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Rx Newsletter

In This Issue

Rx trion
Prescription Drug Coalition

Market Trends

Prescription drug legislation hits a brick wall. Will there be movement or more of the same?

With bipartisan support on the need to address rising prescription drug costs, why is nothing getting done?

2019 saw significant proposed prescription drug legislation, but with Medicare for All proposals continuing to swirl and the logjam caused by the impeachment inquiry, many are left wondering if we will get anything passed or if politically this window of opportunity is quickly shutting. With bipartisan interest in solving the affordability issue, many proposals have been put forth, but the political debate continues, with the likelihood of it becoming a 2020 election issue more of a reality by the day. In fact, a recent Kaiser Family Foundation Health Tracking Poll taken November 7-12, 2019, found that 3 in 4 Americans do not expect congress to take action to lower drug costs before the 2020 election.

Proposed Drug Legislation

There are multiple proposals being considered at this point with varying degrees of bipartisan support. President Trump provided his recommendations for reducing costs within "American Patients First", otherwise known as the Trump Blueprint. Many concepts laid out in the Blueprint have been considered, most notably was the proposed changes to rebates, but ultimately those proposed changes were walked back. Trump continues to push forward on leveraging the International Price Index, to assure the US is not paying higher drug costs than in other developed countries for certain physician administered drugs under Medicare. Critics warn that drug manufacturers, in fear of losing significant revenue, could delay or forgo launching drugs in certain lower-cost international markets to avoid a lower reference price being used in the US; or could shift the drug to being self-administered to get around the physician administered issue. President Trump is also promising more details on the proposed ability for states to import certain drugs from Canada at lower costs, despite Canada advising that they do not have the supplies or infrastructure to support the demand of the US market.

Speaker Nancy Pelosi's (D-CA) "Lower Drug Costs Now Act of 2019" looks to establish a $2,000 out-of-pocket maximum for Medicare beneficiaries, cap prescription price inflation, tie drug prices to the International Price Index, and — potentially most impactful — allow Medicare to negotiate directly with drug manufacturers on 50 drugs annually, with the results being provided to the commercial market, as well as provide protection for private plans from hyperinflation. President Trump initially supported Pelosi's plan, but has since withdrawn support. Senators Ron Wyden (D-OR) and Chuck Grassley's (R-IA) "Prescription Drug Pricing Reduction Act" looks to tie a prescription drug price inflation cap to the Consumer Price Index (CPI) for Medicare beneficiaries by requiring manufacturers to rebate the increased amount by which drugs covered under Medicare Part D exceed the rate of inflation, and reduce the out-of-pocket maximum from $5,100 to $3,100 for Medicare beneficiaries. While this proposal does have bipartisan and Trump Administration support, critics are concerned that drug manufacturers would be incentivized to just increase the initial launch list price of new drugs, knowing they will be penalized if increased later. Trump, in the meantime, is assuring states that the ability to import drugs from Canada will be happening even though HHS has still not approved. Reports are surfacing that there will be action prior to 2020, but given the current delta in positions and Senator Mitch McConnell all but advising there will be no vote on Pelosi's bill before the end of the year, we also remain skeptical.

Pharmacy 101

Lowest Net Cost

For years, rebates have been a dominant factor in the drug pricing equation for plan sponsors. To maintain affordability, employers have had to accept a supply chain where prices are inflated, but reduced through rebates — giving plan sponsors little insight and control over true drug costs. The lowest net cost approach not only considers financial factors such as ingredient cost (discounts) and rebates like traditional pricing options, but also incorporates clinical factors such as lower cost therapeutic alternatives, utilization, and formulary management to measure the total net cost and savings potential.

Background and Pharmaceutical Supply Chain

The high and growing cost of prescription drugs imposes a financial burden on patients and employers who sponsor health benefits. Certain costs — such as for new and effective therapies — can be justified, but costs can also accrue from products that offer little or no value relative to available alternatives. Though there are many reasons this occurs, one key reason is misaligned incentives in the drug supply chain.

