MARSH & McLENNAN AGENCY

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Rx Newsletter

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Rxtron
Prescription Drug Coalition

Market Trends

Recent Legislation Impacting Group Health Plans

If there's anything that employers can be certain of, given the events of the past year and a half, it's that uncertainty is the new normal and there doesn't appear to be an end in sight.

President Biden's Vaccination Mandate

On September 9, 2021, the Biden Administration announced rulemaking was underway for four separate COVID-19 vaccination mandates affecting U.S. workers. Specifically, employers with more than 100 employees, health care entities participating in Medicare or Medicaid, federal contractors, and federal government entities will all be required to ensure workers are vaccinated. Guidance is needed from the Occupation Safety and Health Administration (OSHA) for how to comply, and there seem to be more questions than answers, particularly now that the first Americans who were vaccinated may be considering whether to get a booster or not.

At this time, just over half of the U.S. is fully vaccinated, at 54.5%, with 63.6% of Americans having at least one dose of the vaccine[1]. Critics argue that penalties and mandates are not likely to convince those who have decided not to get vaccinated to change their minds. Those among the first to get vaccinated are now faced with the decision of whether or not to get a booster.

The Pfizer vaccine now has full FDA approval, while the Moderna and Johnson & Johnson vaccines are still under FDA Emergency Use Authorizations. The FDA's Vaccines and Related Biological Products Advisory Committee voted against a broader FDA approval of the Pfizer booster for people who are at least 16 years old and vaccinated six months. They did recommend a booster for adults over age 65 and at-risk individuals. The CDC has endorsed the booster shots for adults over age 65 and for those ages 50 to 64 with underlying health conditions.

With so much uncertainty about the vaccines (e.g. emergency approval vs. full approval and booster status), until the FDA officially weighs in, it may be difficult to enforce the President's mandate. Many employers have already announced strict vaccination policies with penalties ranging from higher health plan premiums to termination of employment. Employers should carefully monitor emerging guidance and continue to consider existing regulations to determine how best to structure vaccination policies.

Transparency Rules – Background

The topic of transparency isn't new...it began gaining traction with the ACA, which requires "transparency in coverage" cost-sharing disclosures by most group health plans and insurers. It recently became a key issue in last year's Presidential election, with each candidate releasing plans for how to tackle the rising cost of health care and prescription drugs specifically. There have been some recent regulations passed that outline requirements for group health plans and insurers, with very little, if any, guidance issued for how to comply with the regulations.

Key Legislative Activity

In October of 2020, there were regulations issued jointly by the IRS, DOL, and HHS requiring group health plans to disclose certain cost information to the public through machine-readable files. In addition, these rules require member cost share information to be available upon request, with a list of 500 specific services that must be available on an internet-based self-service tool.

The No Surprises Act, part of the Consolidated Appropriations Act of 2021 (CAA), also addresses transparency and surprise medical billing, requiring patient-friendly cost comparison tools and up-front cost estimates or EOBs, as well as prescription drug cost and utilization reporting to the DOL, HHS, and Treasury.

Impact on Group Health Plans and PBMs

Some of the above requirements were supposed to become effective as early as 12/27/21, but, as recently as earlier this month, have been delayed due to lack of clarity for how to satisfy the requirements. With little guidance available, health insurers and PBMs are not yet clear on what will be required and how they will support plan sponsors. Plan sponsors will need to work closely with their consultants, health plan TPAs, and PBMs to review and understand guidance as it becomes available and determine the steps to comply.

Industry Implications

There are many objectives to passing the transparency rules. One of the main goals is to encourage and facilitate competition, which should in turn drive lower costs. Another is to ensure that key cost information is readily available to the public, in a uniform and easy-to-understand format. Compliance with the rules is proving to be complex and administratively burdensome, particularly given the lack of clear guidance for how to comply. The availability of the information is still a long way off so the impact it may have on competition and costs is still unknown.

Source:

1. The Mayo Clinic, U.S. COVID-19 Vaccine Tracker, www.mayoclinic.org/coronavirus-covid-19/vaccine-tracker/, September 16, 2021.

Pharmacy 101

Pros and Cons of Prescription Cost Comparison Tools

With the continued rise in cost for prescription medications, many patients and employers are turning to prescription cost comparison tools, such as GoodRx and Blink Health, to find their medications at the lowest cost. There are a few points that employers should know when recommending these tools for their insured employee population. Understanding the different tools available is important for both the employee and the employer.

