17.3%
Ophthalmic antibiotic-steroid combinations	7,798	1,246	16.0%
Hypoglycemics, SGLT2	3,318	497	15.0%
Hypoglycemics, incretin mimetics/enhancers	8,660	1,172	13.5%

Beneficiaries Reverting to Non-Preferred Medication

Myers and Stauffer evaluated the count of continuously eligible beneficiaries who had a non-preferred medication then switched to a preferred medication and subsequently reverted back to a non-preferred medication. This was determined based upon paid point-of-sale claims at the pharmacy. A beneficiary must have received a paid non-preferred, then a paid preferred, then paid non-preferred, respectively, within the same therapeutic drug category.

Overall, approximately 10,000 out of nearly three million (0.3 percent) continuously eligible beneficiaries reverted back to a non-preferred medication after receiving a preferred medication.

Prior Authorizations

A total of 137,081 prior authorization requests were reported by GDIT for SFY 2016. The count of approvals and denials for these PA requests was not available for inclusion in this report and cannot be obtained from the data sets received by Myers and Stauffer.

PDL Program Impact on Medical and Laboratory Services

To comply with the Medicaid state plan, the Division is required to evaluate if the PDL program has an impact on related services, such as hospitalizations. Myers and Stauffer conducted an analysis to determine if there were any changes in the utilization and/or expenditures of beneficiaries' medical or laboratory services as a result of the PDL program. The following services were included in the analysis:

- *Emergency Department Visits*
- *Inpatient Hospital Visits*
- *Physician Office and Outpatient Visits*
- *Laboratory Services*

In order to evaluate the PDL program impact on medical and laboratory services, Myers and Stauffer assigned beneficiaries into a study group (therapy change) or a control group (no therapy change). The study group contained beneficiaries who experienced a change in drug therapy within a PDL drug category and the control group beneficiaries did not experience a change in drug therapy within the PDL drug category. Beneficiaries must have been continuously eligible and on continuous therapy within the PDL drug category to be assigned to one of the two groups.

Myers and Stauffer used the following criteria to evaluate which therapeutic drug categories to include in this analysis:

- *Therapeutic drug categories comprised of maintenance medications used for the treatment of chronic disease states.*
- *Therapeutic drug categories that had PDL changes during the study period which could result in a therapy change.*

The therapeutic drug categories identified with the above criteria did not contain an adequate number of beneficiaries to perform a statistically valid analysis. Since it is difficult to determine if the therapy change was due to the PDL or a provider clinical intervention, it would be difficult to substantiate any conclusions regarding the impact of the PDL on medical and laboratory utilization and expenditures with this approach. In an attempt to isolate beneficiaries who experienced a therapy change due to the PDL, the study group was restricted to those beneficiaries who had a denied non-preferred claim before the therapy change. The top two therapeutic drug categories by study group sample size included beta-blockers and proton pump inhibitors. *Charts 4* through *19* on the following pages illustrate the monthly average utilization and expenditures for medical and laboratory services for the therapy change and no therapy change groups. It is worth noting that because the sample sizes are so small for the therapy change groups, the variability is higher than that compared to the no therapy change group which has a much larger sample size.