Pharmacy benefit managers (PBMs) act as the intermediary between pharmaceutical manufacturers and health plans, negotiating with pharmaceutical manufacturers for price discounts (which typically come in the form of discounts on average wholesale price (AWP) or rebates paid to the plan sponsor). PBMs often keep a portion of the negotiated rebates and other fees in exchange for low or no administration fees. Since rebates are based on sales volume driven by formulary placement, and contracts between PBMs and plan sponsors contain rebate guarantees, the demand for high-rebate drugs, that allow PBMs to maximize rebate revenue, is perpetuated. As such, in some instances, preference on formulary placement is given to some drugs based on rebate revenue, rather than their value and final cost to the patient or plan sponsor.

Privacy agreements have long kept these incentives hidden by prohibiting communication about them by manufacturers or pharmacists. As a result, formularies can contain and even steer patients to more expensive drugs that have little or no additional clinical value. This model can be referred to as a rebate maximization approach. Moreover, plan sponsors often allow broad formularies that include wasteful drugs because they are concerned employees will be disappointed if their prescribed drugs are not covered, and doctors prescribe these drugs because they are often unaware of drug costs. The lure of a high rebate dollar amount on a spreadsheet can overshadow the true net drug cost if formulary differences are not accurately accounted for.

Though many plan sponsors have addressed the resulting high spending by increasing patient cost-sharing on lower-value drugs, manufacturers have counteracted these cost sharing and formulary management efforts by flooding the market with copayment coupons that undermine the benefit structure put in place by plan sponsors.

The Lowest Net Cost Approach: How Is It different?

The lowest net cost approach differs from the rebate maximization strategy in that a formulary uses utilization and formulary management techniques to steer patients away from high-priced/low-value drugs to clinically sound, cost-effective alternatives such as low cost generics and less expensive brands. In turn, this creates a high performance drug mix that delivers the lowest net cost, while still providing the opportunity for the plan sponsor to achieve substantial rebates for those drugs that provide clinical value and do not have lower cost alternatives. “Me-too” or non-essential drugs (where a manufacturer changes a particular ingredient in an existing drug to create a “new” drug that adds no clinical value, but often extends patent protection), combination drugs (drugs that combine two active ingredients into one pill), brands with lower cost generics available, and drugs with over-the-counter alternatives are all examples of wasteful or low-value drugs that could be considered for formulary removal under a lowest net cost approach. Coupling this with utilization management techniques (such as prior authorization, quantity management, and step therapy), helps to further ensure the patient is getting the proper dosage, of the most appropriate drug, at the lowest possible cost for both patient and plan sponsor.

A 2019 study of 15 large plan sponsors conducted by The Commonwealth Fund, showed that wasteful prescriptions represented 3-12% of total claims per plan sponsor evaluated, or 6% across all data, with an estimated potential average savings of $413 per script. The same study concluded that nearly all low-value prescriptions were non-specialty and over 50% of potential savings could be attributed to just three drug groups (dermatologicals, nasal agents, and ulcer drugs). As more studies emerge on the value of the lowest net cost approach, PBMs continue to develop and refine their formulary list offerings to give plan sponsors another option when it comes to managing pharmacy spend.

Disease Spotlight

Oncology

Oncology drugs continue to be the largest driver of pharmacy specialty trend, with continued innovations coming with a steep price tag.

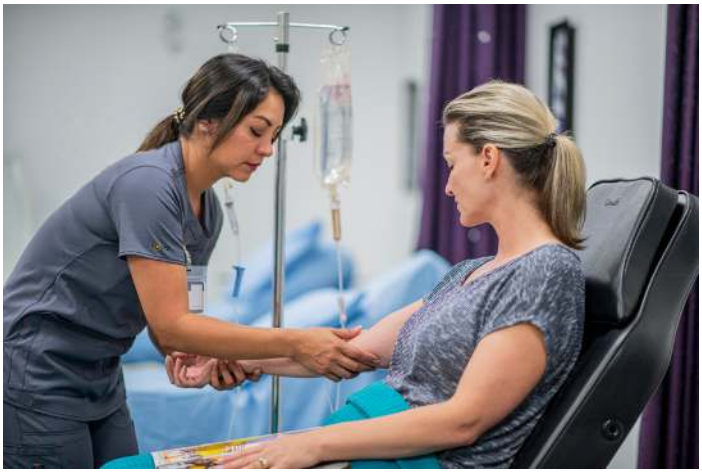
The medical benefit drug spend alone for oncology medications drive one-third of the total PMPM spend today, with an average cost per claim of over $2,300 for commercial plans in 2018.[1] Right now there are over 700 companies in late stage research and development for some 850 new oncology drugs including expanded indications for checkpoint inhibitors and new gene therapies.[2]

