MMIT RADAR

Spotlight on Market Access

Actionable understandings from AIS Health's in-depth coverage

February 15, 2021

Shields' Purchase of Excelera Highlights Integrated Specialty Pharmacy Industry

As more health systems are creating their own specialty pharmacies, two major players in the space are coming together. In mid-January, Shields Health Solutions unveiled a deal to purchase ExceleraRx Corp. for an undisclosed amount. The new company could provide these entities with more leverage when it comes to payer networks and manufacturer distribution.

Launched in 2012, Shields is a specialty pharmacy integrator that partners with health systems to help them create and grow a hospital-owned specialty pharmacy program. Excelera, which also started in 2012, is a network of specialty pharmacies among its members, which are integrated delivery networks (IDNs) and academic medical centers. Created by Minneapolis-based Fairview Health Services almost a decade ago, the group now consists of almost 30 members.

The combined company will be able to work with more than 60 health systems and academic medical centers that have more than 700 hospitals across 43 states, "providing manufacturers with unparalleled access to data insights, and presenting payors the opportunity to help optimize care and improve outcomes for nearly one million patients with complex and chronic conditions," according to a joint press release from the firms.

continued on p. 4

Administration Delays Implementation of Rebate Rule; Congress Is Likely to Repeal It

The Biden administration will suspend implementation until 2023 of the so-called "rebate rule," a Trump administration regulation that would have revamped the Medicare prescription drug rebate system. D.C. insiders expect Congress to eliminate the rule before then for budgetary reasons, but say that drug pricing and PBM regulation will be high on the health care agenda after policymakers address the latest issues arising from the COVID-19 pandemic.

The suspension comes in response to a suit against the rule by a PBM trade group, the Pharmaceutical Care Management Association (PCMA), which sought to overturn the rebate rule on the grounds of its rushed implementation. A court order brokered in the U.S. District Court for the District of Columbia stipulates that all provisions of the final rule that were sched-

uled to take effect on Jan. 1, 2022, are now postponed until Jan. 1, 2023, and it directs the parties involved in the lawsuit to issue a joint status report "identifying whether and how this case should proceed by not later than April 1, 2021."

According to attorney Rachel Sachs, an associate law professor at Washington University in St. Louis and an expert on drug price regulation, PCMA's strongest legal position against the rebate rule stems from the rushed process that created it. The Administrative Procedure Act requires a 60-day comment period between the proposal and finalization of a new regulation, and HHS didn't follow the usual process with the rebate rule.

"The issue is that they initially introduced drafts of them, and then they sat on them for years, or even tried to say that they weren't going forward with them — only to finalize them after the election, in the case of the rebate rule. That's one of the reasons [PCMA] was able to challenge it," explains Sachs. The original rebate rule was pulled in July 2019 amid concerns that it would increase federal spending and Medicare beneficiary premiums, as both the Congressional Budget Office (CBO) and CMS's Office of the Actuary predicted those outcomes.

Rule Faces Numerous Legal Hurdles

Sachs adds that there are other problems with the rule that make it vulnerable to legal challenges from the PBM industry.

"There were several other substantive allegations, including the scope of the OIG [HHS Office of Inspector General] to review these questions," Sachs explains, noting that the rule was promulgated by the OIG instead of the regular CMS rulemaking process. She adds that, in public comments on the rebate rule, former HHS Secretary Alex Azar claimed that it wouldn't increase federal spending despite the CBO and CMS actuarial reports saying the opposite. Sachs says that contradiction further exposes the regulation to legal risk.

Payers and PBMs both applauded the court order and argued the Biden administration should do away with the rebate rule altogether.

David Root, vice president for public affairs for PBM Prime Therapeutics, which is owned by Blue Cross and Blue Shield affiliates, tells AIS Health via email that "we firmly believe the rule as written will significantly increase beneficiary premiums and government costs, and it will not achieve lower prices for the vast majority of consumers. Should the rule move forward without significant changes, we will continue to advocate for a full repeal of the rule."

AHIP Wants Full Withdrawal

Matt Eyles, president and CEO of America's Health Insurance Plans (AHIP), said in a Feb. 1 statement that "we strongly support the stipulation between the Biden Administration and the Pharmaceutical Care Management Association (PCMA) delaying the effective date of the 'rebate rule' until January 2023." The "misguided proposal" will increase premiums for seniors and people with disabilities, Eyles said, adding that it "does nothing to lower prescription drug prices."