Beta Blockers

Chart 4: Average Number of Emergency Department Visits

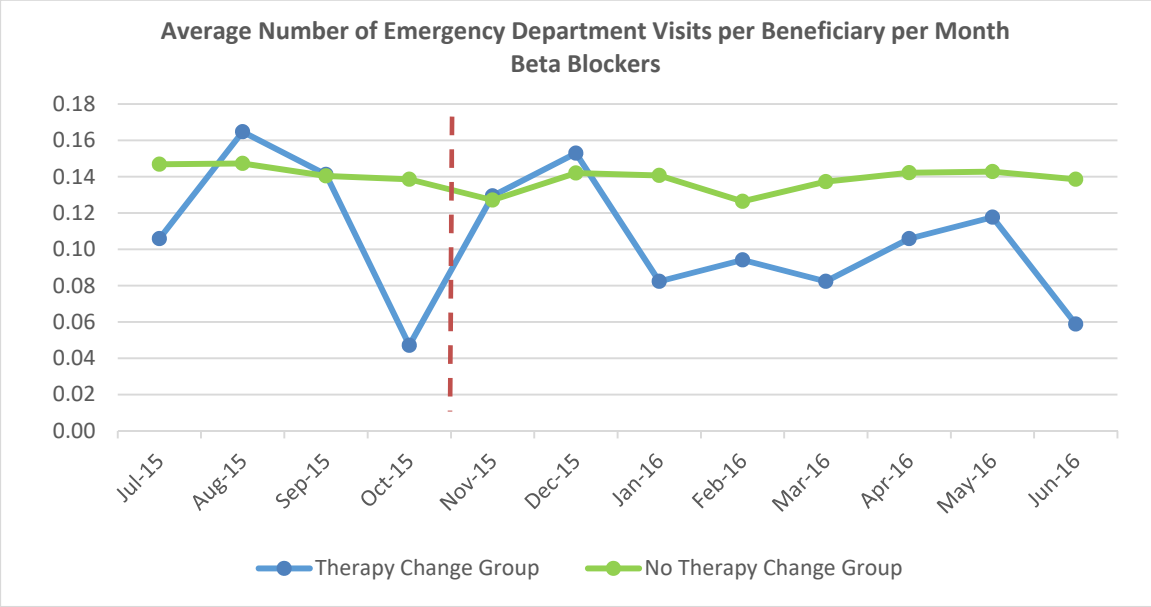


Chart 5: Average Amount Paid for Emergency Department Visits

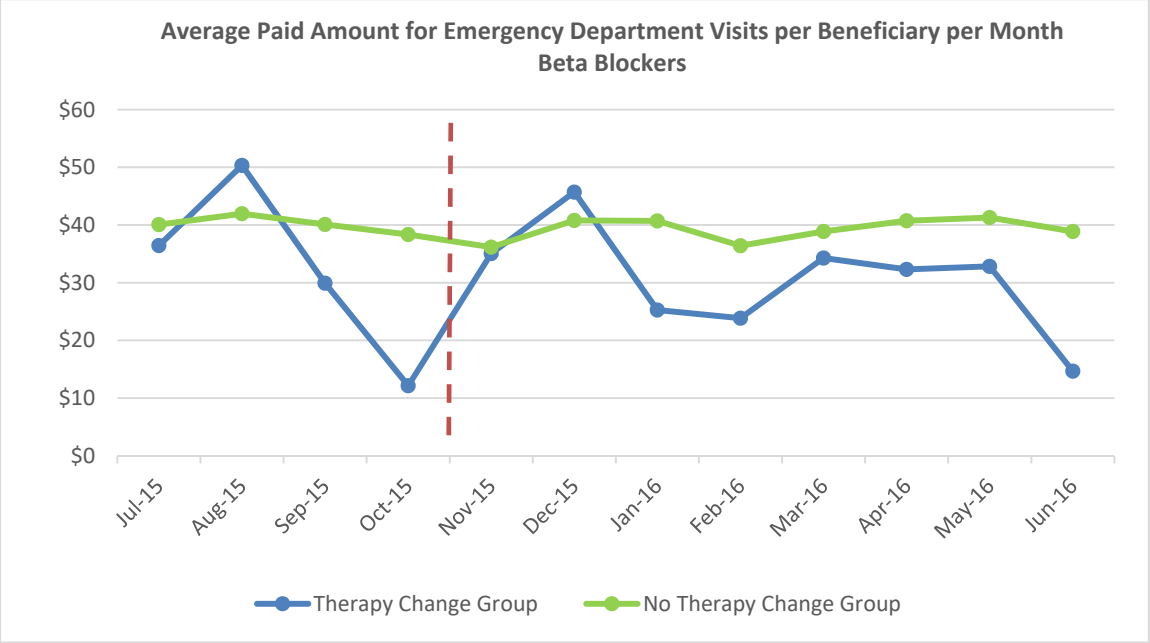


Chart 6: Average Number of Inpatient Admissions

