

MAGELLAN RX MANAGEMENT
MEDICAID PHARMACY
TREND REPORT™

2018 THIRD EDITION





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Magellan Rx Management is pleased to present the third edition of the Magellan Rx Management Medicaid Pharmacy Trend Report™.

State Medicaid Drug Management Continues to Shift

Medicaid continues to be one of, if not the most costly line items in state budgets. States have long experimented with management strategies that would provide alternative coverage options and potential economic relief such as shifting coverage from Medicaid fee-for-service (FFS) to capitated models through managed care organizations (MCO). In 2013, Texas pioneered a single preferred drug list (PDL) for its Medicaid drug program, where the MCO pharmacy benefit must follow the FFS pharmacy PDL.¹ Since the introduction of the Affordable Care Act (ACA), more states experimented with including the pharmacy benefit in managed care, or keeping under direct state management.

As illustrated in last year’s report and accompanying webinar, the 20.5% net trend growth of specialty phar-

macy is untenable and we anticipated legislative action at the state and federal level. Since then, New York state used its Drug Cap legislative authority to publicly pursue additional rebates on drugs that caused the state to exceed the budget cap.

In addition to shifting coverage and drug management, states were confronted with an implementation deadline of April 1, 2017, to amend their pharmacy reimbursement algorithms from average wholesale price (AWP) or wholesale acquisition cost (WAC) to National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee. The idea behind NADAC is to more accurately reimburse pharmacy drug ingredient costs based on survey pricing and separately reimburse the pharmacist a professional dispensing fee. NADAC is updated monthly and is available on both brand and generic drugs. Pricing data is sourced from retail pharmacy invoices, thus, many available National Drug Codes (NDC), do not have a NADAC price. Fortunately, products without a NADAC represent a small percentage of the total utilization. For drugs without a NADAC, actual acquisition cost (AAC), or maximum allowable cost (MAC) price, states may reimburse based on federal upper limit (FUL), WAC, usual and customary, or

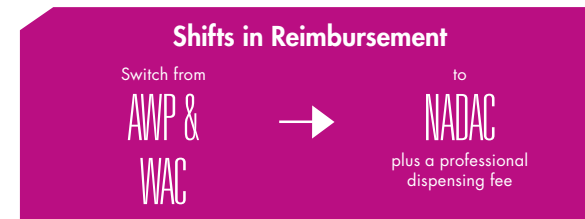
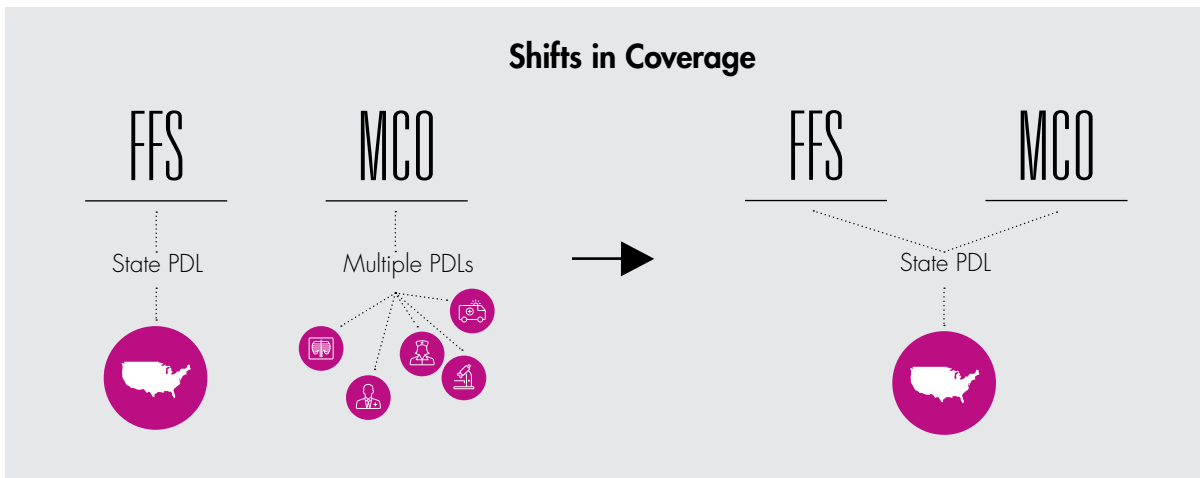
gross amount due. Some states use NADAC or AAC logic first, then the lesser of the other benchmarks, while other states use the lesser of all pricing benchmarks.

With this dynamic landscape, the third edition of the MRx Medicaid Pharmacy Trend Report™ seeks to provide detailed insights on how these shifts affected trends, along with potential management strategies for working within this complex and ever-changing line of business.

Staying Ahead of Trends

In our first edition, we provided updates on the overall Medicaid drug trend, highlighting the drugs and drug classes driving that trend. We improved on that analysis in our second edition, breaking out traditional and specialty drug spend with a focus on the top 10 drug classes and their drugs for both benefits. In this year’s edition, we will again highlight both specialty and traditional drugs, with a focus on the drugs and drug classes driving the trend both positively and negatively. In addition, this year, we have provided a more detailed look at drugs in the Medicaid pipeline to better anticipate trends on the horizon.

We are confident the information contained in this report will be relevant and informational for you and the state Medicaid programs you serve. We welcome comments and feedback for use in enhancing the value of future reports.

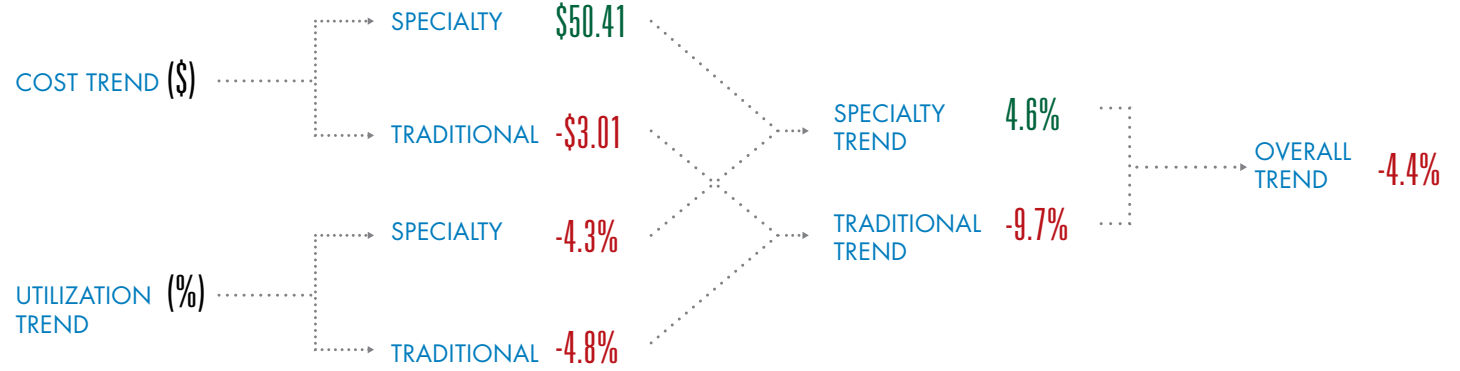


1. Current states: Nebraska, Florida, Washington and, selectively, by Arizona, Minnesota, and Virginia.
 2. 1115 MassHealth Demonstration ("Waiver"). <http://www.mass.gov/service-details/1115-masshealth-demonstration-waiver>. Accessed June 2018.



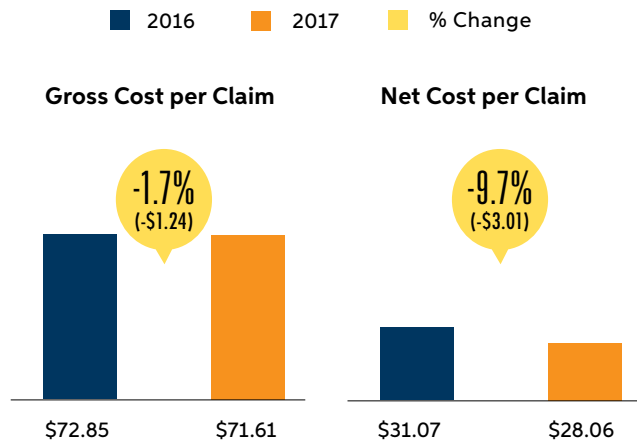
OVERALL MEDICAID TREND*

2016 NCPC = \$47.63
 2017 NCPC = \$45.53
 Difference = -\$2.10

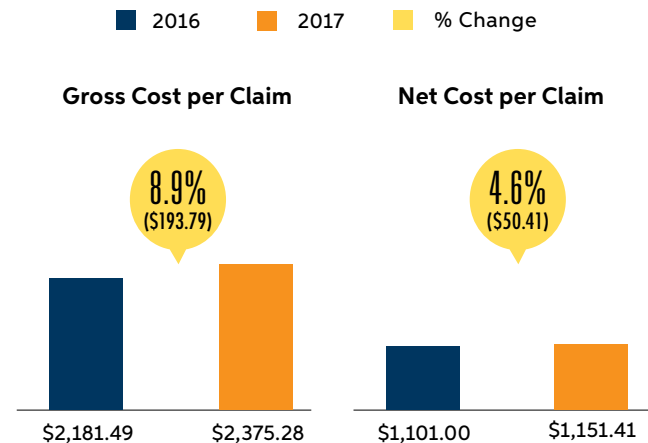


Gross Cost per Claim: 1.8% (\$1.95)
 Net Cost per Claim (NCPC): -4.4% (-\$2.10)

2017 TRADITIONAL MEDICAID TREND



2017 SPECIALTY MEDICAID TREND

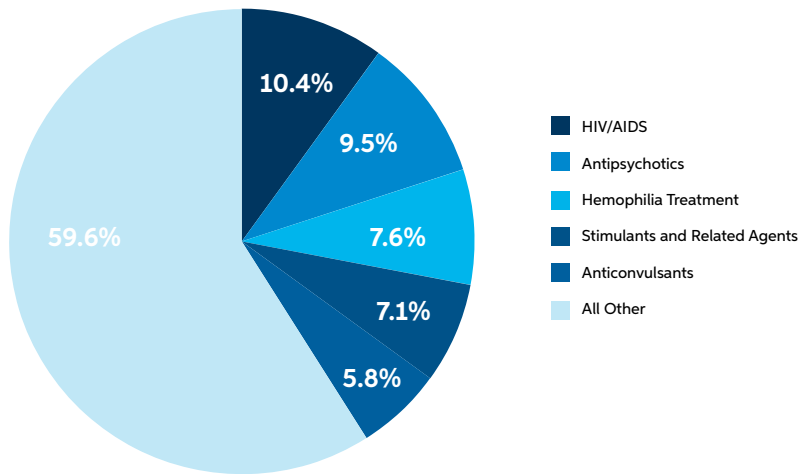


Four of the top 10 net cost drug classes are specialty classes: Hepatitis C Agents, Hemophilia, HIV/AIDS, and Cystic Fibrosis, Oral.

*TRENDS ARE FOR MEDICAID FFS ONLY. FOR AN OVERVIEW OF MEDICAID PHARMACY ECONOMICS, SEE PG 31



2017 TOP CLASSES BY NET SPEND



2017 TOP 10 DRUGS BY NET SPEND

RANK	BRAND NAME	CLASS	TYPE
1	Genvoya (Oral)	HIV/AIDS	Specialty
2	Methylphenidate ER (Concerta) (Oral)	Stimulants and Related Agents	Traditional
3	Advate (IV)	Hemophilia Treatment	Specialty
4	Triumeq (Oral)	HIV/AIDS	Specialty
5	Orkambi (Oral)	Cystic Fibrosis, Oral	Specialty
6	Harvoni (Oral)	Hepatitis C Agents	Specialty
7	Invega Sustenna (Intramuscular)	Antipsychotics	Traditional
8	Eplusa (Oral)	Hepatitis C Agents	Specialty
9	Aripiprazole Tablet (Oral)	Antipsychotics	Traditional
10	Adderall XR (Oral)	Stimulants and Related Agents	Traditional

2017 MEDICAID DRUG REIMBURSEMENT UPDATES

In 2017, at the direction of CMS, many states revised their reimbursement algorithm to move away from AWP-/WAC+ toward acquisition cost-based algorithms such as NADAC or AAC and an enhanced pharmacy dispensing fee. To augment the NADAC pricing algorithm, some states retained their MAC program while others now rely on NADAC alone. In all cases, CMS approval is required before implementing the state reimbursement logic.

Note: NADAC applies to both brand and generic drugs, MAC only applies to multi-source brands and generic drugs

Overall

48.9%

of all NDCs have a NADAC available

93.9%

of all NDCs utilized have a NADAC available

82.7%

of all NDCs have a MAC available

86.9%

of all NDCs utilized have a MAC available

Specialty

16.2%

of all specialty NDCs have a NADAC available

78.5%

of all specialty NDCs utilized have a NADAC available

47.3%

of all specialty NDCs have a MAC available

41.6%

of all specialty NDCs utilized have a MAC available

Traditional

50.4%

of all traditional NDCs have a NADAC available

94.1%

of all traditional NDCs utilized have a NADAC available

84.5%

of all traditional NDCs have a MAC available

87.6%

of all traditional NDCs utilized have a MAC available

Drug Trend Drivers in Medicaid

In 2017, six of the top 10 drugs in Medicaid fell under the specialty categories and two of the top five classes were not typically managed by state Medicaid programs. Only two drugs in the top 10 were generics, aripiprazole, the top net spend drug in 2016, and methylphenidate, the generic for Concerta (see figure 1).