Pros

- Cost comparison tools have made researching medications simple. Most of these tools are online search engines developed with the consumer in mind. They are easy to use on a computer or smartphone and use the patient's location to determine the closest and most affordable medications.
- Patients are shown multiple different pricing points based on pre-negotiated rates from pharmacies in their area. Some of these available rates do require a coupon, which can be printed directly from the website.
- These tools are not just for pricing, but education as well. Consumers can also research drug facts and potential side effects or drug interactions, lower cost alternatives, and manufacturer assistance programs.

Not All Good News

- Pricing found through prescription cost comparison tools and the negotiated pharmacy benefit coverage offered by an employer are mutually exclusive—meaning a member cannot use both benefits at the same time. If a member elects to use a coupon offered by a price comparison tool, the member is not allowed to submit the incurred expenses to their insurance, which means those expenses would not apply to any deductibles or out-of-pocket expenses.
- As of today, most of the third-party prescription cost comparison tools are unconnected to the PBM, therefore the PBM does not have a way to track the data and link it to the current utilization. This could result in the member getting hurt through drug interactions. When a claim processes under the employee benefits, the pharmacy receives error messaging if the member has been prescribed a drug combination that has a drug interaction. This messaging process is extremely important, especially if the member has multiple providers who prescribe based on their specialty. Since the price comparison tool acts as its own insurance company, the drug interaction would not be triggered by the employee's health insurance.

Other Considerations

Some of these tools are offered as part of the PBM offering for self-funded plans. These programs are added on top of the plan's pharmacy benefits to provide the employer's negotiated retail discounts on prescriptions not covered by the plan's pharmacy benefits. Members can research medications on their insurance patient portal either online or through the PBM's app to find the lowest cost of the medication. The plan does not incur the additional expense, but since the program is offered by the PBM, the data is available for drug-drug interactions as well as tracking trends within the employee population. The member's cost does not apply to their deductible or out-of-pocket since these claims are not covered by the plan. The downside of this offering is that it can cause confusion amongst the employee population as the seamless switch from the employee benefits to the savings card is done as soon as a claim is denied at the point of sale by the pharmacy benefit coverage. Members are often confused as to why a claim is "paying", but they have to cover the full cost of the medication.

Please discuss these tools with your account team today to understand the options available to you and the right approach for your population.

Disease Spotlight

Tobacco Use and Treatment Options

As of 2021, tobacco use is the leading cause of preventable disease, disability, and death in the United States.

Cigarette smoking is still widespread with an estimated 34 million Americans smoking regularly. Each year, the U.S. spends more than $225 billion on medical care to treat smoking-related disease in adults. Although the majority report wanting to quit, unfortunately, only a small percentage of smokers succeed, resulting in the common question, why?

In 2021, tobacco use, primarily in the form of smoking cigarettes, is still very common for many Americans. While overall usage is down dramatically from the per-capita highs of the 1960's, we still face tremendous challenges in not only securing more victories against tobacco use, but also immense pressure in protecting the progress that has been achieved so far.

- According to CDC data, in 2019 alone there was an estimated 34 million American cigarette smokers, of which, 23 million reported wanting to quit smoking entirely.
  - In addition, of those 23 million, 21.5 million smokers reported making an attempt in the past year to quit smoking. However, only 2.9 million of those smokers succeeded in quitting.
- These statistics are relatively similar to the trends we see in young Americans, with 3.3 million report attempting to quit using all tobacco products in the past year.
  - While data on young American's effectiveness in attempts to quit is unavailable, there is little reason to expect that their outcomes are better, if not worse, than their adult counterparts.

What this data shows is that the primary challenges facing public health policy and tobacco cessation efforts is not a lack of interest, determination, or willpower, but instead a failure to focus on the importance of medical and pharmaceutical intervention and therapy in achieving cessation.

- The CDC data further reinforces this point by stating that in 2015, "only 31.2% (7.6 million) reported using counseling or medication when trying to quit", when combined with the data that "in 2015, 57.2% of adult smokers (18.8 million) who had seen a health professional in the past year reported receiving advice to quit". The data paints a rather clear image of a very powerful point of intervention—the primary care physician (PCP)—not being utilized effectively in both public health policy and in employer-sponsored population health management.
- The data further suggests that "even brief advice to quit (<3 minutes) from a physician improves cessation rates and is highly cost-effective."