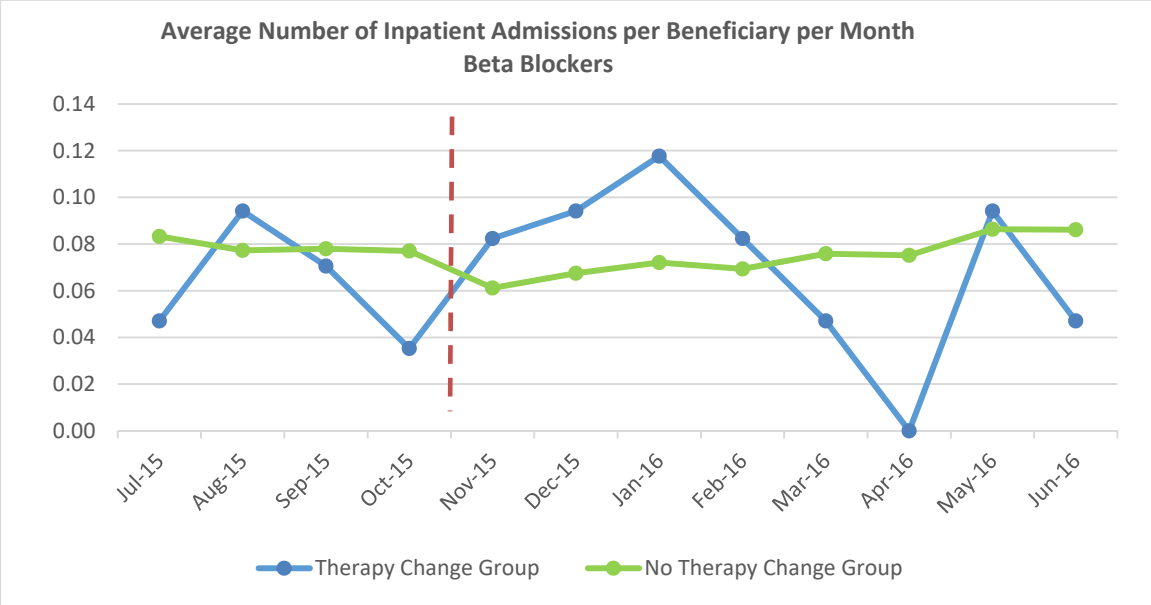


Chart 7: Average Amount Paid for Inpatient Admissions

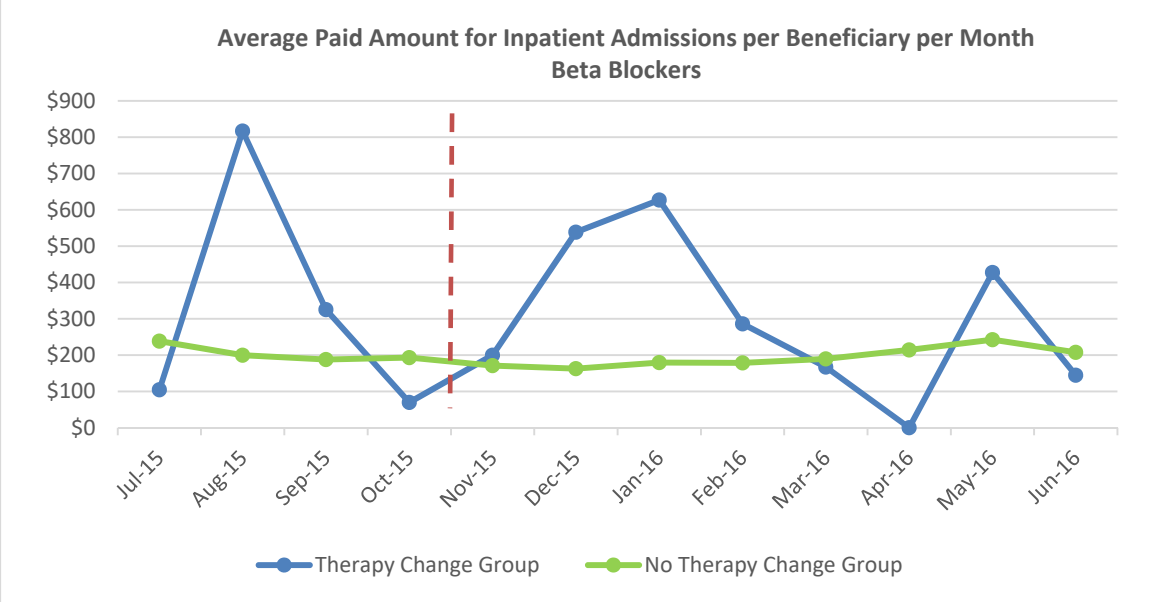


Chart 8: Average Number of Physician Office/Outpatient Visits

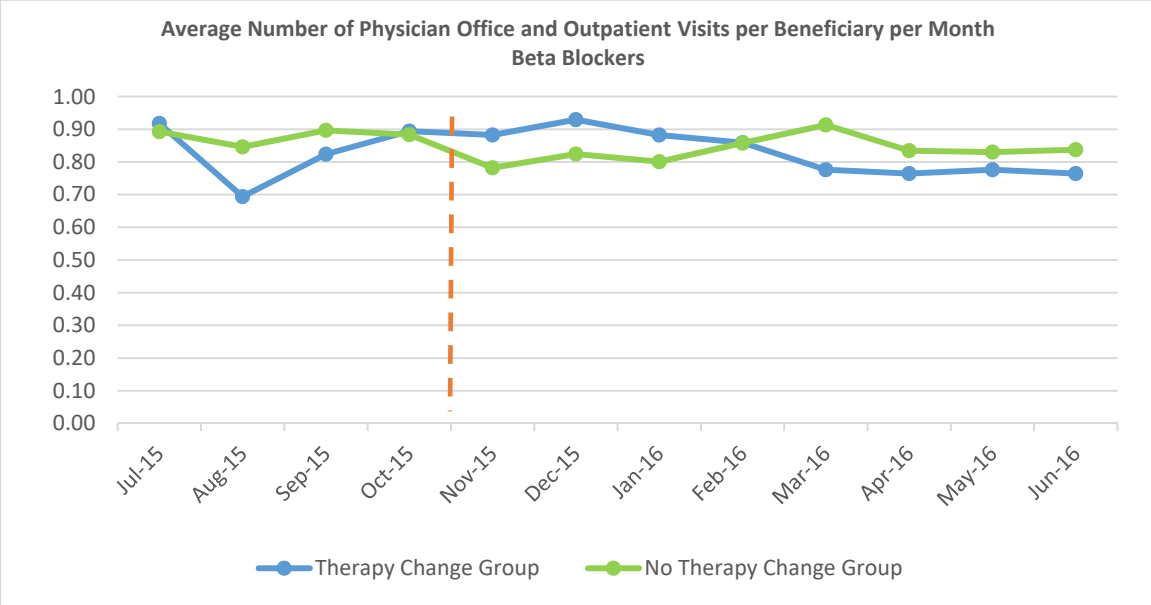