In 2017, HIV/AIDS jumped to the top spot for classes by total net spend and had two drugs in the top 10. Those two drugs, Genvoya (No. 1) and Triumeq (No. 4), represented 36.9% of the HIV/AIDS class total net spend with Genvoya accounting for 21.1% and Triumeq accounting for 15.8% (see figure 1). For the third highest class, hemophilia, almost one-quarter of the total class spend was attributed to the third highest spend drug, Advate (22.6%).

Hepatitis C, the sixth highest class by net spend, had two drugs in the top 10, Harvoni and Epclusa, which accounted for a total of 69.8% of the Hepatitis C class total net spend. That will likely change in 2018 now that lower cost, single-drug regimens have entered the market.

Overall Drug Trend

Year over year, overall drug costs experienced an average 1.8% change in gross cost per claim, but declined 4.4% in net cost per claim (see figure 2). The average overall gross cost per claim was \$105.49 in 2016 and \$107.44 in 2017, an increase of \$1.95 per claim, or 1.8%. The average net cost per claim was \$47.63 in 2016 and \$45.53 in 2017, a decline of \$2.10, or 4.4%.

FIGURE 1

Medicaid Top 10 Drugs by Net Spend

■ Drug net spend ■ Class net spend ■ % of class net spend

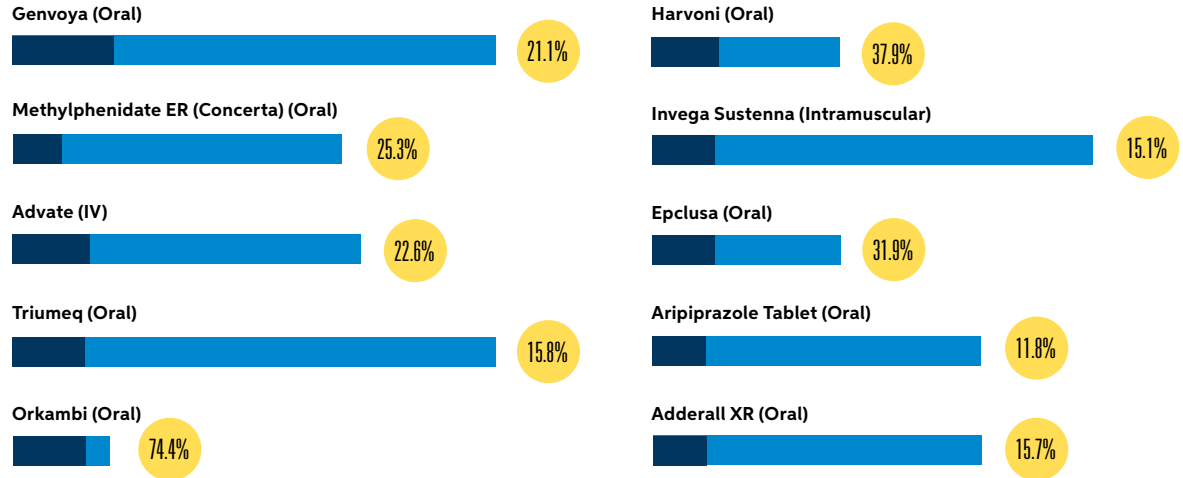
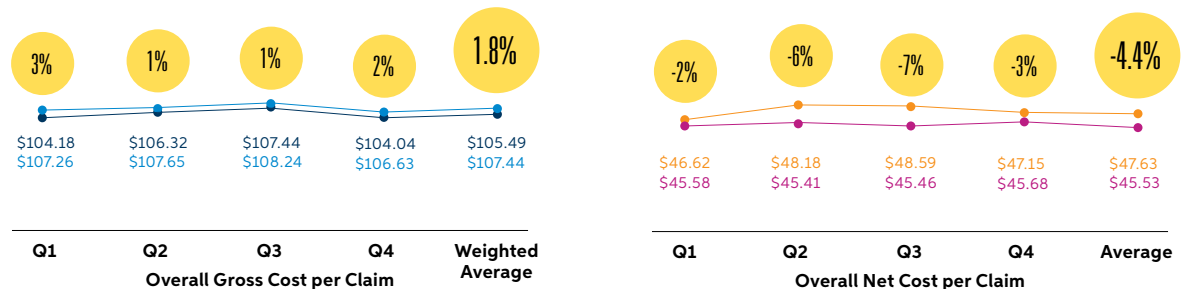


FIGURE 2

Medicaid Overall Gross and Net Cost per Claim 2016-2017

■ 2016 ■ 2017 ■ % change

■ 2016 ■ 2017 ■ % change





Traditional Drug Trend

In 2017, traditional drug costs were relatively flat over the two-year period and experienced a small decline of 1.7% in gross cost per claim, but experienced a 9.7% decrease in net cost per claim (see figure 3). The average gross cost per claim declined from \$72.85 in 2016 to \$71.61 in 2017, while the average net cost per claim declined from \$31.07 in 2016 to \$28.06 in 2017.

Traditional drugs have a lower cost structure and are flush with generics, north of 87% of utilization. A primary contributor to the lower traditional trend was a 70.4% decrease in net cost per claim of aripiprazole tablet combined with a market shift from the brand (Abilify) to aripiprazole. Despite a 35.2% increase in utilization for aripiprazole from 2016 to 2017, the total net spend dropped by \$89 million.

Through the use of management tools such as PDLs, clinical edits, MAC pricing, rebate contracting, and brand-over-generic programs, state Medicaid programs managed utilization and costs for many traditional drugs. States continued their efforts to curb claim volume of short-acting narcotics and reduce abuse of opioids through clinical initiative and prior authorizations (PA).

Specialty Drug Trend

After last year's double-digit trend of 22.8% gross cost per claim and 20.5% net cost per claim, specialty continued to rise with an 8.9% increase in gross cost per claim and a 4.6% increase in net cost per claim (see figure 4). In 2017, the average gross cost per claim increased from \$2,181.49 in 2016 to \$2,375.28 in 2017. The average net cost per claim increased from \$1,101.00 in 2016 to \$1,151.41 in 2017.

Four of the top 10 drug classes by net spend were specialty classes: Hepatitis C Agents, Hemophilia, HIV/AIDS, and Cystic Fibrosis, Oral. In two specialty classes, Hemophilia and Hepatitis C Agents (see sections on pages 21 and 22), we saw lower costs and downward price pressure to the specialty trend line. In Hepatitis C Agents, total

FIGURE 3

Medicaid Traditional Gross and Net Cost per Claim 2016-2017

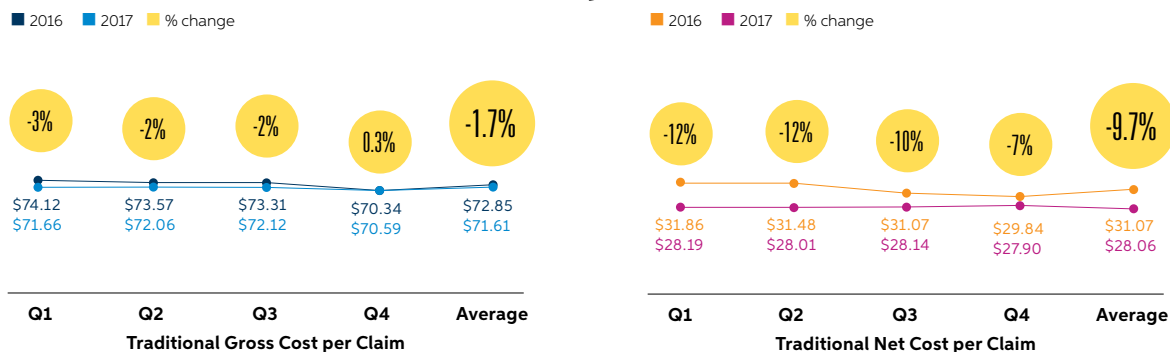
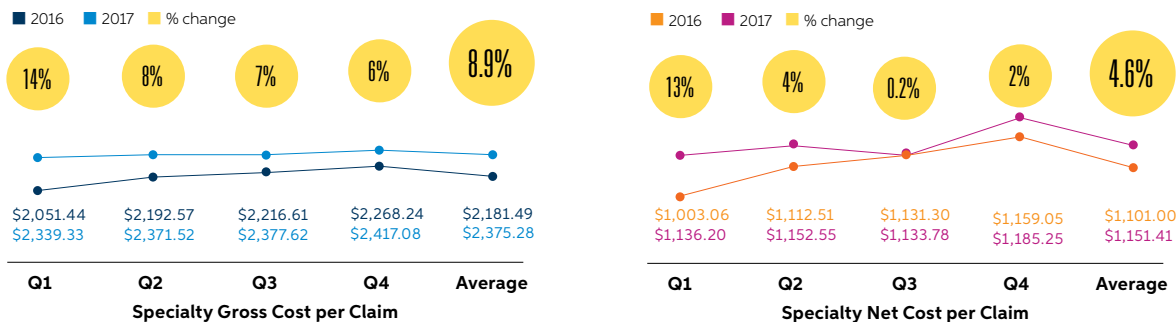


FIGURE 4

Medicaid Specialty Gross and Net Cost per Claim 2016-2017



claims were down 5.7% year over year and total spend was down 16.2% as competition drove price concessions in this class. In Hemophilia, total claims were down 11.3% year over year and total spend was down 11.5% as the market moved toward products with less frequent dosing.

The 2017 data identified 63 new specialty drugs within 30 drug classes. These drugs accounted for approximately 5,000 claims in 2017, but no claims in 2016, and represented more than \$68 million in new net drug spend.

Unlike with traditional drug classes, state Medicaid programs are limited in the number of management tools available within the specialty classes due to unique indications, lack of competition, and complexity of the disease state being treated. While states use clinical edits and PA to manage the specialty drug trend, MAC pricing, rebate contracting, PDLs, and brand-over-generic programs are generally less effective here.



Opioid Management

States are facing an opioid epidemic of historic proportions. From municipalities to state legislatures, Congress and the Trump administration, healthcare stakeholders and decision-makers—all are engaged in new policy solutions to help address the epidemic, many of which directly impact state Medicaid programs opioid-related drug management strategies and drug utilization review initiatives. One initiative, morphine milligram equivalent (MME) dosing, led to a decline in utilization for long- and short-acting narcotics, with an increase in utilization in the opioid use disorder treatment class (see figure 5).

Opioid Epidemic and Medicaid TRUMP ADMINISTRATION'S EFFORTS

In November 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis released its final report of 56 recommendations, many of which now fall to Congress for action. While the commission did not identify new federal funding to address the crisis, the report recommended consolidating federal funding from a variety of sources for substance use disorder (SUD) treatment and services into uniform block grants to states. Of note to state Medicaid programs, the commission recommended:

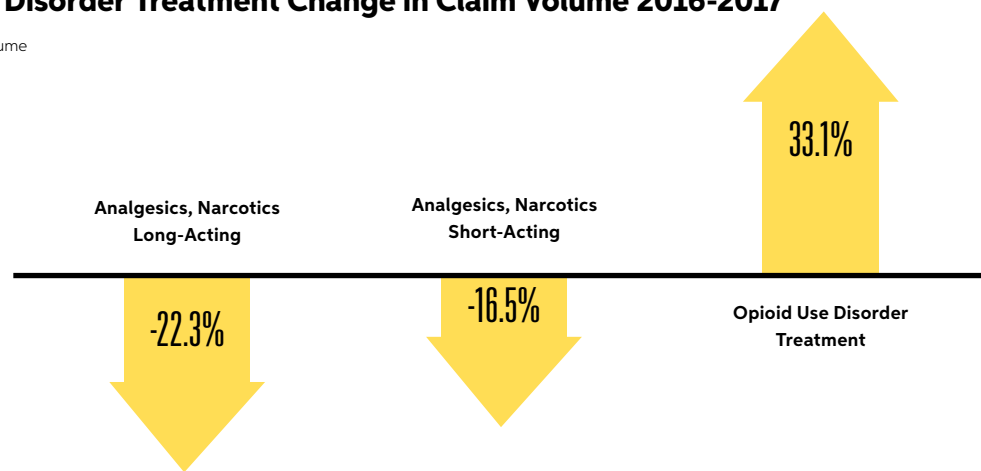
- CMS remove reimbursement and policy barriers to SUD treatment that may limit access to any form of U.S. Food and Drug Administration-approved medication assisted treatment;
- CMS revise rate-setting policies discouraging the use of non-opioid treatments for pain;
- Updated guidelines for pain medications, including to supplement the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain; and,
- Healthcare payers, including state Medicaid programs, "expand programs for hospital and primary care-based SUD treatment and referral services," among others.