"While we continue to urge full withdrawal of the prior Administration's rule, this delay will allow Medicare Part D plans in 2022 to provide the benefits and premiums seniors have come to expect," Eyles concluded.

Ge Bai, Ph.D., an associate professor at Johns Hopkins University's Carey Business School and Bloomberg School of Public Health, says that "there are two reasons the rule was established: One was to reduce patient cost sharing at the pharmacy counter. Second would be to optimize PBMs' product selection, so that they would put more cost-effective drugs in their formulary."

"There's a trade-off between premiums and patient cost sharing."

Bai observes that PBMs don't always put the drug that would be cheapest to consumers into a formulary. Instead, PBMs may choose a drug whose manufacturer offers the PBM a more generous rebate than the competition, even if it's a pricier brand-name drug.

The bottom line, Bai says, is that "there's a trade-off between premiums and patient cost sharing. Rebates

that come back [to insurers and PBMs] will reduce premiums, but patients who actually use the drug won't see savings at the pharmacy counter from the rebates....You can't have both."

In any case, politics could mean the legality and impact of the rule may be a moot point. Dan Mendelson, founder of Avalere Health, tells AIS Health that the balance of power in Congress creates a strong incentive for the rule to be repealed by legislators.

"Because the Senate is so tight, one of the only ways to get things through is this budget reconciliation process," Mendelson explains. "Budget reconciliation

Hike in Drug List Prices Has Downstream Effect on Patient, Payer Costs

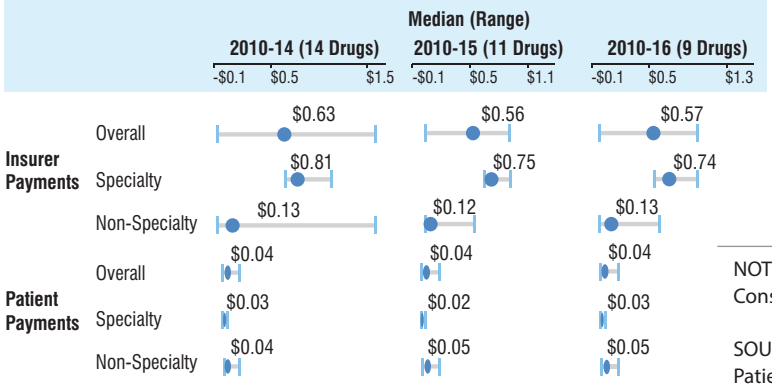
by Jinghong Chen

Even though drug manufacturer discounts and rebates have been rising, when wholesale list prices for prescription drugs more than doubled over a period of seven years, that still triggered large increases in patient out-of-pocket costs and insurer payments, according to a recent study published in JAMA Network Open. The researchers analyzed pharmacy claims for five patent-protected specialty drugs and nine brand-name drugs associated with the highest total expenditures by commercial insurers in 2014 and found that their average wholesale price (AWP) increased by 129% from 2010 to 2016. Median insurer expenditures on the 14 drugs analyzed grew 64%, while median patient out-of-pocket costs went up 53% during that time.

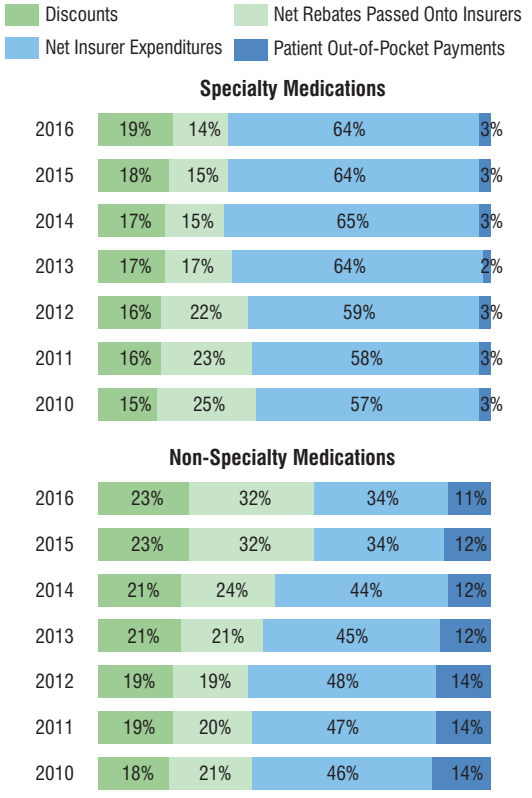
Annual Change in AWP & Cost After Rebates per Unit of Medication