Chart 9: Average Amount Paid for Physician Office/Outpatient Visits

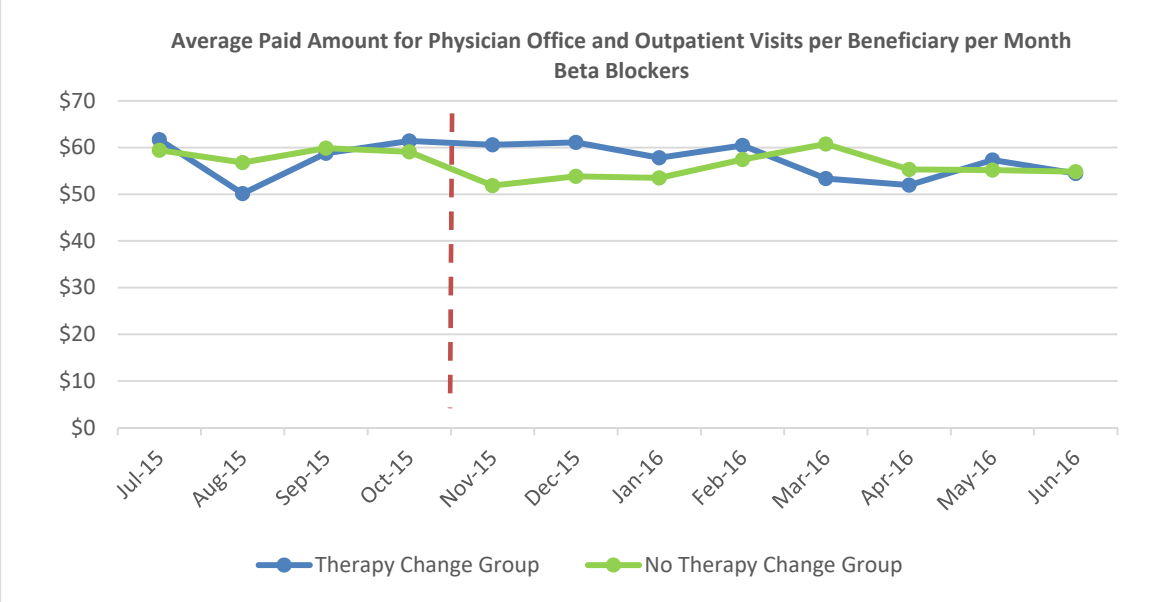


Chart 10: Average Number of Laboratory Services

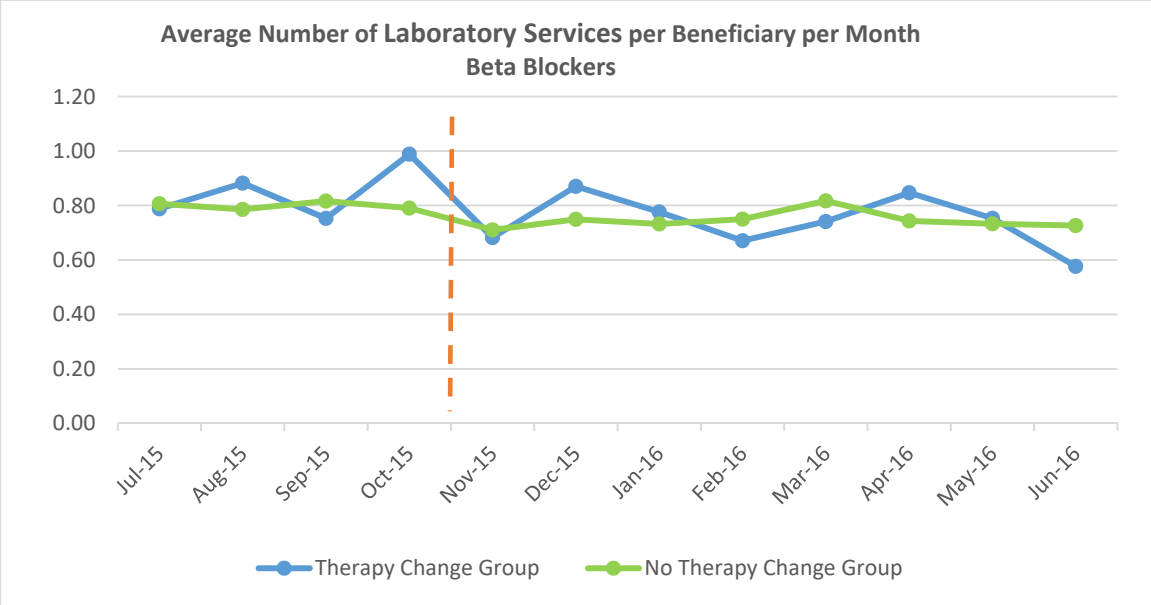
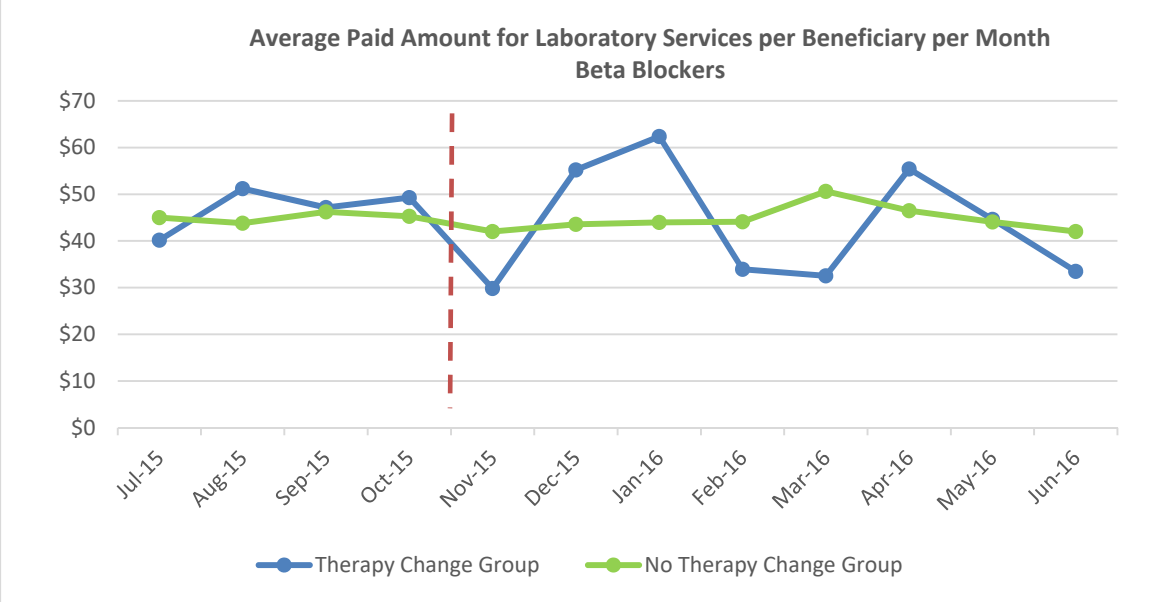