The White House hosted a summit on the Trump administration's efforts since the commission's report addressing

FIGURE 5

Opioid Use Disorder Treatment Change in Claim Volume 2016-2017

■ % change claim volume



the opioid crisis released in November 2017.¹ At the March 2018 summit, U.S. Department of Health & Human Services (HHS) Secretary Alex Azar discussed his department's role in convening top data scientists to develop new tools for preventing opioid use disorder and establishing a streamlined process through which states can obtain Medicaid Section 1115 waivers to support expanded access to SUD treatment.

CONGRESSIONAL EFFORTS

Beginning concertedly in December 2017, various committees within the House and Senate have been working to develop federal legislation to address the opioid epidemic. By June 2018, the U.S. House of Representatives passed its package of more than 60 bills, which were combined into a single bill, H.R. 6, and passed the chamber on a 396-14 vote. On September 17, the Senate passed Senate Amendment 4013, the Opioid Crisis Response Act, by a vote of 99 to 1; this measure incorporated more than 70 separate Senate bills addressing multiple issues related to the epidemic. The Senate bill has a number of differences with the House-passed bill. The bills must be reconciled and voted on by each chamber before a final, enacted bill

can be sent to the president for signature. As of this writing, work is underway to conference the two bills.

STATE EFFORTS

Since state laws and regulations govern prescribing practices, the 2018 state legislative session was actively engaged to address the opioid epidemic. The bulk of activity centered on prescribing limits for opioids. At least 29 states enacted prescribing limits either outright or called for regulation to do so, and the limits ranged from a three-day maximum initial fill (for "opioid naïve" patients) in some states to a 14-day maximum in others, with the predominant limit being seven days. A few states also set dosing limits, indicating a provider could not use an opioid dosage in excess of a 180 MME dose, for example. Most states that enacted prescribing limits included exceptions for chronic pain, SUD treatment, and oncology and palliative care, and many of these prescribing limits affect a broad set of payers, including Medicaid. While the 2018 state legislative sessions were active on opioids, 2019 sessions also are likely to address issues related to opioid misuse and prevention.

1. White House, Remarks by President Trump at the White House Opioids Summit* (March 1, 2018), <http://www.whitehouse.gov/briefings-statements/remarks-president-trump-white-house-opioids-summit>.

Antipsychotics

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Antipsychotics had the largest impact on overall trend and drove down the overall average net cost per claim by \$0.83, resulting in a ranking drop from No. 1 to No. 2 in overall net spend by class. The decrease in net cost was primarily demonstrated by the shift from Abilify to its generic, aripiprazole, accounting for a decrease average net cost per claim of \$1.13. This shift was partially offset by increased utilization of more expensive long-acting injectable antipsychotics and newer oral drugs.

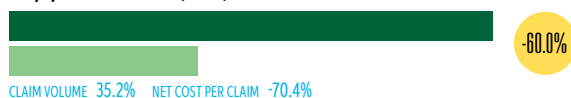
- Aripiprazole contributed -\$0.70 toward net cost per claim and fell from the No. 1 product to No. 8 in overall net spend despite a 35.2% increase in utilization.
- Despite the lower net cost for Seroquel XR, the aripiprazole/Abilify dynamic was repeated for quetiapine ER/Seroquel XR. Preferring the brand instead of quetiapine ER resulted in nearly \$1 million in savings for state Medicaid programs.
- New market entrants Latuda, Rexulti, and Vraylar saw the largest increases in trend. Their overall net spend demonstrates the potential for continued contribution to net spend growth despite developing use of injectables. This spend did not approach that of Invega Sustenna, which remained the No. 6 overall net spend product again in 2017, but it indicates the significant impact that continued oral brand presence has in this class.

FIGURE 6

Antipsychotics Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

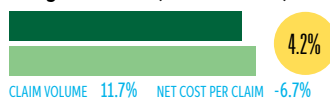
Aripiprazole Tablet (Oral)



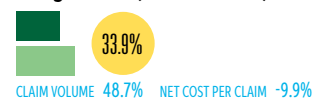
Seroquel XR (Oral)



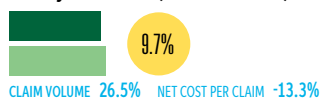
Invega Sustenna (Intramuscular)



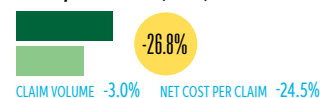
Invega Trinza (Intramuscular)



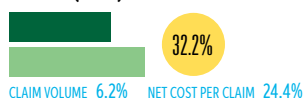
Abilify Maintena (Intramuscular)



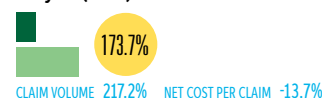
Chlorpromazine (Oral)



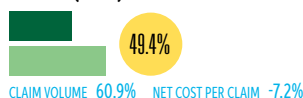
Latuda (Oral)



Vraylar (Oral)



Rexulti (Oral)



Risperdal Consta (Intramuscular)



MARKET STRATEGY

Maintain low utilization on oral branded products until they demonstrate a proven clinical advantage or lower net cost per claim.



CLINICAL STRATEGY

Consider requiring multiple generic trials for patients on oral therapy.
Clinical advantages of long-acting injectables should be weighed against their increased net cost and evaluated for potential decreased medical costs in nonadherent patients.



BRAND STRATEGY

Quetiapine ER net price erosion should be monitored against Seroquel XR net pricing for the appropriate time when the brand is no longer cost-effective compared to the generic.



Epinephrine (Self-Injected)

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Breaking the trend of the past few years, the net spend in the Epinephrine, Self-Injected category contributed the second largest impact on trend in the traditional classes by decreasing the average net cost per claim \$0.46. That decline resulted in a drop in the rankings from the No. 12 to the No. 99 overall net spend class.

- > The decreased trend in Epinephrine, Self-Injected was almost entirely due to a shift from brand EpiPen and EpiPen Jr. to its generic equivalents. In total, average net cost per prescription of EpiPen and EpiPen Jr. contributed to \$0.42 of the \$0.46 decrease in the class.
- > As projected in the 2017 edition, the authorized generics for the EpiPen product line drastically reduced the net spend in this class.
- > State Medicaid programs will find prolonged relief in this trend as the shift is expected to continue indefinitely.

FIGURE 7

Epinephrine, Self-Injected Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

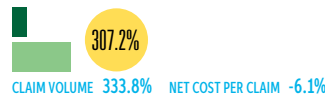
EpiPen (Intramuscular)



Epinephrine 0.3 mg (EpiPen) (AG) (Injection)



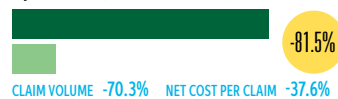
Epinephrine 0.3 mg (Adrenalick) (AG) (Injection)



Epinephrine 0.15 mg (EpiPen Jr.) (AG) (Injection)



EpiPen Jr. (Intramuscular)



Epinephrine 0.15 mg (Adrenalick) (AG) (Injection)



Auvi-Q 0.3 mg (Intramuscular)



Adrenalick 0.15 mg (Intramuscular)



Auvi-Q 0.15 mg (Intramuscular)



Adrenalick 0.3 mg (Intramuscular)



MARKET STRATEGY

States must make epinephrine products readily available to patients as dictated by clinical necessity as well as federal law.

Product availability in Medicaid, whether by participation in the Medicaid Drug Rebate Program or the absence of production issues, will continue to be monitored lest states experience a potential reversal of the trend toward decreased net spend.



BRAND STRATEGY

The EpiPen and EpiPen Jr. generics will continue to be the heavy favorites for preferred status based on current law governing the pricing of authorized generics.



Neuropathic Pain

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Neuropathic Pain treatment contributed the third largest impact on trend in the traditional classes by decreasing the average net cost per claim by \$0.33. This decrease dropped the class from the No. 7 to No. 11 class by total net spend. Despite a substantial increase in utilization of this class by 6.7%, it experienced a 36.8% drop in net spend.

- In 2017, Lyrica Capsule net cost fell precipitously (-80.8%), making it the largest contributor to trend with a \$0.25 decrease in average net cost per claim. Lyrica Capsule plummeted from the No. 19 overall net spend product to No. 158.
- Lidoderm's 95.2% drop in utilization was another major driver in decreased net spend (see figure 8), due to state Medicaid pharmacy department scrutiny of appropriate use in the pain category and falling Lidocaine patch prices.

FIGURE 8

Neuropathic Pain Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

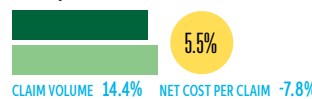
Gabapentin Capsule (Oral)



Duloxetine (Cymbalta) (Oral)



Gabapentin Tablet (Oral)



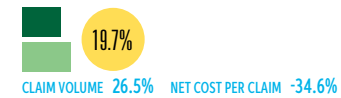
Lyrica Capsule (Oral)



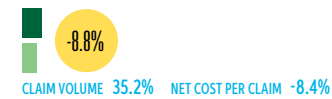
Lidocaine (Topical)



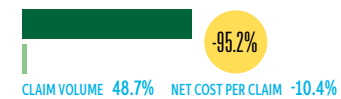
Lidocaine (AG) (Topical)



Gabapentin Solution (Oral)



Lidoderm (Topical)



Duloxetine (Irenka) (Oral)



Cymbalta (Oral)



MARKET STRATEGY

States that have employed clinical PA criteria through gabapentin and other drugs may consider lifting those requirements in anticipation of continued low net costs on Lyrica. However, it remains to be seen how the net spend of the generic will erode beyond 2019. Gabapentin net costs stabilized between various formulations. Combined with the falling net costs of duloxetine and the aforementioned Lyrica Capsules, a flare-up for the net spend in this class is unexpected as long as utilization of new entrants is appropriate.



BRAND STRATEGY

The expected generic launch of Lyrica in the middle of 2019 may not bring as much needed financial relief as once anticipated, as it is happening now instead.



Glucocorticoids (Inhaled)

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Glucocorticoids, Inhaled contributed a \$0.29 decrease in the average net cost per claim as the net cost on brands continued to decline. This dropped the overall rank for class net spend from No. 14 to No. 50.

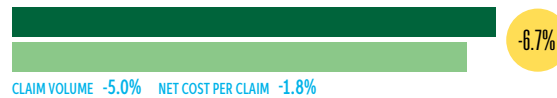
- > The largest contributor to the trend was Advair, with a \$0.08 decrease for Advair Diskus and a \$0.03 decrease for Advair HFA.
- > The decrease in net cost per claim for budesonide 0.25 mg and budesonide 0.5 mg resulted in a contribution to the overall trend of -\$0.05.
- > In 2017, the strategy of preferring Pulmicort respules over its generics saved state Medicaid programs \$8.4 million, despite a decline in generic prices.
- > Generics of non-oral formulations typically do not experience net cost decreases as quickly as those for oral products, so continued brand presence in this class is expected, even before accounting for the difficulties generics manufacturers are finding while gaining FDA approvals for these inhalers.

FIGURE 9

Glucocorticoids, Inhaled Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

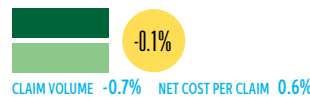
Pulmicort 0.25 mg, 0.5 mg Respules (Inhalation)



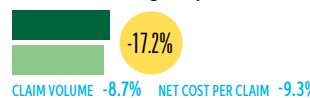
Budesonide 0.25 mg, 0.5 mg Respules (Inhalation)



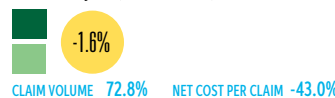
Pulmicort 1 mg Respules (Inhalation)



Budesonide 1 mg Respules (Inhalation)



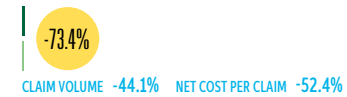
Breo Ellipta (Inhalation)



Dulera (Inhalation)



Flovent Diskus (Inhalation)



Arnuity Ellipta (Inhalation)



Asmanex HFA (Inhalation)



Aerospan (Inhalation)



BRAND STRATEGY

Brand-over-generic strategy for Pulmicort Respules continues to keep the net spend in this category down.



BRAND STRATEGY

Brand-over-generic savings opportunities will continue to be recommended until the eventual approval of an Advair generic and budesonide respules net costs undercut those of the brand.



Anticonvulsants

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



The Anticonvulsants class had the fifth largest impact on trend for traditional classes. Despite contributing a \$0.27 decrease in the average net cost per claim, this class maintained its overall net spend rank at No. 5.

- > The largest contributor to trend was divalproex ER due to a 42.5% decrease in net cost per claim (see figure 10).
- > This class is a microcosm of Medicaid in that generic utilization increased, and drove down net cost, but increased utilization of a few new brands had enough financial impact to keep average net cost per prescription within the class higher than it otherwise might have achieved.