Here are some figures to keep in mind when we consider cancer prevalence and costs:

- According to the American Cancer Society, 762,450 Americans are estimated to be diagnosed with some form of cancer in 2019. This is in addition to the 15.5 million Americans with a history of cancer that are still living today.
- Spending on all medicines used in the treatment of patients with cancer reached nearly $150 billion in 2018, up 12.9% for the year and marking the fifth consecutive year of double-digit growth. In the US, spending on cancer drugs has doubled since 2013 and exceeded $56 billion in 2018, according to the IQVIA Institute for Human Data Science Global Oncology Trends 2019 report.
- Stop loss provider Sun Life reported book of business numbers on the impact of cancer from 2015 to 2018 —26.8% of total stop loss claims and $936.3 million in stop-loss reimbursements were due to cancer.

While many employers have focused their efforts around wellness programming —including promoting recommended preventive care, anti-tobacco strategies, and programs to address diet and exercise —we continue to see more cancers being tied to excess weight. Cancers that are thought to be driven in part by excess weight gain are on the rise in people under the age of 50, according to a new study released by the American Cancer Society. People born between 1981 and 1996 have a higher risk of developing six obesity-linked cancers when compared to people born in the 1950s. These cancers include cancer of the kidney, pancreas, gallbladder, endometrium, and colon or rectum, as well as multiple myeloma.

With this significant pipeline and increased rate of prevalence, understanding the benefit and potential impact of new drugs and therapies can help PBMs, payers and plan sponsors determine which drugs should be covered, and what utilization management strategies may be most effective. For example, while drugs like Neulasta are very effective in terms of preventing infection in patients undergoing chemotherapy, where and how this drug is administered significantly



impacts the costs. Avastin is another cancer medicine that interferes with the growth and spread of cancer cells in the body, but, according to Magellan's Medical Pharmacy Trend Report 2018, with significant variations based on site of care, with a reported $2,034 in the physician's office compared to $7,794 per claim when delivered in a hospital outpatient setting.

What Can Plan Sponsors Do?

When it comes to managing oncology costs, payers and plan sponsors have to weigh the cost/benefit of different strategies, including member impact. Traditional utilization management programs can only go so far when it comes to managing these costs. More aggressive approaches include site of care solutions, limited supply programs that look to reduce waste due to complications, dose optimization programs that address limited vial size issues, and genomic testing programs. For example, CVS Health just announced the Transform Oncology Care program which uses genomics at the point-of-prescribing to help patients start on the best treatment faster, based on their clinical and genetic profile, as well as matching eligible patients to clinical trials — improving patient outcomes and reducing overall costs for late stage cancer patients. Digital health technology is expected to enable clinical trial participants to receive physician support for adverse events, improving patient safety and overall outcomes. Biosimilar strategies should also be considered, in addition to offering comprehensive support for members dealing with cancer, such as cancer support programs like ones offered through Johns Hopkins and Memorial Sloan Kettering. Employers should also consider how some of these more aggressive pharmacy management strategies can align to hopefully reduce the prevalence and overall costs related with oncology.

Sources:

1. Magellan Rx Management. Medical Pharmacy Trend ReportTM 2018 Ninth Edition, 2019.
2. IQVIA Institute for Human Science. Global Oncology Trend Report 2019. May 2019.

Clinical Spotlight

Outcomes-based Contracting

With the continued rise of healthcare costs, what do you do if outrage over the cost is so much louder than the excitement over the treatment? How do you convince payers that the value outweighs the actual cost to treat complicated diseases?