Chart 11: Average Amount Paid for Laboratory Services



Proton Pump Inhibitors

Chart 12: Average Number of Emergency Department Visits

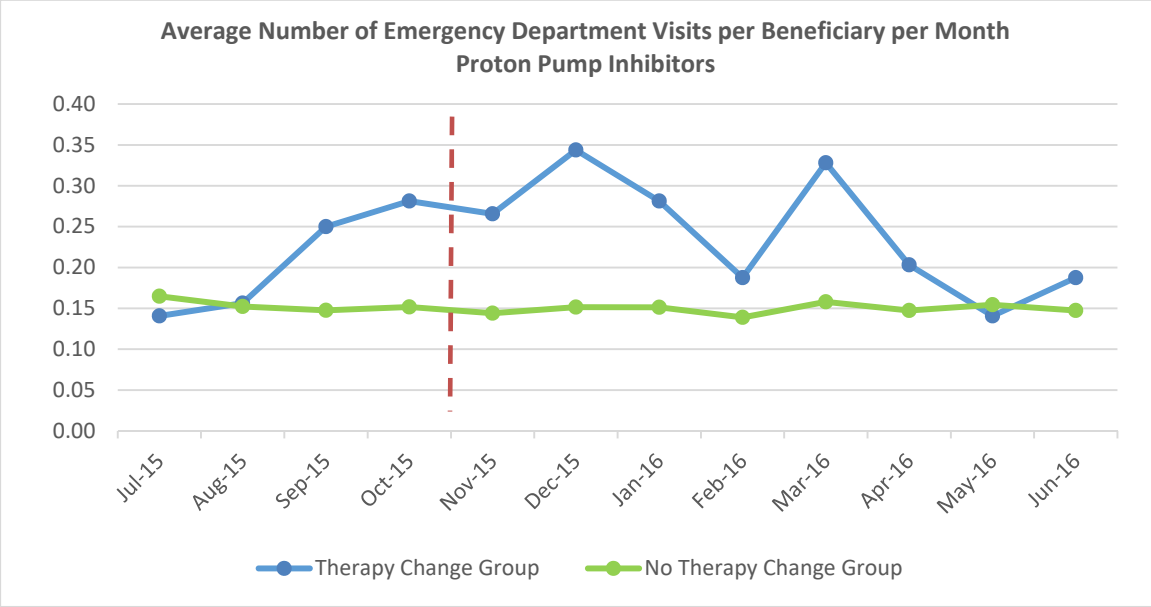


Chart 13: Average Amount Paid for Emergency Department Visits

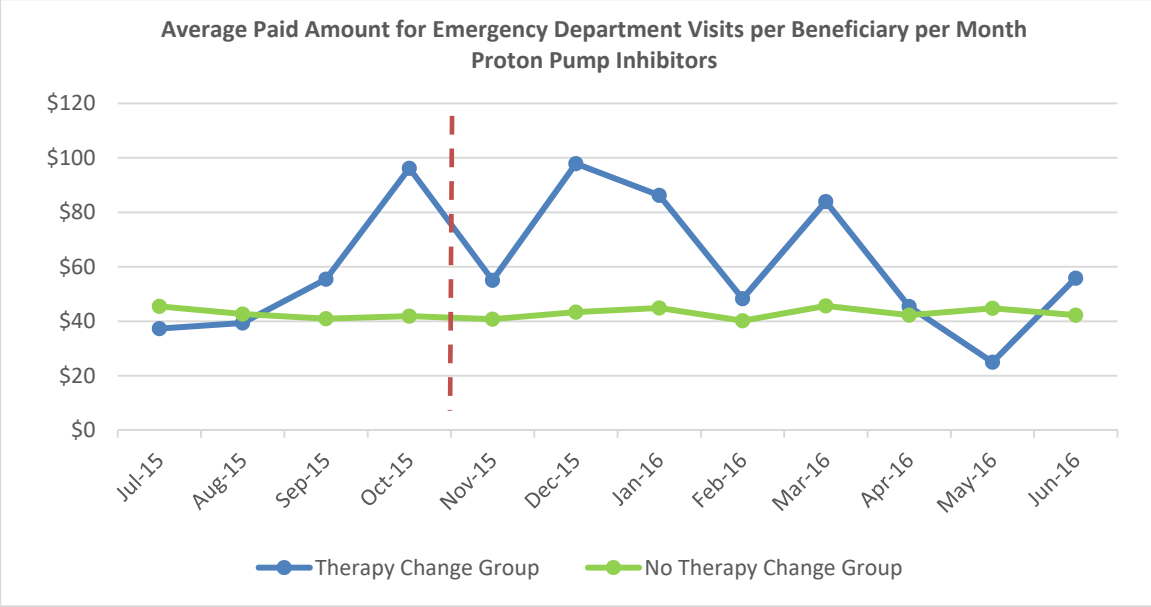


Chart 14: Average Number of Inpatient Admissions

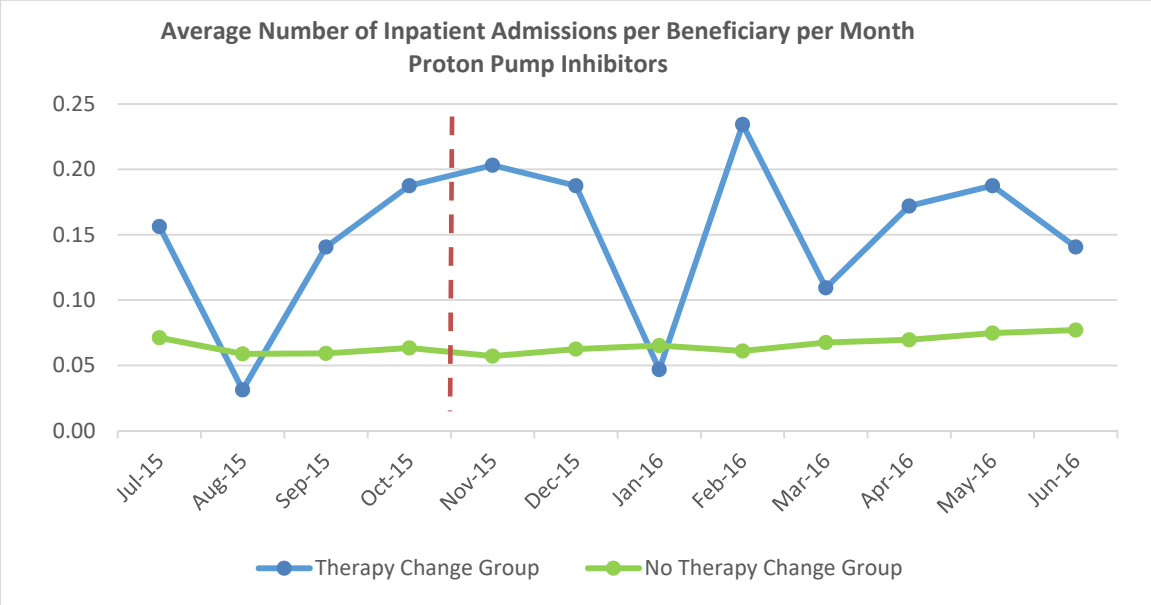


Chart 15: Average Amount Paid for Inpatient Admissions

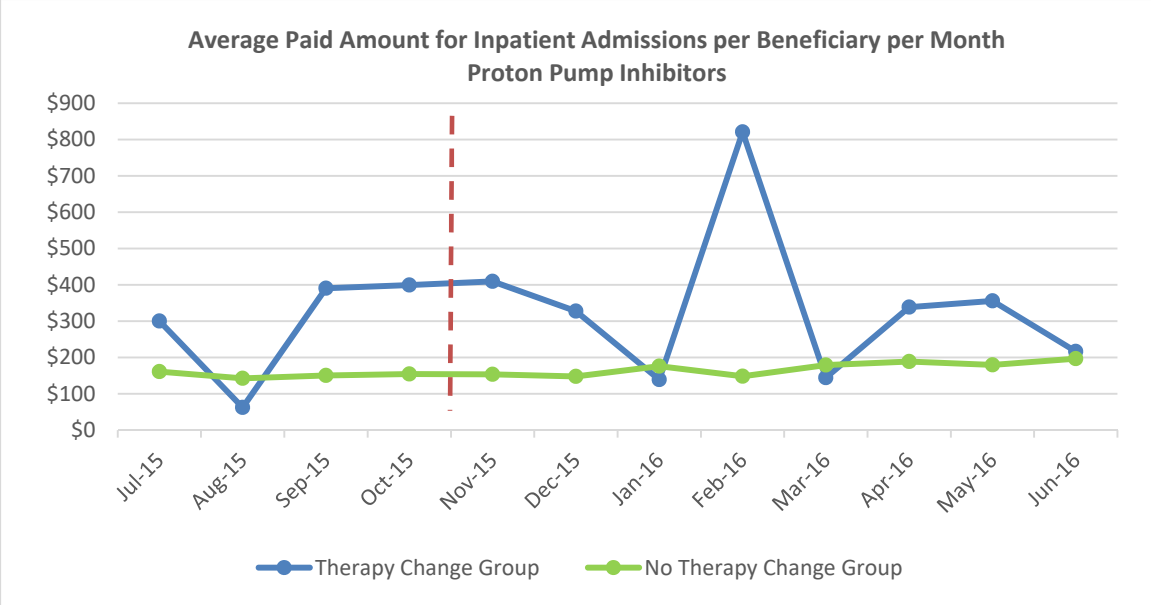


Chart 16: Average Number of Physician Office/Outpatient Visits

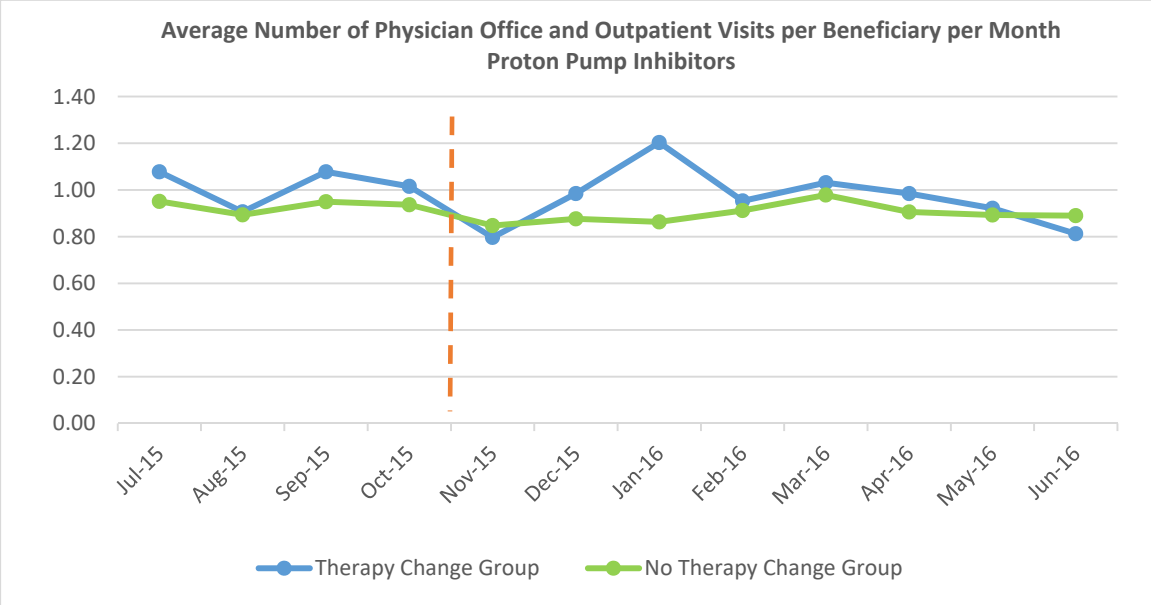


Chart 17: Average Amount Paid for Physician Office/Outpatient Visits

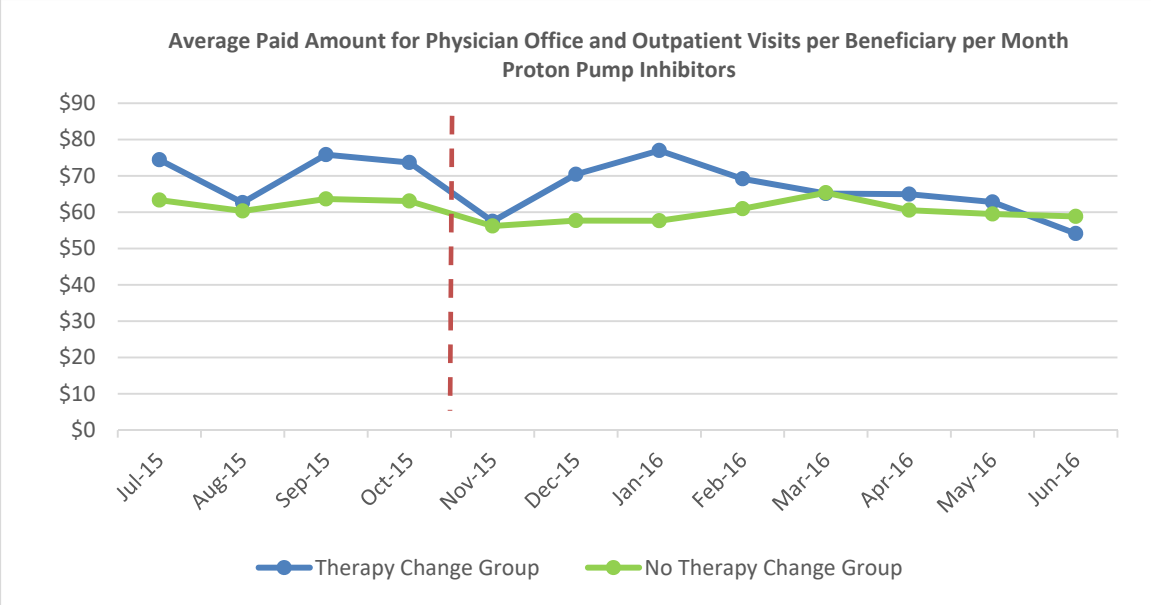


Chart 18: Average Number of Laboratory Services

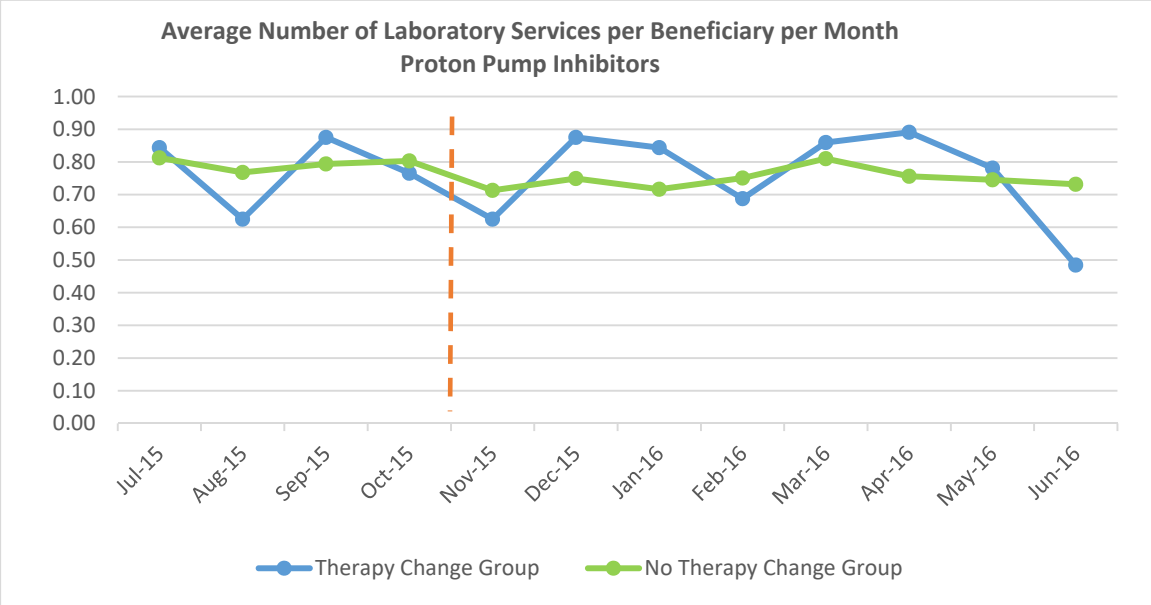
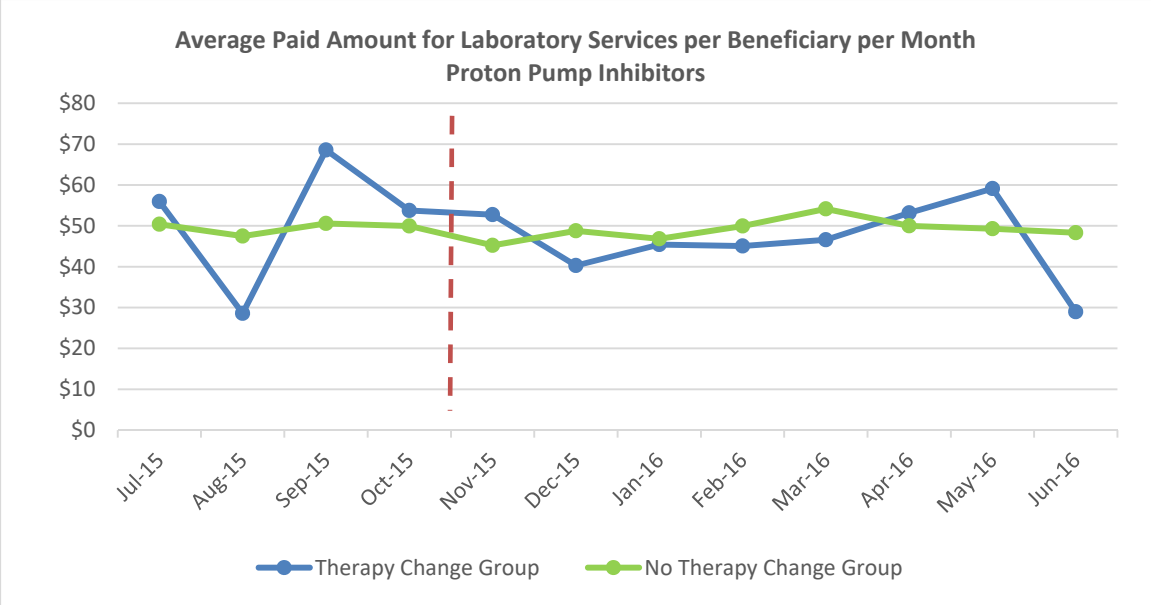


Chart 19: Average Amount Paid for Laboratory Services



Assumptions, Exclusions and Limitations of Analysis