FIGURE 10

Anticonvulsants Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

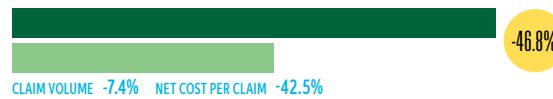
Vimpat Tablet (Oral)



Onfi Tablet (Oral)



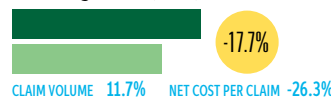
Divalproex ER (Oral)



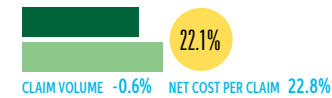
Onfi Suspension (Oral)



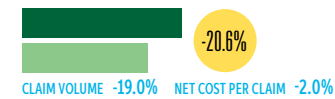
Lamotrigine XR (Oral)



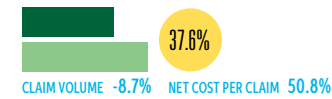
Lamotrigine Tablet (Oral)



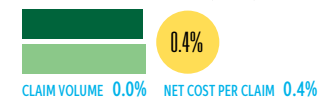
Oxcarbazepine Suspension (Oral)



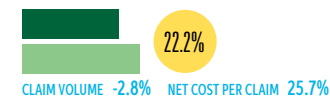
Clonazepam (Oral)



Levetiracetam Tablet (Oral)



Topiramate Tablet (Oral)



MARKET STRATEGY

State Medicaid programs were successful in the key management strategy of deterring utilization of high-cost brand medications that share indications with generics.



MARKET STRATEGY

Pricing for highly utilized generics should also be monitored since small changes in the cost per claim can have a large impact due to the high utilization.



Hypoglycemics, Insulins

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)

\$-0.21

Hypoglycemics, Insulins contributed a decrease of \$0.21, the sixth-largest impact in the traditional drugs and eighth largest overall. The overall impact of the insulin class was small compared to that in commercial plans and fell from the already low total net spend position of No. 90 to No. 446.

- > Trend decreases were due to decreases in net cost per claim across seven of the top 10 drugs, not due to decreases in utilization, which remained relatively steady.
- > Established brands in basal and rapid-acting insulins saw the largest total discounts and brought down the net spend in the class to a rock-bottom level.
- > Not surprisingly, new brands drove increased net cost, but new formulations of existing brands also played a part. New pen devices in particular could present financial challenges for state Medicaid programs as well as historically common challenges such as biosimilars and “follow-on” products.

FIGURE 11

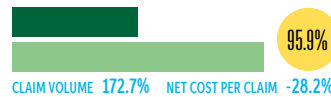
Hypoglycemics, Insulins Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

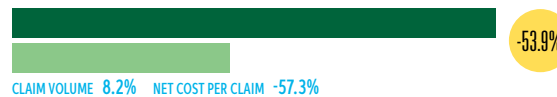
Humulin Vial OTC (SubQ)



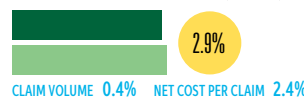
Tresiba FlexTouch 200 U/mL Pen (SubQ)



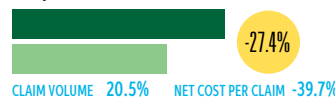
Humalog KwikPen (SubQ)



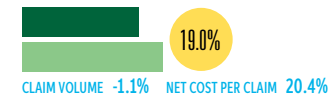
Humulin 70/30 Pen OTC (SubQ)



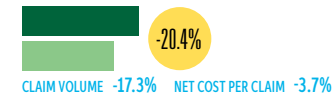
Toujeo SoloStar Pen (SubQ)



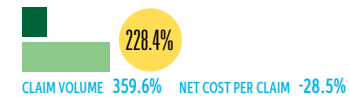
Humulin Pen OTC (SubQ)



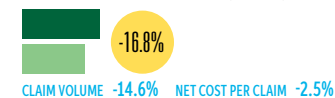
Novolin Vial OTC (SubQ)



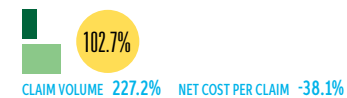
Tresiba FlexTouch 100 U/mL Pen (SubQ)



Novolin 70/30 Vial OTC (SubQ)



Humulin 500 U/mL KwikPen (SubQ)



MARKET STRATEGY

The next generation of insulin products has not shown significant uptake in Medicaid utilization to date, likely owing to the low net spend on market leaders.



CLINICAL STRATEGY

Unless substantial clinical benefits develop, new market entrants and generics will not see great uptake due to lack of competitive pricing.



Narcotics, Long-Acting

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



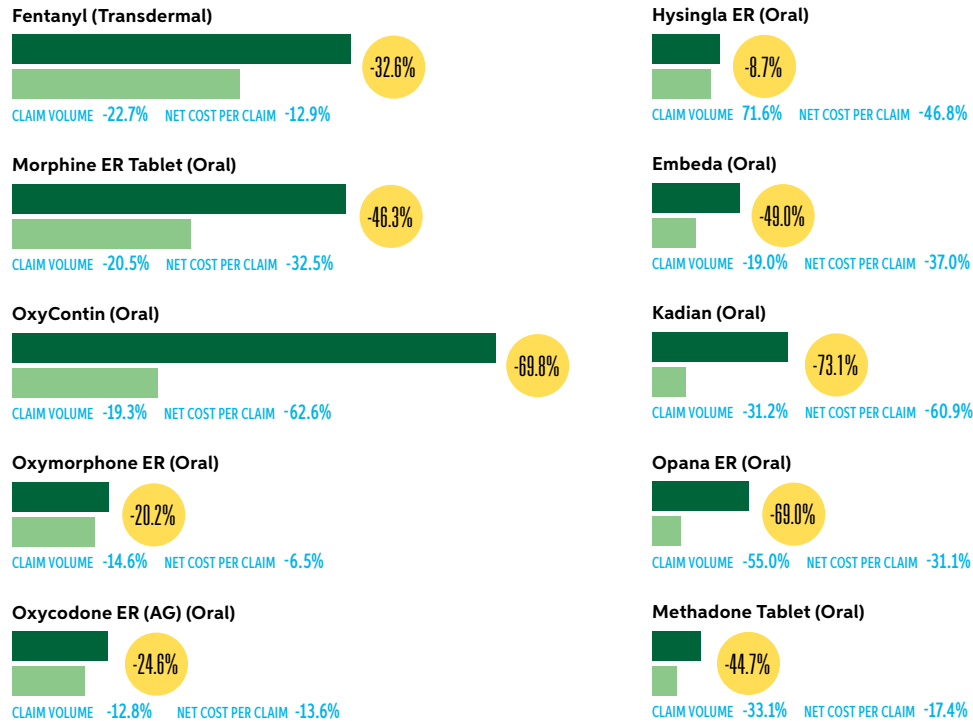
Narcotics, Long-Acting had the seventh-largest impact on average net cost per claim by decreasing the trend by \$0.20. The class had a 22% reduction in utilization likely due to the various state initiatives aimed at the opioid epidemic and the Narcotics, Long-Acting class. The class fell from No. 21 to No. 42 in net spend.

- As significant as the decrease in utilization was (nine of the top 10 drugs), it is perhaps more impressive that this class' impact on trend was mostly due to the decrease in net cost per claim of brands such as OxyContin, Kadian, Opana ER, Embeda, and Butrans.
- Despite the reduction in utilization for the class overall, products with abuse-deterrent properties, such as OxyContin and Embeda, did not make notable market share gains. This is perhaps due to conflicting opinions on the usefulness of the mechanisms of their active ingredient that prevent abuse.

FIGURE 12

Narcotics, Long-Acting Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)



MARKET STRATEGY

Focus on low net cost brands and generics. States continue to implement strategies to decrease overall utilization in the class due to the opioid epidemic.



CLINICAL STRATEGY

Set MMEs and dosing limits along with continued monitoring for abuse.

Not all states listed an abuse-deterrent formulation as preferred, as the state Medicaid department focus appears to be on treating those with opioid use disorder.



Intranasal Rhinitis

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Intranasal Rhinitis had the eighth-largest impact on the average net cost per claim by decreasing the net cost \$0.19. This decrease resulted in a drop in rank from No. 42 to No. 38.

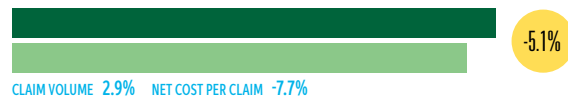
- > Nasonex's net cost per claim decreased the average cost per claim by \$0.20. Although it did not have an impact on year-over-year trend since it was in place last year, preferring Nasonex over the higher net cost generic saved state Medicaid programs \$1.2 million in 2017.
- > The example of Nasonex illustrates the complexity of Medicaid pricing as it pertains to the availability of authorized generics. In short, the presence of authorized generics can lead to wild fluctuations in the federal rebate. In 2017, the overall impact was a favorable net cost to Medicaid, but that net cost was not steady over the course of the year. For this reason, brands with authorized generics available should be viewed with caution from a financial standpoint. The presence of a guaranteed price is essential in order for states to be comfortable with a preferred status in this situation.

FIGURE 13

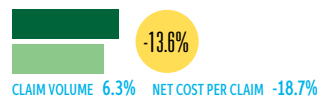
Intranasal Rhinitis Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

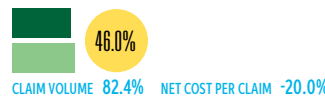
Fluticasone



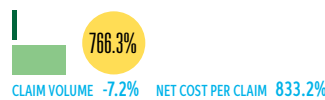
Mometasone



Mometasone (AG)



Patanase



Ipratropium



Azelastine (Astellin)



Azelastine (Astepro)



Nasacort OTC



Olopatadine



Qnasl 40 mcg



MARKET STRATEGY

Savings potential is focused on monitoring brand-over-generic pricing. Most states have long shifted to generics, but savings opportunities may still exist.



Narcotics, Short-Acting

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Narcotics, Short-Acting had a 16% decrease in utilization along with a decrease in cost per claim of \$0.18. This decrease resulted in a fall from the No. 8 net spend class to No. 9. Despite decreased utilization, the class is still primarily driven by volume in low-priced generics.

- What popped in this class was a double-digit reduction in utilization of acetaminophen-containing combination products. This is likely due to the continued effort toward reducing utilization of all opioids and/or attention to potential acetaminophen overdoses in unsuspecting users.

FIGURE 14

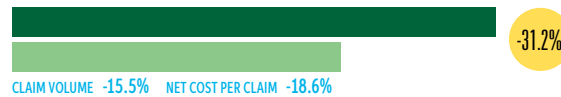
Narcotics, Short-Acting Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

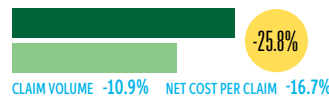
Hydrocodone/APAP Tablet (Oral)



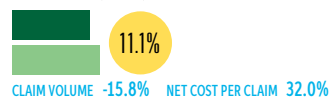
Oxycodone/APAP Tablet (Oral)



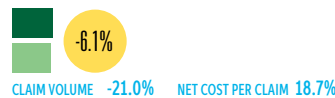
Oxycodone Tablet (Oral)



Tramadol (Oral)



APAP/Codeine Tablet (Oral)



Hydrocodone/APAP Solution (Oral)



Oxycodone Solution (Oral)



Hydromorphone Tablet (Oral)



Oxymorphone (Oral)



Morphine IR Tablet (Oral)



MARKET STRATEGY

Focus on low-cost generics and general avoidance.

States continue to implement appropriate use strategies to address the opioid epidemic.



CLINICAL STRATEGY

States set MMEs and dosing limits along with continued monitoring for abuse.



Opioid Use Disorder Treatment

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Opioid Use Disorder Treatment was the only traditional class in the top 10 trend impacts that resulted in an increased average net cost per claim of \$0.18. This change was primarily due to the 33% increase in utilization. The increased utilization aligns with the increased patient, prescriber, and public awareness of opioid use disorder medication-assisted treatment modalities. Accordingly, it was the No. 1 positive trend driver among traditional classes. This is especially encouraging as the 2017 MRx Medicaid Trend Report™ showed only a 10% increase in utilization. Increased utilization resulted in a rise in rank from No. 10 to No. 8.

- ▶ Despite the 30.3% increase in Suboxone Film volume, the net cost per claim decreased 13.9%. The higher Suboxone Film utilization would have resulted in a \$0.14 increase in average net cost per claim, but lower net prices for Suboxone Film resulted in a -\$0.08 offset, resulting in a net increase of \$0.06.
- ▶ The No. 2 drug in this class, Vivitrol, increased the average net cost per claim by \$0.06 through its 52.4% increase in utilization.

FIGURE 15

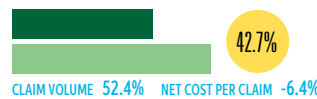
Opioid Use Disorder Treatment Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

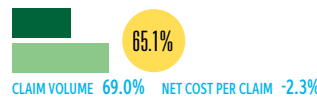
Suboxone Film (Sublingual)



Vivitrol (Intramuscular)



Zubsolv (Sublingual)



Buprenorphine (Sublingual)



Buprenorphine/Naloxone Tablet (Sublingual)



Narcan Spray (Nasal)



Naltrexone (Oral)



Bunavail (Buccal)



Evzio (Injection)



Naloxone Syringe (Injection)



MARKET STRATEGY

Focus on competition for preferred positioning of buprenorphine-containing products.

The opioid epidemic and political pressure will continue to make state Medicaid staff focus on expanding preferred status while corraling net costs.