Medication		Annual Cost Increase Above Rate of Inflation		
		AWP	Insurer	Patient
Specialty	Stelara	8.6%	14.1%	6.3%
	Gleevec	15.4%	17.8%	7.6%
	Atripla	6.2%	8.5%	10.5%
	Enbrel	13.6%	16.2%	11.0%
	Humira	14.3%	13.3%	11.3%
Non-Specialty	Crestor	10.5%	4.4%	3.2%
	Januvia	10.3%	0.8%	3.5%
	Lantus	15.9%	5.0%	3.8%
	Abilify	12.7%	13.4%	4.5%
	Androgel	10.1%	23.4%	4.6%
	Nexium	7.6%	-4.9%	4.6%
	Lyrica	14.5%	17.0%	6.0%
	Humalog	13.8%	-1.9%	7.3%
	Vyvanse	9.6%	4.3%	8.6%

Median Absolute Increase in Payments per $1 Increase in AWP for Medications Maintaining Patent Protection



Proportions of AWP Accounted for by:



NOTE: All results have been adjusted to 2016 dollars using the Consumer Price Index.

SOURCE: "Changes in Drug List Prices and Amounts Paid by Patients and Insurers," JAMA Network Open. 2020;3(12):e2028510.

gives you a world where you can pass with 50 votes in the Senate — but it comes along with liability that new programs have to be fully offset; you have to have cost reductions that you pass at the same time. And so, as a result, there's an all-out scramble for cost reductions that could be layered into a reconciliation bill to make the whole thing work."

Mendelson adds that repeal of the rebate rule is a tantalizing opportunity for lawmakers under those circumstances. Since the rebate rule would be costly but hasn't actually been implemented, eliminating it would create a massive savings on paper without the political cost that would come from cutting a real program of similar scale.

"It's a cute trick if you can repeal a regulation and score a savings even though nothing happened. It is truly a budget gimmick of the highest order," Mendelson says.

"The rebate rule has a very Trump flavor."

However, Mendelson says that the drug pricing issue won't end with the repeal of the rebate rule. He expects this Congress to take up the matter at some point with support from the administration. "The problem with using pharmaceutical policy as a cost offset is what you really want to do is reduce the out-of-pocket spend for consumers," Mendelson observes. "And that's frankly what people want, and it is ultimately the only solution to this. You don't want to take those savings and then just shovel them back into Medicare cost offsets. You want to solve the problem."

He says that conversation could include changes to Medicare's and Medicaid's drug pricing models.

"Trump and Biden have similar positions on drug pricing policies, particularly as it relates to differences between drug prices in the U.S. compared to other countries," Lance Grady, practice leader for market access at Avalere Health, tells AIS Health via email. "Specifically, President Biden's platform includes allowing for drug importation from other countries, allowing Medicare to negotiate drug prices, and establishing a drug price review board for new high-cost drugs that would recommend a price based on the drug's value and the average price paid in other countries. Because Medicare negotiation/international reference pricing is unlikely to get enough votes to pass in Congress, the Biden Administration may also look to [the Center for Medicare and Medicaid Innovation] to implement Medicare negotiation via international reference pricing and/or a drug price review board."

Indeed, the Trump administration tried a similar approach through executive action, finalizing a rule in November 2020 that would have tied Medicare Part B drug prices to the cost of pharmaceuticals in other countries. Two federal judges have issued injunctions to block implementation of that rule, which was meant to be phased in as a model starting on Jan. 1, 2021.

In a similar way, Bai says that the rebate rule was ultimately done in by its association with Trump — even though many Democrats dislike the PBM rebate model. "I think that, politically, the new administration probably won't want to be perceived as continuing these policies," Bai explains. "The rebate rule has a very Trump flavor."