An Employer's Role and Opportunity in Cessation and Treatment Options

Employer-sponsored health benefits create a unique environment where employers are not only paying the majority of the direct cost of the co-morbidities associated with tobacco use, but also one in which the opportunity for intervention towards employees and members can result in healthier, happier, and ultimately a more productive employee population.

Tobacco cessation is not a one size fits all approach. The most successful smoking cessation programs are tailored to an individual's needs and utilize a combination of clinician counseling, behavioral reinforcement, community resources, technology support tools, and medication therapy (both nicotine-based and non-nicotine medications). Treatments that can lessen cravings include nicotine replacement skin patches, lozenges, gum, inhalers, or nasal sprays. Non-nicotine medication, such as varenicline (Chantix) can help reduce nicotine withdrawal symptoms, often a primary barrier to smoking cessation, by mimicking how nicotine functions in your body.

- Drugs such as CHANTIX often fall under the preferred brand/non-preferred brand tier on a formulary, meaning that depending on the tobacco usage in an employer population, a holistic approach to cessation, including CHANTIX or other smoking cessation aids can result in a notable increase in employer Rx related spend. While some generics are available, the generic for Chantix has been in short supply since release, meaning most members are still filling the brand medication.

Smoking cessation is a measurable and achievable goal for both individuals and employers managing their population health. However, a holistic and realistic approach using all available points and types of interventions is essential to achieving tangible outcomes. The effectiveness of cessation cannot just be how many smokers attempt to quit. Instead we must also be mindful of those who attempt, how many succeed, and of those who fail, how many try again.

Clinical Spotlight

Utilization Management

Utilization management programs are well-recognized approaches to cost management in the health care service industry.

Utilization management is a set of managed care techniques that assess the appropriateness of the use of healthcare services, procedures, and facilities under a health benefits plan. These techniques in turn help payers manage the cost of health care benefits. Utilization management techniques can be implemented before, during, and after clinical intervention otherwise known as:

- Prior authorization – done before a clinical encounter occurs.
- Concurrent review – takes place while the patient is receiving care.
- Retrospective review – occurs after care is delivered.

Utilization management programs often address the excessive use of services that lead to waste. This helps with cost management by cutting out medically unnecessary overutilization. Ultimately, these programs are designed to deliver the right care at the right time to the patient while avoiding unnecessary costs associated with care the patient does not need.

Prior Authorization

Prior authorization, also known as preauthorization or precertification, is when a health care provider must obtain prior approval from a health plan before a service or medication is delivered to the patient to qualify for payment by the health plan. This method ensures that the procedure or medication is medically necessary. Prior authorization can also be used to limit off-label use, limit treatment duration, ensure compliance, limit miss-use, and more. According to the National Business Group on Health, in 2021, 96% of large employers are intent on requiring prior authorization for specialty medications billed under the pharmacy benefit.

Step therapy

Step therapy is a form of prior authorization. Step therapy manages high cost drugs prescribed as the first line of treatment. Step therapy programs have a preferred medication or medications that the member must try prior to receiving approval from the health plan for alternative medications. These preferred medications are more cost effective. If the prescriber of the medication indicates that the member has tried these preferred medications or first-choice drugs without success, then they are normally approved for the medication originally requested. In step therapy, there are two different drug categories: first-choice drugs and second-choice drugs. First choice drugs are the first step, lower cost alternatives. Second-choice drugs are the back-up, less preferred, more costly alternatives.

Quantity Limit

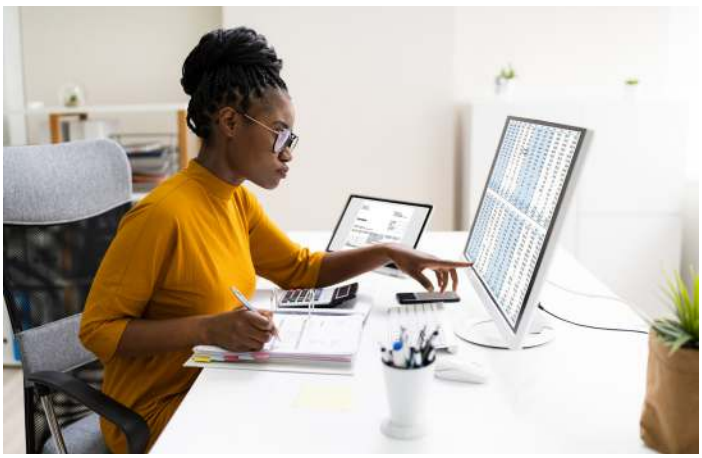
A quantity limit is a restriction on the amount of medication that a health plan covers during a specific amount of time. Different quantity limits apply to different drugs. For example, a health plan may only cover one pill of a medication per day so if a patient receives a 30-day supply they will receive 30 pills. Quantity limits are normally clinical in nature, but also can be placed due to cost concerns.