CLINICAL STRATEGY

New buprenorphine delivery systems as well as novel products that help manage withdrawal symptoms are in the pipeline. These will continue development of treatment guidelines for opioid use disorder medication-assisted treatment.



HIV/AIDS

Net Dollar Impact (Overall pharmacy spend went down by \$2.10.)



HIV/AIDS had the largest impact on overall specialty trend with a continued shift in utilization to newer, more expensive single-tablet regimens. It drove the overall average net cost per claim up by \$0.52, which resulted in the class overtaking antipsychotics as No. 1 in overall net spend by class. Despite the increased spend, states are continuing to examine cost-efficacy measures appropriate to this drug category, and have yet to implement specific measures in a broader way.

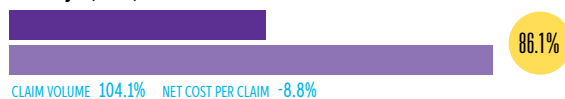
- > Genvoya, Descovy, Odefsey, Trimeq, and Tivicay more than doubled in utilization and contributed \$1.23 to the overall average net cost per claim. The contribution resulted in the class having five drugs ranked in the top 21 by overall net spend.
- > The increase in overall average net cost per claim from these drugs was partially offset by decreased utilization in their less expensive predecessors and other older brands. Decreased utilization in Stribild, Truvada, Complera, and Atripla lowered the average net cost per claim by \$0.52 through a combination of decreased utilization and lower net cost per claim.

FIGURE 16

HIV/AIDS Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

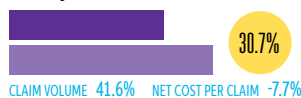
Genvoya (Oral)



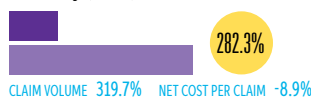
Trimeq (Oral)



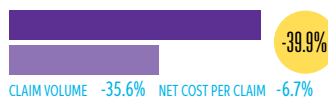
Tivicay (Oral)



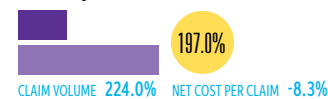
Descovy (Oral)



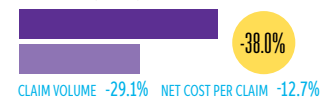
Stribild (Oral)



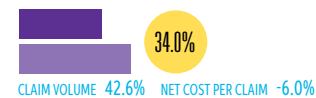
Odefsey (Oral)



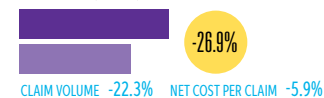
Truvada (Oral)



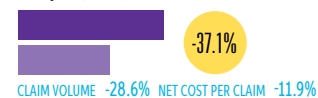
Prezcobix (Oral)



Prezista (Oral)



Atripla (Oral)



MARKET STRATEGY

Net spend in this class will continue to rise and account for a larger percentage of the Medicaid budget. States are continuing to examine cost-efficacy measures that preserve and promote access, while also improving quality of care and lowering overall costs.



CLINICAL STRATEGY

Market share continues to move to the newer, higher net cost products with claims of incrementally improving patient care versus the existing treatments.



Spinal Muscular Atrophy

Net Dollar Impact (Overall pharmacy spend went down by \$2.10.)



Spinal Muscular Atrophy, a new specialty class, had the second largest impact on overall trend by driving the overall average net cost per claim up by \$0.30. With only one drug, Spinraza, an orphan drug for the treatment of Spinal Muscular Atrophy injected intrathecally, the substantial impact on trend was unexpected.

- Spinraza, the sole contributor to the class, ended the year as No. 20 in net spend. Although there was relatively low utilization, the high cost per claim drove the high net spend.
- It is unclear if Spinraza was predominantly administered through the medical or pharmacy benefit. If utilization was on the medical benefit, the true impact of the class could have been larger.

FIGURE 17

Spinal Muscular Atrophy Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ■ Net spend (% change '16-'17)

Spinraza (Intrathecal)



MARKET STRATEGY

Management should include both the pharmacy and medical benefits.



CLINICAL STRATEGY

Focus on clinically appropriate use of Spinraza, including administration by a healthcare professional trained in intrathecal injection.



Hemophilia

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



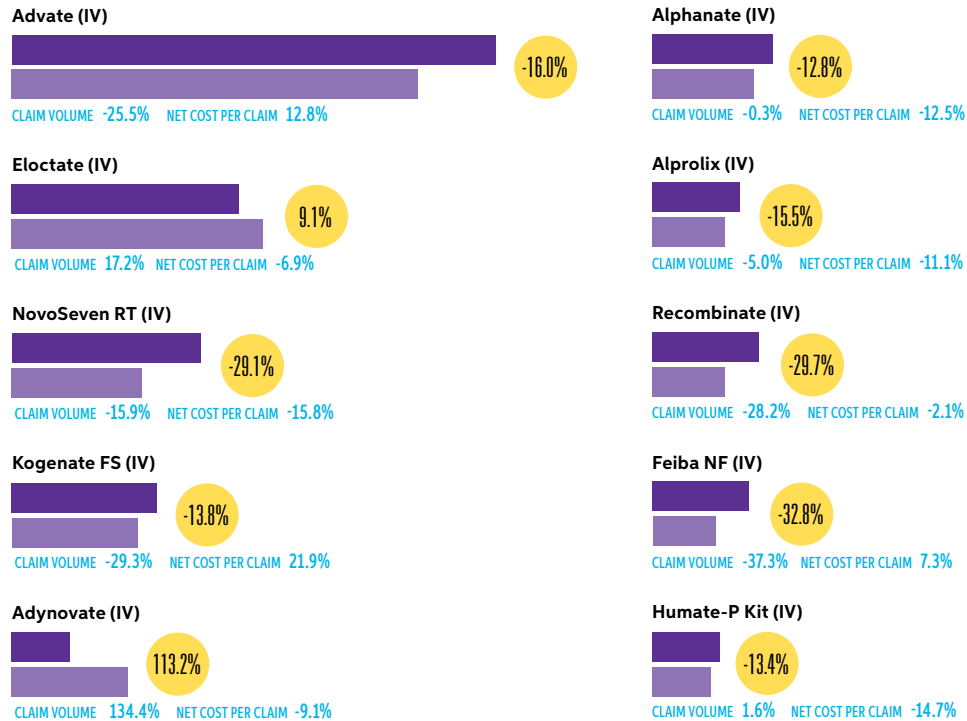
Hemophilia had the largest negative impact on trend in the specialty classification by driving the overall average net cost per claim down by \$0.26. The negative impact on trend was mostly driven by an 11.3% decrease in utilization in the class. Despite the decrease in trend in 2017, the class maintained the No. 3 rank in overall net spend.

- Advate and NovoSeven RT drove the decrease in overall net cost per claim. Despite the decrease in trend, Advate moved up the overall net spend rankings from No. 3 to No. 2.
- NovoSeven RT decreased the overall net spend per claim by \$0.09 (-15.8%) with a relatively even mix of decreased utilization (-15.9%) and lower net price per claim.
- Newer products trended in 2017 with Adynovate utilization climbing 134.4%, increasing the average cost per claim by \$0.13 and moving the drug from No. 97 to No. 33 in the net spend rankings.
- Eloctate experienced a 17.2% increase in utilization, moving average cost per claim up by \$0.06 and the drug from No. 13 to No. 11 in net spend rankings (see figure 18).

FIGURE 18

Hemophilia Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)



MARKET STRATEGY

Management is complex and should encompass a holistic approach. Although PDL implementation is important, additional cost-management initiatives are equally necessary.



CLINICAL STRATEGY

Hemophilia management should include care management to coordinate care for this vulnerable patient population.



Hepatitis C

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



Hepatitis C had the second-largest negative impact on trend in the specialty classification by driving the overall average net cost per claim down by \$0.25. Despite the decrease in trend, the class maintained the No. 6 rank in overall net spend. The decrease was predominantly due to a utilization shift from higher- to lower-costs drugs. Utilization was relatively similar, with only a 5.7% decrease.

- Although the sixth most expensive class by net spend, drug cost decreased. However, lower per-treatment cost was offset by increased utilization. This increase should be viewed as a positive. Lower pharmaceutical costs in this class have led to states lowering the METAVIR fibrosis score requirement for treatment (see figure 20).
- Harvoni, Viekira, Sovaldi, and Daklinza were the largest contributors to decreased trend, reducing overall average net cost per claim by \$0.93. The decrease was offset by increased utilization in lower net cost drugs Epclusa, Mavyret, and Zepatier accounting for an increase in average net cost per claim by \$0.60.

FIGURE 20

Coverage by Fibrosis Score

F0 F2 F3 F4

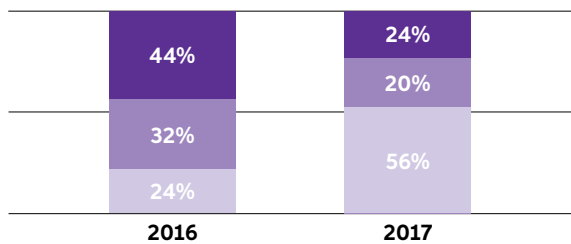
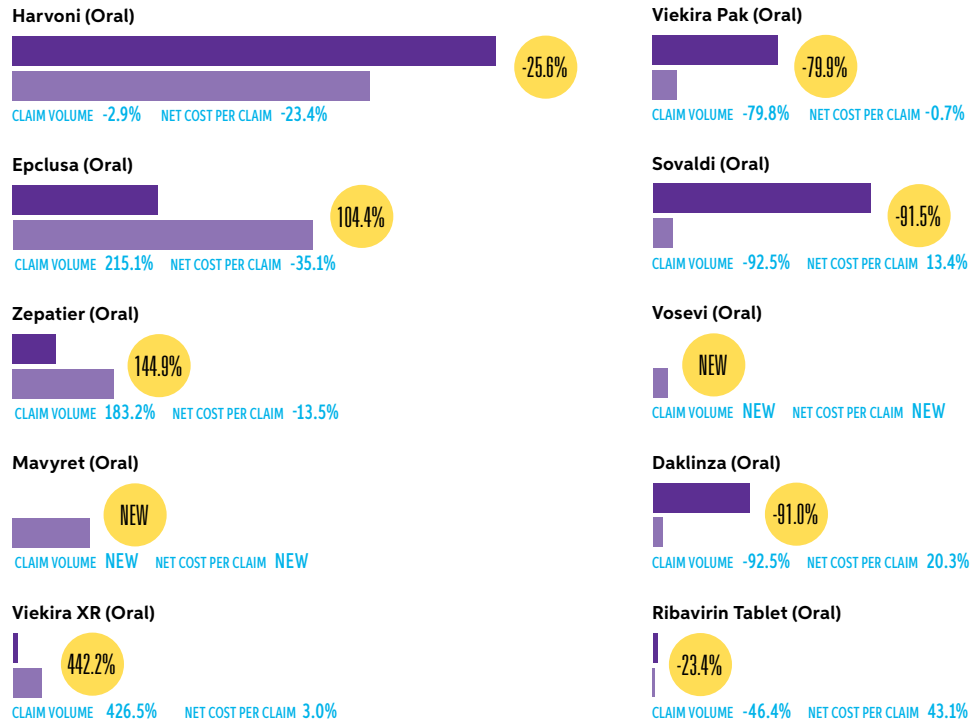


FIGURE 19

Hepatitis C Spend and Utilization Trend 2016-2017

2016 total net spend 2017 total net spend Net spend (% change '16-'17)



CLINICAL STRATEGY

A majority of states are easing restrictions and removing or lowering Metavir score requirements due to the decline of cost per claim for drugs in the class. Reduced restrictions have decreased the number of patients waiting for a new treatment or a less restrictive Metavir score before acquiring treatment.



Cystic Fibrosis

Net Dollar Impact (Overall pharmacy spend went down by \$2.10.)



Cystic Fibrosis had the third-largest positive impact on overall trend by driving the overall average net cost per claim up by \$0.22. Despite being a small drug class consisting of only two drugs, Orkambi and Kalydeco, the increased spend moved the class to No. 7 in the overall net spend rankings.

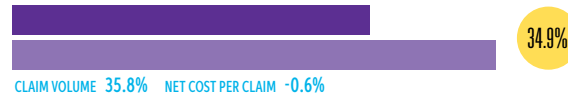
- > The impact on trend was almost solely due to an increase in Orkambi utilization of 35.8% driving the overall net cost per claim up \$0.21. Orkambi utilization was the sole driver as net cost per claim stayed relatively flat at -0.6% (see figure 21). The increased utilization moved Orkambi up in overall net spend rankings from No. 7 to No. 4.
- > A shift in Kalydeco utilization from the tablets to the packets resulted in the remaining \$0.01 increase in net cost per claim.

FIGURE 21

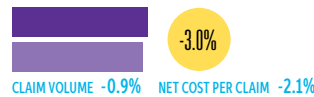
Cystic Fibrosis Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)

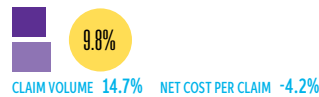
Orkambi (Oral)



Kalydeco Tablet (Oral)



Kalydeco Packet (Oral)



CLINICAL STRATEGY

With only two drugs in the class, management is focused on appropriate use by Cystic Fibrosis patients with certain gene mutations. PA criteria should be in place to assure appropriate use.