Read the court order at https://bit.ly/3rrcy4r. Contact Bai at gbai@jhu.edu, Grady and Mendelson via Liz Moore at lmoore@avalere.com and Sachs at rsachs@wustl.edu. ✧

by Peter Johnson

This story was reprinted from AIS Health's weekly publication Health Plan Weekly. For more information, visit https://aishealth.com/product/health-plan-weekly.

Deal Spotlights Growing Industry

continued from p. 1

Those health systems represent "nearly 30% of non-profit healthcare systems based on net patient service revenues," giving the new entity $30 billion in specialty pharmacy revenue opportunity based on the $100 billion-plus specialty pharmacy market.

As part of the transaction, six Excelera investors and equity holders — Avera Health, Banner Health, CommonSpirit Health, Fairview Pharmacy Services, Intermountain Healthcare and Monument Health — have invested in Shields.

According to the press release, almost 90% of large hospitals in 2019 operated a specialty pharmacy, double the amount in 2015. In fact, the industry is growing so much that a group of seven health systems and Shields formed the Health System Owned Specialty Pharmacy Alliance (HOSP) this past fall. Tanya Menchi, executive director of HOSP, tells AIS Health that this integrated specialty pharmacy approach "helps keep critical parts of patient care — such as medication management and treatment — inside the health system that is caring for the patient, instead of a more fragmented approach to care. This important care integration strategy helps improve medication adherence, reduce hospital readmissions and lower overall health care costs."

Menchi, who also serves as director of public policy for Shields, says that HOSP will advocate for the integrated specialty pharmacy industry and unite members around common interests and issues for the industry. Some of those issues include "educating stakeholders and policymakers on the benefits of the integrated model that result in better patient outcomes, sharing best practices for implementation and operation of the model, and advocating for common industry interests, like [the] 340B [drug pricing program], access to limited-distribution drugs and payer networks, and patient choice. In addition, HOSP will serve as a knowledge-sharing platform for members to collaborate and share data-based research focused on improved patient outcomes."

Report Reveals Dynamics of Situation

However, integrated specialty pharmacies still struggle somewhat when it comes to working with payers. A report conducted by Reckner/Blueberry on behalf of Trellis Rx, LLC, a specialty pharmacy integrator, reflects on the dynamics between health systems and payers. The study, released last summer, was based on interviews with 10 hospital pharmacy leaders and 10 health plan leaders.

"Health systems continue to struggle building partnerships with health plans while health plans continue to rely on pharmacy operational metrics as surrogate markers of specialty patient outcomes," according to the report. "Currently, there is little incentive for health plans' business models to consider patients' lifetime value and/or lifetime costs. Likewise, there is little benefit compelling health plans to accept health system pharmacies into their networks; it simply hurts preferred pricing arrangements."

According to Dustin Lewis, the specialty pharmacy manager at Nationwide Children's Hospital, "without a doubt, access to health plan networks is my biggest challenge," per the report. "I know that I can only fill prescriptions for about a third of the patients who come through our doors. And it's not for lack of willingness to negotiate, it's that we cannot even get a meeting with a payor or talk to an actual person about obtaining a contract. It's not like I've been playing hardball with the payors, it's that I can't even play. I don't even have a baseball glove."

"Eight years ago we couldn't get PBMs or drug manufacturers to talk to us."

Indeed, Jack Shields, founder and chairman of Shields, told the Boston Globe that "eight years ago we couldn't get PBMs or drug manufacturers to talk to us," according to a Jan. 12 article. He said that should change with the Excelera addition. The Globe also states that "the merged company is expected to reach a $2 billion revenue rate next year." That, writes executive editor and longtime industry expert Bill Sullivan in a Jan. 19 AntonRx Report, is "more than enough volume to finally impress payors and manufacturers."

He tells AIS Health that "both companies have been successful in contracting a significant number of hospital health systems….But there are a lot more to go to fully penetrate the market."

"The merged company negates competition from a top-tier competitor in the same market niche and simultaneously becomes the market-dominant force in that niche," observes Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates. "By combining, ExceleraRx and Shields are able to offer health systems experienced specialty pharmacy support based on either of their business models."

"There is some extra icing on the ExceleraRx cake," Sullivan added in the article. "They bring a robust

manufacturer marketing program, a home infusion solution to create health system-owned infusion operations, and even a PBM to the party."