With specialty drug trend continuing to soar and the emergence of high cost gene therapies, payers and plan sponsors are looking to assure the intended clinical outcome is being achieved. While innovation in pharmaceutical is beneficial to most, innovation comes at a cost — especially as the focus shifts away from traditional disease states to more complex genetic diseases like Multiple Sclerosis, Alzheimer's, or Spinal Muscular Atrophy. With this shift, more payers and plan sponsors are considering how outcomes-based contracting may help confirm the outcomes are being achieved and the value for their high costs are being realized. In outcomes-based contracts (OBC), reimbursement is linked to a set of value-based attributes that can be measured and tracked to evaluate performance of a drug over time, and manufacturers then pay retrospective rebates based on the measurement of clinical outcomes.[1]

Key Challenges

Measuring success is based on a defined understanding of what success is for the payer, not always the individual. Success can be measured as a cure, suppression of symptoms, or increased quality of life. Quality of life for Subject A may be completely different than for Subject B. It's as difficult as reading a pain scale for two different patients and assuming level 10 pain means the same for both.

Measuring outcomes is time-dependent, which makes most pharmaceutical treatments unacceptable candidates for OBC. The longer the treatment, the less likely the medication outcomes can be tracked. Employee turnover makes it difficult to track completion of treatment, especially since patients tend to change employers, providers, and insurance carriers at the same time. If the patient shifts mid-treatment, who gets the rebate if it is not successful? This reason alone is why most agree OBC should be limited to drugs promising treatment completion within 6-12 months.

Data is another key issue in the OBC debate. Tracking long-term success of a medication is difficult. Electronic Health Records were not built to support the data needed to track success of the medication. For example, most systems note if a medication was discontinued. It does not have the ability to track the reasons for discontinuation, indications, interactions, or expected outcomes. Even if the provider submits every detail of the treatment, access to this information is often inaccessible as HIPAA limits plan sponsors and payers access to the details.

Baby Steps

In theory, outcomes-based contracting could be the cure the healthcare industry is looking for, but for many payers, the lack of evidence and cost to implement and administer has prevented them from pursuing. With continued market interest and need, we should expect to see more solutions for plan sponsors to take advantage of in the future. One program with some components of OBC is the Express Scripts (ESI) Health Connect 360 clinical management option, which is a pay for performance model with ROI savings guaranteed for specific drugs, with identified guaranteed measures, such as improved statin use in diabetics. While it is a good first step, given the trajectory of specialty spend, we believe plan sponsors will want a larger opportunity to share in savings should outcomes not be achieved.

Source:

1. Singh, Surya. "A look at Value-Based Drug Contracting Strategies," available at https://cvshealth.com/thought-leadership/a-look-at-value-based-drug-contracting-strategies, accessed December 2, 2019.

Pipeline:
Pending Drug Approvals

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
Luspatercept	Acceleron	Beta-thalassemia	12/04/2019
Cabotegravir + rilpivirine	Viiv	HIV-1 infection	12/27/2019
Ubrogepant	Allergan	Migraine treatment (adults)	December 2019
Semaglutide (Ozempic®)	Novo Nordisk	T2DM-related CV risk reduction	1/20/2020
Crizanlizumab	Novartis	Sickle cell disease-related vaso-occlusive crisis	January 2020
Tazemetostat	Epizyme	Epithelial sarcoma	1/23/2020
givosiran	Alnylam	Acute hepatic porphyria	2/4/2020
avapritinib	Blueprint	Gastrointestinal stromal tumor (PDGFRA exon 18 mutant)	2/14/2020
Voxelotor	Global Blood Therapeutics	Sickle cell disease	2/26/2020
inebilizumab	Viela	Neuromyelitis optica (Devic's syndrome)	Feb-March 2020
teprotumumab	Horizon	Graves' ophthalmopathy/ orbitopathy	3/6/2020
enfortumab vedotin	Astellas	Bladder Cancer	3/13/2020
cysteamine delayedrelease oral granule (Procysbi®)	Horizon	Nephropathic cystinosis	Mar-Apr 2020

Brands Losing Patent

While these drugs are nearing the end of their patent term, the release of generics may be delayed due to litigation or exclusivities.

Brand Name	Generic Name	Indication/Use	Date Generic Available
Juxtapid®	Lomitapide mesylate	Lower total cholesterol	2/21/2020
Delzicol®	Mesalamine	ulcerative colitis (UC)	4/13/2020
Aptivus®	Tipranavir	HIV infection	4/29/2020
Ablavar®	Gadofosveset trisodium	Contrast agent	5/4/2020
Chantix®	Varenicline tartrate	Smoking cessation	5/10/2020
Fortovase®	Saquinavir	HIV infection	5/16/2020

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