Progestational Agents

Net Dollar Impact (Overall pharmacy spend went down by \$2.10.)



Progestational agents impacted the overall trend by driving the overall average net cost per claim up by \$0.13. This increase caused the class to increase in the net spend rankings from No. 136 to No. 58.

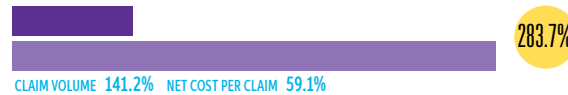
- > Makena single-dose (SDV) and multi-dose vials (MDV) contributed \$0.14 of the increased net cost per claim due to increased utilization of 141.2% for the newer SDV and increased net cost per claim of 157.9% for MDV (see figure 22). This drove Makena SDV up to No. 77 in the net cost rankings. Makena MDV net cost per claim increases resulted in only a \$0.01 offsetting decrease in average cost per claim.
- > Management strategy has shifted due to the increased regulation surrounding compounded drugs, causing large decreases in utilization of compounded hydroxyprogesterone products. Decreased compounded drug utilization and decreased cost per claim for Makena increased access and utilization of the drug. Part of the increased access has come from state Medicaid programs opening access on the pharmacy benefit to obtain lower costs than those in the medical benefit.

FIGURE 22

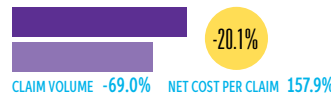
Progestational Agents Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ■ Net spend (% change '16-'17)

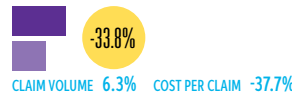
Makena SDV (Intramuscular)



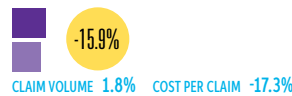
Makena MDV (Intramuscular)



Progesterone Capsule (Oral)



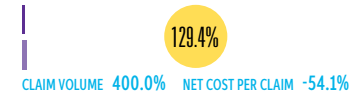
Norethindrone Acetate (Oral)



Medroxyprogesterone Acetate (Oral)



Hydroxyprogesterone Caproate (Intramuscular)



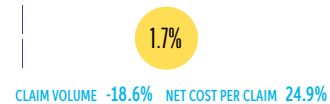
Progesterone (Intramuscular)



Prometrium (Oral)



Provera (Oral)



Crinone (Vaginal)



MARKET STRATEGY

Due to compounded drug regulations mentioned above, the shift to Makena on the pharmacy benefit will likely continue. State Medicaid programs should monitor the price difference between the two Makena products and assure clinically appropriate use.



Oncology, Breast

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



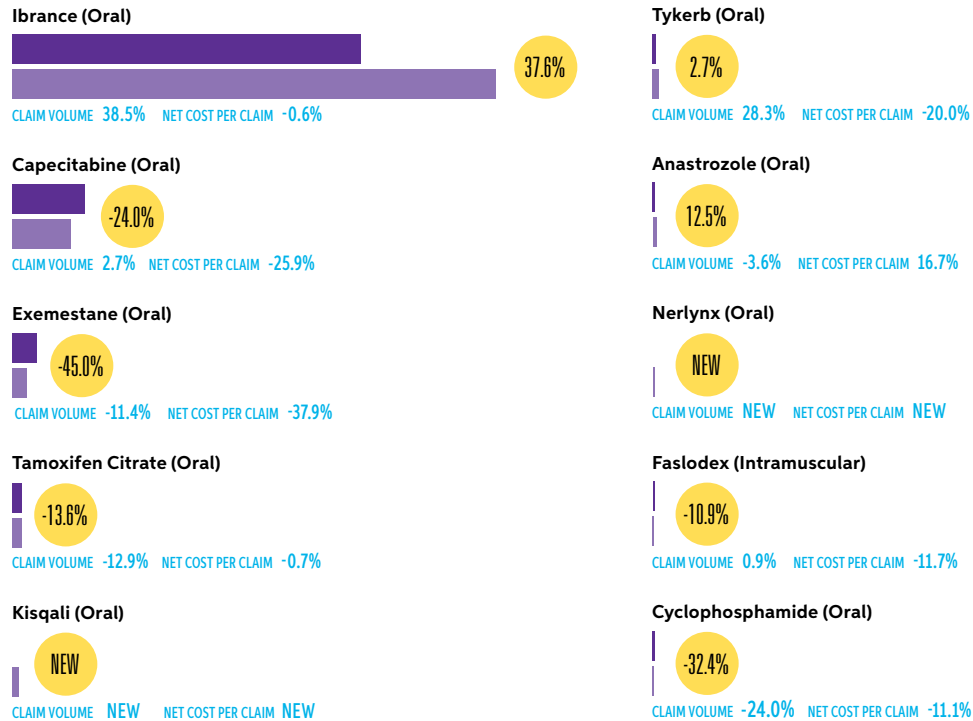
Oncology products to treat breast cancer impacted the overall trend by driving the overall average net cost per claim up by \$0.10. This increase caused the class to move up eight spots in the net spend rankings from No. 22 to No. 14.

- > The main driver of trend, Ibrance increased utilization by 38.5%, driving the overall net cost per claim up \$0.12. Net cost per claim stayed relatively flat at -0.6%. The increased utilization moved Ibrance up in the net spend rankings from No. 30 to No. 16.
- > The increase from Ibrance was slightly offset by a reduction in the overall net cost per claim from capecitabine (24.0%) and exemestane (45.0%). Decreased cost per claim for both drugs resulted in an offsetting \$0.02 decrease in the overall net cost per claim.
- > A Medicaid strategy that might otherwise go unappreciated was the continued preferred status for Xeloda compared to its generic. The utilization for both remained virtually unchanged from 2016 to 2017, as the net cost of the brand remained lower than that of the generic.

FIGURE 23

Oncology, Breast Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)



CLINICAL STRATEGY

Like other specialty classes, the complexity of breast cancer requires more than PDL management. State Medicaid programs should have clinical oncology pathways with additional patient support in place to assure patients receive the most clinically and financially beneficial treatment.



Endocrine and Metabolic Agents (Miscellaneous)

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



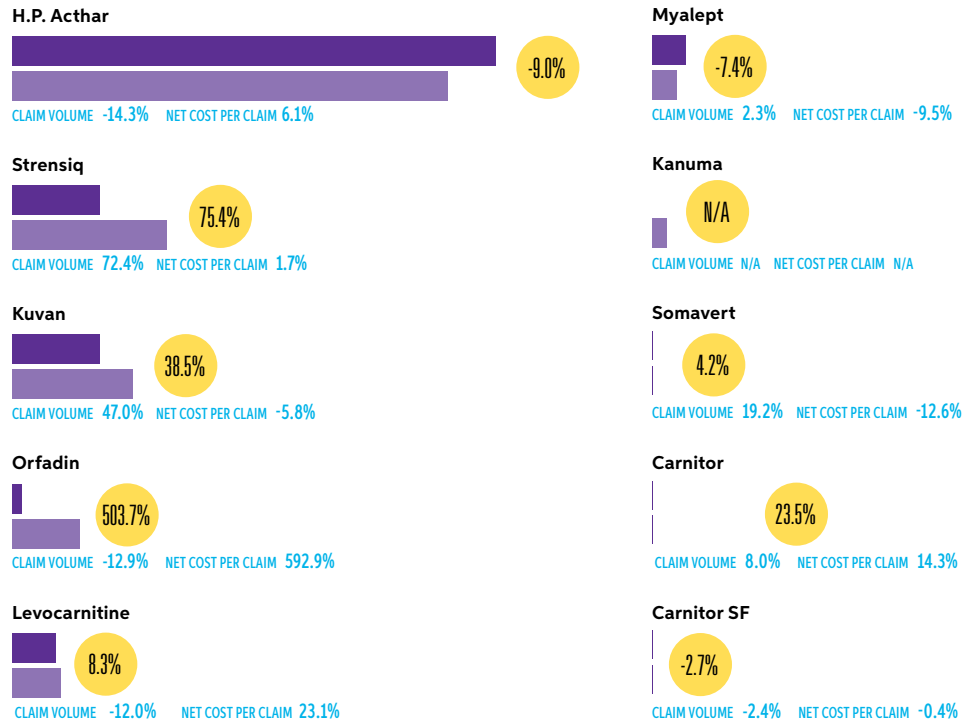
The Endocrine and Metabolic Agents (Miscellaneous) class impacted the overall trend by driving the overall average net cost per claim up by \$0.08. This increase caused the class jump in the net spend rankings from No. 23 to No. 16.

- Four orphan drugs, Strensiq, Orfadin, Kuvan, and Kanuma, had the greatest impact on the class. Strensiq had a 72.4% increase in utilization, which resulted in an increase in overall net cost per claim by \$0.04. Orfadin had a 12.9% decrease in utilization but a 592.9% increase in net cost per claim (see figure 24), contributing a \$0.03 increase to the overall average net cost per claim. Kuvan and Kanuma contributed \$0.02 and \$0.01 to overall net cost per claim, respectively.
- Increases in these four drugs were partially offset by a 14.3% decrease in H.P. Acthar utilization along with decreased utilization in a combination of several other drugs to decrease the contribution to overall average net cost per claim by \$0.02.

FIGURE 24

Endocrine and Metabolic Agents (Miscellaneous) Spend and Utilization Trend

■ 2016 total net spend ■ 2017 total net spend ■ Net spend (% change '16-'17)



CLINICAL STRATEGY

Clinical criteria should be implemented to assure appropriate use for rare disease indications. States are increasingly looking for input from disease state specialists to assist with creation of clinical use criteria.



BRAND STRATEGY

Drugs in this class are indicated for varying orphan disease states such as Hereditary Tyrosinemia Type 1 (HT-1), Hyperphenylalaninemia, and Lysosomal Acid Lipase Deficiency, which presents a management challenge for state Medicaid programs.



Oncology, Injectable

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



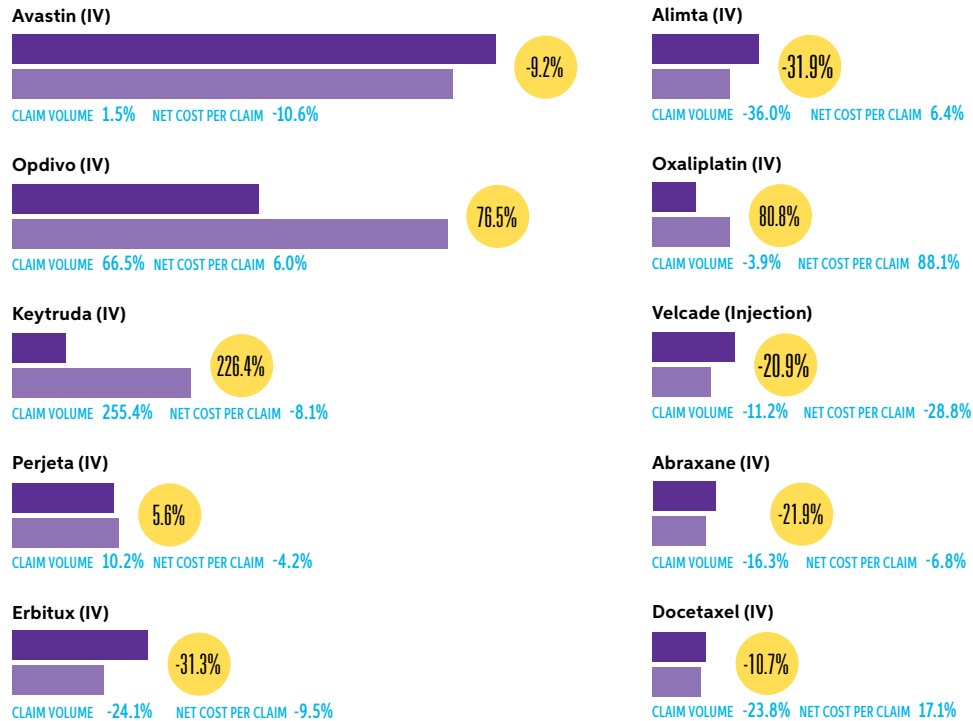
The Oncology, Injectable class impacted the overall trend by driving the overall average net cost per claim up by \$0.06. This increase caused the class to move net spend rankings from No. 62 to No. 40.

- > Alimta and Opdivo each contributed an additional \$0.02 to the overall average cost per claim. Alimta saw an increase in average cost per claim, which was not fully offset by a 36% decrease in utilization. Opdivo saw a 66.5% increase in utilization likely due to the approval of several new indications.
- > A 255.4% increase in Keytruda utilization, likely from new and expanded indications, added \$0.01 to the overall average cost per claim (see figure 25).

FIGURE 25

Oncology, Injectable Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ● Net spend (% change '16-'17)



MARKET STRATEGY

States should evaluate the most financially beneficial delivery channel as many of these drugs could be reimbursed on the pharmacy and medical benefit.



CLINICAL STRATEGY

Similar to other oncology classes, state Medicaid programs should have clinical oncology pathways with additional patient support in place to assure patients receive the most clinically and financially beneficial treatment.