According to the Globe, Shields in July 2019 sold about a 50% combined ownership stake to Walgreens and investment group Welsh, Carson, Anderson & Stowe "in a deal valued at between $850 million and $900 million." Of that agreement, states Sullivan, "it will be interesting to see how the synergies play out and if the relationship can be leveraged."

"We remain convinced that healthcare system-owned specialty pharmacies pose one of the greatest threats to independent specialty pharmacies given their ability to self-direct specialty prescriptions within their walls," he says, adding, "I am sure manufacturers are getting concerned as these big hospital customers control their own internal preferred formularies."

"The merged company negates competition from a top-tier competitor in the same market niche and simultaneously becomes the market-dominant force in that niche."

Research shows that more and more IDNs are interested in negotiating directly with pharma. According to Zitter Insights' IDN Formulary Insights, per its white paper Why in the World Would IDNs Want to Contract Directly with Pharma? The IDN Perspective, "81% of the highly integrated IDNs targeted by pharmaceutical manufacturers can push a formulary change to the entire system at the press of a button. Moreover, 79% and 64% of these IDNs report that their system-wide formularies cover specialty pharmacy products and retail medications, respectively."

Zitter Insights and AIS Health are both owned by MMIT. Welsh, Carson owns a majority stake in MMIT.

The Zitter Insights white paper, released in March 2018, included responses from 35 contracting directors at IDNs across the country. Almost all reported that they could get better pricing from direct contracting with pharmaceutical manufacturers than through working with a group purchasing organization. That's even more important when it comes to purchasing costly specialty drugs. Citing Zitter Insights' IDN Formulary Insights, the report notes that "62% of the highly integrated IDNs targeted by pharmaceutical manufacturers now own specialty pharmacies; that number rises to 81% for onsite retail pharmacies."

Group Calls for Industry to Share Data

In a recent open letter to the integrated specialty pharmacy industry, the HOSP board of directors maintained that "we need industry-wide benchmarks to both demonstrate our success and measure our performance to further improve patient outcomes. As an industry, we haven't done a good job of publicizing the data that showcases our successes, which is what distinguishes us from other specialty pharmacies. Sharing data will allow us to establish metrics to demonstrate our value and measure performance. These metrics will help us develop our own industry best practices."

The letter also called for the industry to support patient choice and open access, as well as prioritize health equity. "Health system owned specialty pharmacies provide exceptional patient care, and it is time we collaborate and share data to attest to our ability to provide improved patient care and outcomes," the board wrote. "We are asking you to join your voice with ours. Working together we can ensure we have the opportunity to manage the destiny of our own industry."

According to the Trellis report, "a pharmacy director at a Northeast health plan covering 5 million patients, put it this way: 'A pharmacy is a pharmacy is a pharmacy. They all have the ability to order a product. They all have the ability to dispense a product. There is absolutely no difference' between health system specialty pharmacies and others....It is imperative, therefore, that health systems invest in developing strong specialty pharmacy programs wherever possible. They must understand the value of their pharmacy services and prove that value to health plans. Health plans, too, must shift their mindset about health system specialty pharmacies from 'commodity service' to 'strategic partner.'"

Contact Rubinstein at elan.b.rubinstein@gmail.com and Sullivan at bsullivan0011@gmail.com. ✧