- *The analysis was based on outpatient pharmacy claims data with dates of service from July 1, 2015 through June 30, 2016. Claims with a date of service between January 1, 2016 and June 30, 2016 were being reprocessed by the Division due to a pharmacy reimbursement methodology change. Although the majority of these claims should have been reprocessed within the dataset, additional paid claims data within these dates of service may alter the results of this analysis.*
- *Although rebates are collected for third party liability (TPL) claims, Myers and Stauffer excluded these claims because the Division is not the primary payer of these claims and the PDL and PA edits are bypassed during claims processing.*
- *340B claims and Title XXI Children's Health Insurance Program (CHIP) claims were excluded from the analysis because these claims are not eligible for rebates.*
- *Compound drug claims were excluded from the analysis because the header paid amount is split evenly across the line items and the paid amount per NDC cannot be accurately determined from the data. Compound drug claims represent a small number of claims; therefore, the impact on the results of this analysis would be minimal.*
- *To estimate federal rebates, Myers and Stauffer utilized the federal unit rebate amount (URA) assigned to each NDC. In cases where the Centers for Medicare and Medicaid Services (CMS) URA unit and the NCPDP billing unit were not equal, a rebate unit conversion was applied. A comprehensive list of rebate unit conversions was not able to be provided to Myers and Stauffer; therefore, not all unit rebate conversions may have been identified. Myers and Stauffer reviewed rebate amounts for reasonableness and performed a manual conversion for those NDCs that were identified during the review.*
- *To estimate the federal and state shares, Myers and Stauffer calculated a weighted federal medical assistance percentage (FMAP) of 66.15 percent utilizing the two associated FMAPs for the study period. It was assumed that administrative costs related to operation of the PDL and PA Programs were likely categorized as administrative expenses subject to FMAP of 50 percent.*
- *The estimated state share of savings did not account for the Affordable Care Act (ACA) offset of rebates.*
- *For purposes of the PDL and PA savings estimates, Myers and Stauffer calculated savings throughout the study period as long as the beneficiary remained eligible. Medication therapy compliance was assumed for maintenance medications and may have resulted in an overestimate of savings, particularly for beneficiaries who did not receive a subsequent paid claim after the initial non-preferred denial.*

- *Market shift savings estimates did not account for beneficiaries receiving concurrent preferred and non-preferred medications within the same therapeutic drug category and may have resulted in a potential overestimation of savings.*
- *For this analysis, Myers and Stauffer relied upon data, as well as other sources of information as described in this report. Myers and Stauffer relied upon this data without independent audit; however, the data was reviewed for reasonableness and consistency.*
- *Due to the proprietary and confidential nature of federal and supplemental drug rebates, the savings estimates were provided in the aggregate to avoid any potential disclosure of this confidential financial information.*