Antibiotics, Inhaled

Net Dollar Impact (Overall pharmacy spend went down by \$2.10)



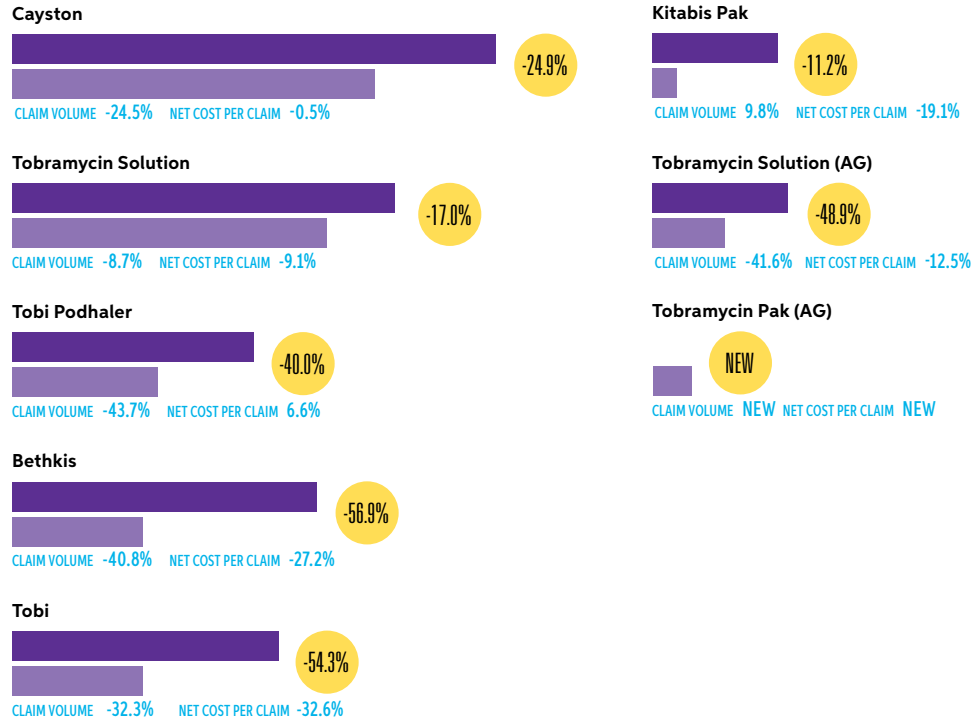
Antibiotics, Inhaled impacted the overall trend by driving the overall average net cost per claim down by \$0.06. This decrease caused the class to fall 18 spots in the net spend rankings from No. 48 to No. 66.

- > In total, the class experienced a 26% decrease in utilization spread fairly evenly throughout all drugs with the exception of Kitabis Pak and tobramycin pak, which experienced small increases in utilization.
- > Decreased utilization accounted for \$0.01 of the decrease in the average overall cost per claim for Bethkis, Tobi, Cayston, tobramycin solution, and Tobi Podhaler.
- > Decreased cost per claim for Bethkis and Tobi also added an additional \$0.01 decrease in average cost per claim in the class.
- > With the decrease in average cost per claim for Tobi, the brand-over-generic strategy for the drugs continued to be a cost-saver. State Medicaid programs saved more than \$900,000 by preferring brand Tobi over the more expensive generic.

FIGURE 26

Antibiotics, Inhaled Spend and Utilization Trend 2016-2017

■ 2016 total net spend ■ 2017 total net spend ■ Net spend (% change '16-'17)



CLINICAL STRATEGY

Clinical criteria should continue to be used in this class to ensure appropriate utilization.



BRAND STRATEGY

Drive utilization to the lowest net cost brand medication. Several of the products contain the same active ingredient, opening the door for a preferencing strategy easier to execute than in other specialty classes.

Brand-over-generic opportunities should continue to be monitored for changes in the generic price that no longer make the brand a less expensive option.

Trump Administration's Blueprint to Lower Drug Prices

On May 11, 2018, HHS released *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.¹ With respect to Medicaid, the *Blueprint* included the president's federal fiscal year (FFY) 2019 budget proposal for new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms. The president's FFY 2019 budget and the *Blueprint* also call for tightening how drugs are classified as brand or generic under the Medicaid Drug Rebate Program (MDRP) — recommendations originally made by the Medicaid and CHIP Payment and Access Commission (MACPAC) to help ensure Medicaid programs receive the proper drug rebates due to them from manufacturers. (MACPAC estimates state Medicaid programs' prescription drug costs were reduced by more than \$31 billion in FFY 2016 as a result of the MDRP.)

The *Blueprint* discusses Medicaid "best price," including whether this provision, which allows Medicaid to pay the lowest possible prices, should be changed. It also highlights the administration's concerns that excluding pharmacy benefit manager-negotiated rebates and other discounts from the determination of best price may encourage list price increases and cost shifting to other healthcare payers.

Together, the questions within the *Blueprint* and the accompanying HHS request for information (RFI) offer an opportunity to ensure the MDRP continues to guarantee states and taxpayers pay the lowest possible costs for drugs under the Medicaid program. The questions posed may be examined further in future federal rulemaking or by Congress; for example, the White House Office of Management and Budget currently is

reviewing an HHS proposed rule that may remove the current discount exception ("safe harbor") to the Anti-Kickback Statute for prescription drug rebates negotiated with manufacturers on behalf of the Medicare and Medicaid programs.

States Explore New Medicaid Waivers

Similar to the new Medicaid demonstration authority included within the *Blueprint* and the president's FFY 2019 budget proposal, the commonwealth of Massachusetts submitted a waiver request² to CMS Administrator Seema Verma detailing several ways it would like to work with the federal agency on health

MACPAC estimates state Medicaid programs' prescription drug costs were reduced by more than \$31 billion in FFY 2016 as a result of the MDRP.

insurance and Medicaid issues, specifically to limit the drugs the commonwealth would cover through its Medicaid program but retain access to the rebates guaranteed under the MDRP. (Under existing law, state Medicaid programs are required to cover nearly all drugs that have been approved by the FDA in order to receive the rebates.) The letter was submitted in response to an earlier March 13, 2017, letter³ inviting states to work with CMS to amend their Medicaid programs through state plan amendments and Section 1115 waivers. On June 27, CMS rejected the proposal; the federal

agency expressed, however, its willingness to consider a demonstration that would allow the commonwealth to exclude coverage of certain drugs from the Medicaid program, so long as Massachusetts forgoes all manufacturer rebates available under the MDRP. States opting for such a demonstration would no longer receive the 23.1% and 13.1% rebates guaranteed under the MDRP, and would have to negotiate their own discounts with manufacturers.

CPI-U Generic Impact

The Bipartisan Budget Act (BBA) of 2015 requires manufacturers of generics to pay additional federal rebates (under the MDRP) for a non-innovator multi-source drug when the AMP increases at a rate exceeding inflation, as measured by the Consumer Price Index-Urban (CPI-U). Effective the first quarter of 2017, manufacturers of generics are required to pay the additional federal rebate. This requirement is similar to the additional federal rebate already applied for manufacturers of single-source and innovator multi-source drugs.

Impact: When considering CY 2017 data, states measured in the data achieved additional federal rebates from the generic CPI-U penalty equal to approximately 0.6% of their total drug cost on average. For example, if a state spent \$100 million on drugs in its pharmacy program during 2017, it could anticipate \$600,000 in additional federal rebates resulting from the generic CPI-U penalty. The following top 10 non-innovator multi-source drugs accounted for nearly 33% of the additional federal rebates: Chlorpromazine HCL, Fluphenazine HCL, Levorphanol Tartrate, Guanfacine HCL ER, Suprax, Eryped 200, Eryped 400, Mupirocin, Methylphenidate ER, Bupropion XL.

1. U.S. Department of Health & Human Services, "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (May 11, 2018), <http://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

2. Secretary Marylou Sudders, Executive Office of Health and Human Services, the Commonwealth of Massachusetts, "Letter to Seema Verma, Administrator, U.S. Centers for Medicare and Medicaid Services" (March 22, 2017), http://www.scribd.com/document/343231298/Administrator-Verma-Letter-3-22-2017-Final#from_embed.

3. Thomas E. Price, MD, former secretary of HHS, "Dear Governor" (March 13, 2017), <http://www.hhs.gov/sites/default/files/sec-price-admin-verma-1tr.pdf?language=en>.



Other Notable Market Events

The Omnibus Budget Reconciliation Act (OBRA) of 1990 was landmark legislation for Medicaid programs. This act created the pathway for supplemental rebate programs that have now been in existence for more than 15 years. OBRA also leveraged a significant tool that is readily used in formulary management — guaranteed coverage. A manufacturer that enters into an agreement with HHS to provide a federal rebate for its products knows that a state accepting federal matching funds for its Medicaid program must reimburse pharmacies for those products. Federal funding is essential to states; it constitutes 50% to 90% of the cost of pharmaceuticals. Twenty-seven years later, state Medicaid programs sought to establish additional levels of control over ballooning expenditures. One major 2017 trend was the shift of state Medicaid programs to single-PDL (also known as universal- or statewide-PDL) formats. This PDL

One major 2017 trend was the shift of state Medicaid programs to single-PDL (also known as universal- or statewide-PDL) formats. This PDL design is followed by FFS providers as well as those in Medicaid MCOs to which the state has delegated the responsibility of pharmacy reimbursement.

design is followed by FFS providers as well as those in Medicaid MCOs to which the state has delegated the responsibility of pharmacy reimbursement. Although Medicaid MCOs are compensated by the state in exchange for providing pharmaceuticals for Medicaid recipients, more and more states are retaining PDL control due to net pricing advantages specific to the FFS side.

In 2010, the ACA provided states with the ability to invoice any Medicaid pharmacy utilization (FFS or MCO) for federal rebates. States were therefore able to collect federal rebates on MCO utilization, while MCOs could continue to contract with manufacturers on the typical percent discount basis. Initially, there was greater interest in this model. In 2013, Texas was the first state in the country to develop and implement a single-PDL program. This program has been extended by its legislature from 2018 to 2023. This decision, combined with several other states' moves toward single-PDL programs, definitively comprised a trend in Medicaid pharmacy. Other early single-PDL states include Florida, Delaware, and New Hampshire. In January 2017, Nebraska became the latest to join the club.

Several states had come to agreements with MCOs even before ACA became law. Many resumed control over classes where net expenditures were deemed more advantageous under FFS than MCO. This idea originated during the stretch of several years when hepatitis C costs drove state spend well beyond state budgets. Minnesota carved hepatitis C out of MCO responsibility and implemented a one-class single PDL in 2017. Virginia implemented a single PDL in 2017 that focused on a select number of classes that had high negotiating leverage through FFS pricing. Arizona continued to develop a similar model that it had started in 2015. Finally, the Washington state legislature approved a single-PDL

design starting this year. Looking forward, at least three other states intend to put full single-PDL models in place in the 2018-20 time frame.

The attraction of the single-PDL model is not fully appreciated outside of Medicaid FFS. This method combines common commercial management practices with best price-exempt discounts. As discussed in the Medicaid Pharmacy Economics Primer in this report (see page 31), federal and supplemental rebates can push the 100% AMP ceiling set by the ACA.

The attraction of the single-PDL model is not fully appreciated outside of Medicaid FFS. This method combines common commercial management practices with best price-exempt discounts.

A couple of states took steps in 2017 to achieve the ability to exclude coverage. Massachusetts was unsuccessful in securing a waiver from CMS that proposed they be allowed to not pay for select products. New York implemented a budget cap by which products may undergo special reviews to determine the need for enhanced discounts or more restrictive clinical criteria. Specialty expenditures are driving net spend higher on an annual basis. Until that trend line flattens, we anticipate states will continue to explore every available tool, including state legislative action, and new, innovative Medicaid waivers in their efforts to best control net drug spend.



This Medicaid economics primer is truncated from previous editions to assist in interpreting net cost data presented in this report. For a more detailed version, see previous iterations of this report at www.magellanrx.com.

Background

The pharmacy economics of Medicaid are different from commercial and Medicare drug pricing and rebate management strategies. Medicaid is a state-run program with federal oversight that demands full government transparency. All Medicaid FFS federal and supplemental rebates are paid directly to the state and then shared with the federal government.

For Medicaid, pharmaceutical cost evaluation should focus on the net cost after all discounts (federal, supplemental, and rebate offset amount), not on the total supplemental rebates collected. In 2017, the states' average federal rebate (net of the rebate offset amount) was 53.1% of gross pharmacy reimbursement. New brands have a minimum rebate of 23.1% AMP. Established brands can approach and exceed 90% of AMP after years of discounting and CPI-U penalties. Supplemental rebates are best price exempt and average 3-6% off of a state's gross spend, depending on state utilization management, unit cost management, and drug mix. In 2017, the average supplemental discount was 4.5% for an average total discount of 57.6%.