by Angela Maas

Reality Check: **Epilepsy**

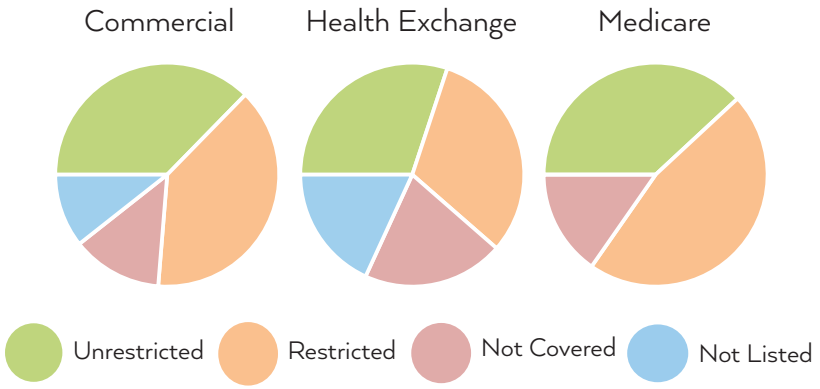
Our Point of View

Many generic options are used in the treatment of epilepsy. New players have emerged, but big prescription sales are illusive in comparison with previous generic and brand antiepileptic drugs (AEDs). Significant restrictions are observed for the most recently launched products in this class. Treatment relies on a wide variety of drugs; the Epilepsy Foundation lists more than three dozen different medications used to treat various forms of the disorder. "There are various types of medications used to treat epilepsy, most of which do not fall neatly within a defined drug class," says Mesfin Tegenu, R.Ph., CEO and chairman of RxParadigm, Inc. "Treatment is based on the type of epilepsy diagnosed, and labeled and off-label indications of the individual products. There is a fair amount of overlap, as many drugs share multiple indications. However, many newer agents are narrowly indicated."

Coverage

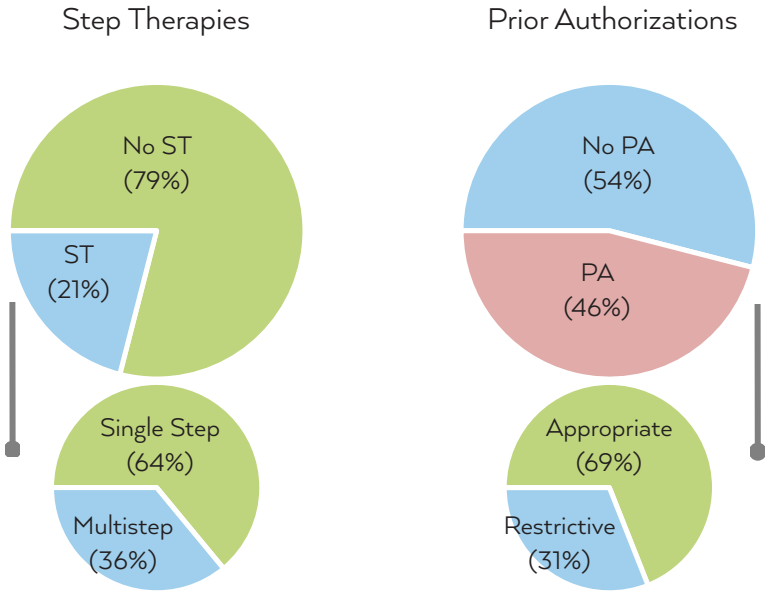
Pharmacy Benefit

Under the pharmacy benefit, almost 39% of the lives under commercial formularies are covered with utilization management restrictions. Around 15% of the lives under Medicare Part D formularies are not covered for at least one of the drugs.



Payers

For about 79% of the covered lives, payer pharmacy benefit formularies do not require step therapy (ST). Of the lives that require ST, 36% require multiple steps. Around 46% of payer-controlled pharmacy benefit covered lives require prior authorization, with 31% of those lives covered by policies that are restrictive as compared with a product's FDA-approved label.



DATA CURRENT AS OF Q1 2021

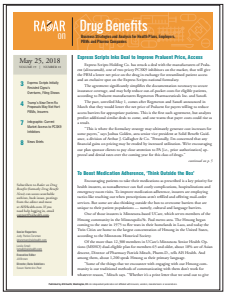
Reality Check: **Epilepsy**

AIS Health's View

Utilization management is uncommon with the generic products used to treat epilepsy, says Tegenu, while "on some of the newer, more expensive brand products, prior authorization can be used." He points out that SK Life Science, Inc.'s Xcopri (cenobamate) launched in May 2020, but various plans have not added it to their formularies. "Some plans have opted to take a cautious approach and leave the medication as nonformulary to start," he tells AIS Health. "It is difficult to tell the impact of this new drug launch on the treatment of epilepsy. However, Xcopri trials demonstrated high efficacy in partial onset seizures and refractory epilepsy, lending it a strong clinical profile. One could reasonably suspect a high impact on the epilepsy treatment paradigm."

Trends From AIS Health

Plans Stick With Generics for Epilepsy


RADAR on Drug Benefits
May 25, 2018

Pharmaceutical treatment for different types of epilepsy generally still relies on tried-and-true generics, despite recent efforts by drug manufacturers to introduce new branded medications into the mix, PBM insiders say. Xcopri (cenobamate tablets) launched in May 2020 for the treatment of partial-onset seizures in adults. However, multiple plans haven't jumped to add Xcopri — which carries an average price of around $1,200 for a 30-day supply — to their formularies, says Mesfin Tegenu, R.Ph., CEO and chairman of RxParadigm, Inc.