Concurrent and Retrospective Reviews

Often members have prescriptions from multiple physicians, or they fill them at different pharmacies. This makes it tough to track drug utilization and benefit compliance. That's where the PBM comes in. The PBM uses its database of member information to conduct drug utilization reviews (DUR), which flag potential drug interactions, therapeutic duplication, drug misuse, and quality of care. The two most common DURs are concurrent and retrospective.

Concurrent reviews take place while the patient is receiving care (i.e. actively taking their medication). This type of utilization management uses checks to make sure there are no adverse drug interactions or inappropriate utilization. These checks include interaction between drugs, duplicate prescriptions, ensuring a member is taking the medication as prescribed, and more.

Retrospective reviews take place after a physician prescribes medication and the bill has been submitted. Retrospective reviews help to identify any potential prescribing and dispensing issues. For example, a DUR may reveal that a physician is consistently prescribing a brand name drug instead of a generic substitute. The review can also detect individual prescriptions that may have been inappropriately used. PBM's can do several retrospective DUR programs per year on topics such as appropriate use of controlled substances, level of generic utilization, and tighter management of certain conditions such as diabetes, hypertension, and even overdosing of certain medications such as acetaminophen and more.



Pipeline:

Pending Drug Approvals

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
ciltacabtagene autoleucel (cilta-cel)	Janssen/Legend	Relapsed or refractory (R/R) multiple myeloma (MM)	9/29/21
maralixibat	Mirum	Alagille syndrome-related cholestatic pruritus	9/29/21
reltecimod	Atox Bio	Necrotizing soft tissue infection (NSTI)-related organ dysfunction/ failure	9/30/21
somatrogon	Opko/Pfizer	Growth hormone deficiency (GHD) in pediatrics	Oct 2021
tisotumab vedotin	Seagen/Genmab	Recurrent or metastatic cervical cancer	10/8/21
narsoplimab	Omeros	HSCT-associated thrombotic microangiopathy	10/15/21
mobocertinib	Takeda	Metastatic non-small cell lung cancer (NSCLC)	10/26/21
bevacizumab (biosimilar to Genentech's Avastin)	Bio-Thera	Brain cancer; Cervical cancer; CRC; NSCLC; Ovarian cancer; RCC	11/27/21
sodium thiosulfate	Fennec	Chemotherapy-induced ototoxicity prevention	11/27/21
ciltacabtagene autoleucel	Janssen/Legend	Multiple myeloma (relapsed/ refractory)	11/29/21
pacritinib	CTI Biopharma	Myelofibrosis (MF) with severe thrombocytopenia	11/30/21
adalimumab (biosimilar to Abbvie's Humira)	Coherus	RA; AS; PSO; PsA; JIA; CD; UC	Dec 2021
balstilimab	Agenus	Cervical cancer	12/16/21
efgartigimod	Argenx	Generalized myasthenia gravis (MG)	12/17/21

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
Bystolic	nebivolol	high blood pressure	Sept 2021
Adasuve	loxapine	schizophrenia or bipolar I disorder	Oct 2021
Eovist	gadoxetate disodium	magnetic resonance imaging (MRI)	Nov 2021
Brovana	arformoterol tartrate	bronchoconstriction	Nov 2021
Amturnide	aliskiren, amlodipine, and hydrochlorothiazide	Hypertension	Nov 2021
Licart	diclofenac epolamine	topical treatment of acute pain	Dec 2021
Dulera	formoterol fumarate/ mometasone furoate	Asthma therapy	Dec 2021
Vazalore	aspirin	Aspirin therapy	Dec 2021
Femtrace	Estradiol acetate	vasomotor symptoms	Dec 2021

For more information about Rx and other solutions visit www.MMAEast.com, or contact your local representative.

Lynn Moakley
+1 484 844 5114
lynn.moakley@MarshMMA.com

Shannon LaBarre, CPhT
+215-530-8118
Shannon.LaBarre@MarshMMA.com

Contributors:
Jenna Berger
Shannon LaBarre, CPhT
Sophia Corso
Jeff Mitchell
Joy Ringo