The Economics

To understand Medicaid economics, as illustrated in **figure 27**, assume pharmacy reimbursement, WAC, and AMP are all the same. A new brand drug enters the market with a minimum mandatory rebate of 23.1% AMP. This drug enters a competitive class with three clinically equivalent therapeutic alternatives, each with higher discounts and lower net costs than the new drug. With a pharmacy reimbursement cost of \$100, the net cost to the state is \$76.90 (\$100 minus 23.1%, or \$23.10). In order to be competitive, the manufacturer of the new brand will offer an additional discount, known in Medicaid as a supplemental rebate, to lower the net cost from \$76.90 to a competitive price of

\$50. The value of the supplemental rebate at time zero is thus equal to \$26.90 and the total discount is 50%, or \$50. Moving through time, manufacturer pricing actions drive the total discounts up; but due to the inverse relationship between supplemental and federal rebates, supplemental discounts decline over time as the total discount increases. As the patent expiration approaches, the manufacturer generally increases the cost of the drug and the CPI-U penalty accelerates the growth of the federal rebate in the quarters just prior to that event.

Generic Impact

At patent expiration, the launch of a generic is a welcomed event by commercial plans as a way to lower reimbursement and overall drug cost. In Medicaid, the launch of a generic can have the exact opposite effect. When generics first enter the market, they typically launch at a price point that is discounted to the brand's full price but have a federal rebate at 13% AMP. The net cost of a brand drug can be markedly less than the generic at this time. Factors

affecting the availability of this new generic can cause the net cost of the generic to remain relatively high for periods lasting from six months to multiple years. In 2017, brand-over-generic programs accounted for \$188 million in savings at an average cost of \$90 per claim.

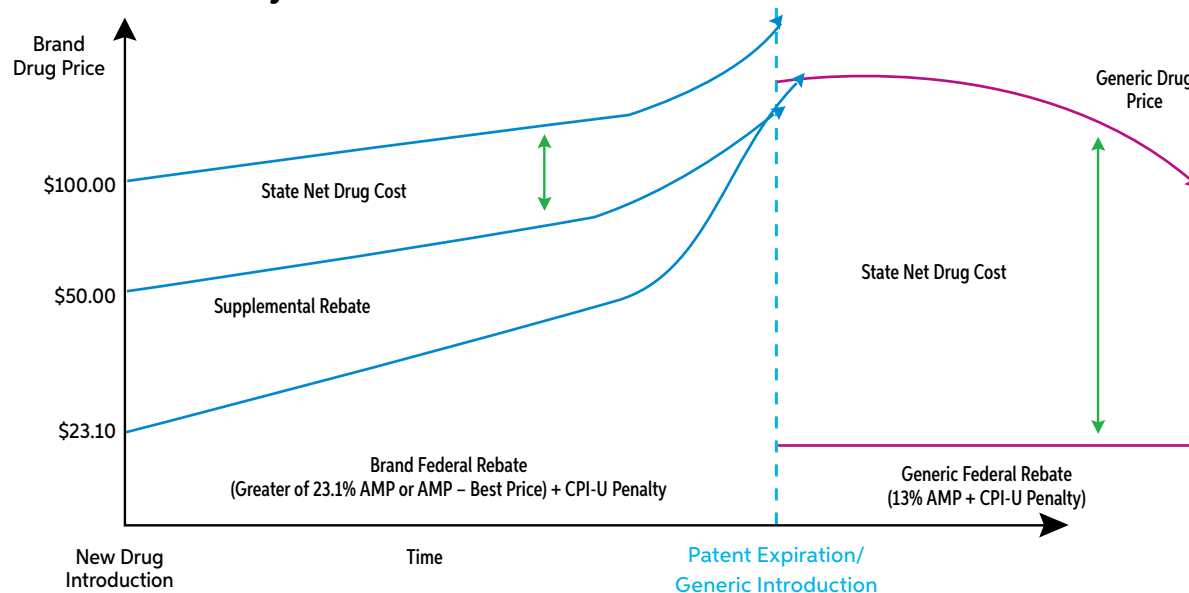
AUTHORIZED GENERICS

Authorized generics (AG) can complicate the determination of PDL statuses for brands and their generic equivalents. Brought to market under the innovator new drug application (NDA), AGs have a brand federal rebate structure. These drugs are marketed under their generic name and often enter the market during the six-month "exclusivity period" following patent expiration to compete with the first generic approved via abbreviated NDA (aNDA).

The overall impact of an AG's presence is that its net price is substantially lower than that of the non-AG due to the federal rebate calculation for the AG.

FIGURE 27

Medicaid Pharmacy Economics



In 2017, a record number of drugs, 46 novel agents, received FDA approval, ushering in a shift for several drug categories integral to the Medicaid line of business. The categories below represent the notable pipeline events looking out one year starting in 2018.

Migraine Prevention

- A new class of medications, calcitonin gene-related peptide (CGRP) blockers, introduces a new treatment modality for migraines.
- Erenumab-aooe (Aimovig) was approved for migraine prophylaxis in May 2018.

Women's Health

- Elagolix, is a first-in-class oral gonadotropin-releasing hormone (GnRH) antagonist for pain associated with endometriosis.
- Ulipristal, which is currently approved as an emergency contraceptive as Ella, is pursuing a lower-dose oral formulation for uterine fibroids.

Infectious Diseases

- Several drugs garnered qualified infectious disease product (QIDP) designation from the FDA.

Hemophilia

- There is a trend toward the development of long-acting agents, yet product impact on annualized spontaneous bleed rates remains a central indicator of product efficacy.

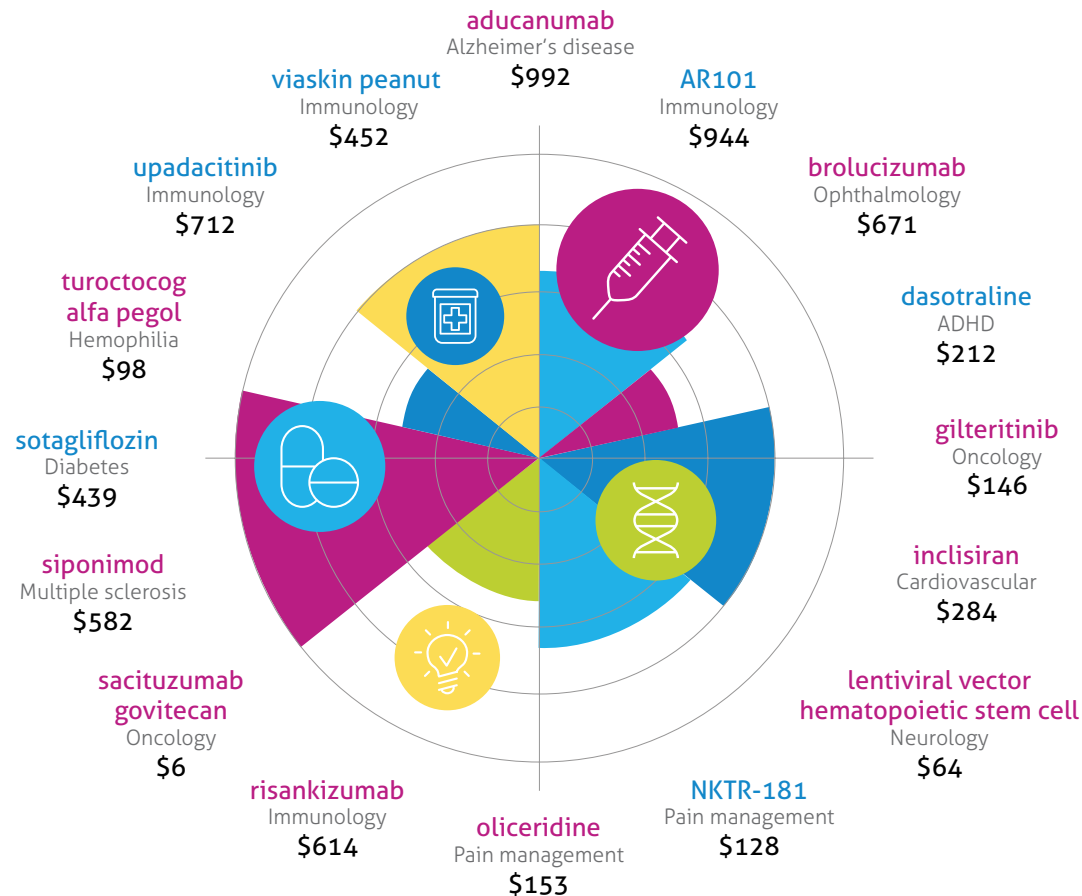
Influenza

- Baloxavir, (approved in Japan, Feb. 2018), is a first-in-class, single-dose influenza antiviral regimen. It targets influenza A and B viruses, including strains resistant to oseltamivir (Tamiflu) and avian strains (H7N9, H5N1).

For more detailed information on the pipeline, please see the latest MRx Pipeline Report on our website.¹

Notable agents that are further from approval have been identified in the unique watch list illustrated below. These pipeline products, their respective class or proposed indication, as well as an estimated financial forecast for the year 2022 (in millions), are displayed (see figure 28).

FIGURE 28



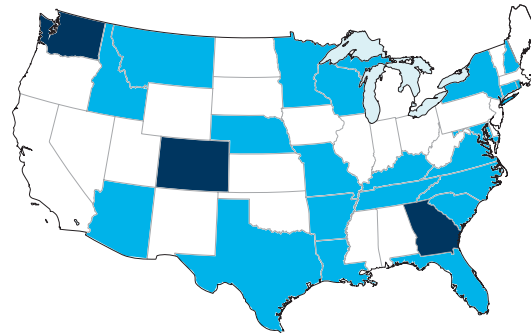
1. <http://www1.mogellanrx.com/mogellan-rx/publications/mrx-pipeline.aspx>.



Methodology

The MRx Medicaid Trend Report™ focuses exclusively on Medicaid FFS drug spend and does not include managed care utilization. It provides a comprehensive year-over-year analysis of Medicaid FFS claims data on a cost-per-claim basis.

- > The report trends are based on a gross-cost and net-cost-per-claim basis and compare the 2016 and 2017 calendar year data.
- > Data was obtained from 24 Medicaid FFS clients across the country from which two years of complete FFS data is available.
- > The data set used in this evaluation contains more than 116 million claims with a gross cost of \$12.5 billion and a net cost of \$5 billion.
- > Similar to commercial plans, both traditional and specialty drug trend are not immune to manufacturer price actions at the gross-cost level; however, the increase at the net-cost level is somewhat mitigated by supplemental rebates (where applicable) and the CPI-U penalty component of the federal rebate.






■ MRx customer data used in analysis
 ■ New MRx customers 2016/2017

- > To achieve the highest level of accuracy for the Medicaid FFS space, this report incorporates the CMS federal rebate data for both 2016 and 2017. Federal rebate data at the drug level is confidential and protected by federal law under the Social Security Act at 42 U.S.C. 1396r-8 (b)(3)(d). Therefore, this report does not disclose net-cost pricing information on a per drug basis.

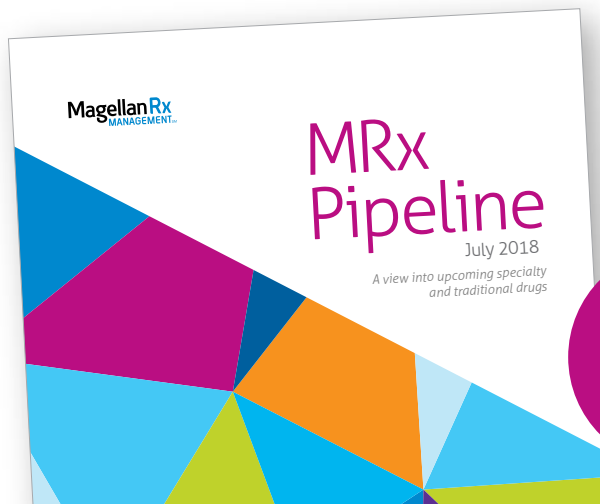
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AAC..... actual acquisition cost
 ACA..... Affordable Care Act
 ADHD..... attention deficit hyperactivity disorder
 AG..... authorized generics
 AMP..... average manufacturer price
 aNDA..... abbreviated new drug application
 AWP..... average wholesale price
 BBA..... Bipartisan Budget Act
 CGRP..... calcitonin gene-related peptide
 CMS..... Centers for Medicare & Medicaid Services
 CPI-U..... Consumer Price Index-Urban
 FDA..... U.S. Food and Drug Administration
 FFS..... fee-for-service
 FFY..... federal fiscal year
 FUL..... federal upper limit
 GnRH..... gonadotropin-releasing hormone
 HHS..... U.S. Department of Health & Human Services
 IV..... intravenous
 MAC..... maximum allowable cost
 MACPAC..... Medicaid and CHIP Payment and Access Commission
 MCO..... managed care organization
 MDRP..... Medicaid Drug Rebate Program
 MDV..... multi-dose vial

MME..... morphine milligram equivalent
 NADAC..... National Average Drug Acquisition Cost
 NCPC..... net cost per claim
 NDA..... new drug application
 NDC..... National Drug Code
 OBRA..... Omnibus Budget Reconciliation Act
 PA..... prior authorization
 PDL..... preferred drug list
 QIDP..... qualified infectious disease product
 RFI..... request for information
 SDV..... single-dose vial
 SUD..... substance use disorder
 WAC..... wholesale acquisition cost



**PLEASE
RECYCLE**