Subscribers to AIS's *RADAR on Drug Benefits* may read the in-depth article online

FDA Approves Fintepla


RADAR on Specialty Pharmacy
May 2018

In June 2020, the FDA approved Zogenix, Inc.'s Fintepla (fenfluramine) to treat seizures associated with Dravet syndrome in people at least 2 years old. The recommended initial and maintenance dose is 0.1 mg/kg twice daily, which may be increased weekly. The price for a 30 mL bottle is $1,278.

Subscribers to AIS's *RADAR on Specialty Pharmacy* may read the in-depth article online

FDA Expands Indication for Epidiolex


RADAR on Specialty Pharmacy
May 2018

In August 2020, the FDA gave another indication to GW Pharmaceuticals plc and its U.S. subsidiary Greenwich Biosciences, Inc.'s Epidiolex (cannabidiol) to treat seizures associated with tuberous sclerosis complex in people at least 1 year old. The agency also broadened the drug's patient population to include people at least 1 year old who experience seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.

Subscribers to AIS's *RADAR on Specialty Pharmacy* may read the in-depth article online

Reality Check: **Epilepsy**

Key Findings

Market Events Drive Changes

In August 2020, the FDA gave another indication to GW Pharmaceuticals plc and its U.S. subsidiary Greenwich Biosciences, Inc.'s Epidiolex (cannabidiol) to treat seizures associated with tuberous sclerosis complex in people at least 1 year old. The agency also broadened the drug's patient population to include people at least 1 year old who experience seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. In June 2020, the agency approved Zogenix, Inc.'s Fintepla (fenfluramine) to treat seizures associated with Dravet syndrome in people at least 2 years old.

Pharmacy Benefit Implications

AEDs are one of the protected Medicare classes, so management of brand-name products is restrictive but less so than in other classes. AEDs are also included in some state carve-out plans, such as Michigan's. When prior authorization is defined, diagnosis and trial and failure of generic AEDs or use as adjunctive therapy will be required. Coverage of this class is under the pharmacy benefit.

Characteristics

Indication

Epilepsy

Step-Therapy (ST) Policies

Payer pharmacy benefit formularies require ST for roughly 21% of covered lives. Of those, 36% require multiple steps.

Prior-Authorization (PA) Policies

Roughly 46% of payer-controlled pharmacy benefit covered lives require PA, with 31% of those lives covered by policies that are restrictive as compared with a product's FDA-approved label.

DATA CURRENT AS OF Q1 2021

AIS Health's View

April Kunze, senior director of clinical formulary development and trend management strategy for Prime Therapeutics LLC, tells AIS Health that she sees a rationale for using newer branded products in some circumstances: "Newer products may offer additional treatment options, as it often takes more than one therapy to effectively treat patients with seizures." Tegenu points out that some cases of epilepsy are resistant to treatment with common medications. "There are still various areas of unmet need in the epilepsy market, particularly in refractory cases and the rare epilepsies," he says. However, "in the near-term pipeline — one-year outlook — there are a handful of drugs pursuing indications for epilepsy, but they are all reformulations of older molecules."

About AIS Health

The mission of AIS Health — a publishing and information company that has served the health care industry for more than 30 years — is to provide readers with an actionable understanding of the business of health care and pharmaceuticals. AIS Health's in-depth writing covers the companies, people, catalysts and trends that create the richly textured contours of the health care and drug industry.

AIS Health, which maintains journalistic independence from its parent company, MMIT, is committed to integrity in reporting and bringing transparency to health industry data.

Learn more at https://AISHealth.com and https://AISHealthData.com.

About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today's rapidly changing healthcare market.

MMIT has been 100% focused on market access for decades. We combine deep domain expertise around drug coverage with innovative technology and trusted data to answer key business questions related to access. MMIT data is trusted by U.S. physicians and sourced through a combination of direct partnerships with payers and PBMs and a technology infrastructure that is powered by smart business logic, artificial intelligence and human validation.

Learn more at https://www.mmitnetwork.com.