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Rx newsletter

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Market trends

Pharmacy Brown Bagging vs. White Bagging

What is "Bagging"

"Bagging" is a method of delivery, transportation, and administration typically reserved for specialty medications. Each year, more and more health plans incorporate PBM's with their own specialty pharmacies to push towards the method of white bagging versus the traditional brown bagging.

White bagging for specialty medications, especially transfusions, has become an increasing trend amongst pharmacy plan designs since brown bagging adds additional responsibility to the member.

Difference between Brown and White Bagging

The key factor to differentiate between brown bagging and white bagging is by how the medication is provided to the specialty facility administering the medication to the patient.

Brown Bagging:

- Patient is responsible to obtain the prescribed medication through an eligible pharmacy and take the medication to the facility in which the prescriber will administer the medication to the member.

White Bagging:

- The approved specialty pharmacy will dispense and ship the specialty medication to the facility that will be administering the medication to the patient.

The brown bagging method has the member actively involved whereas the second option, white bagging, does not have the patient handle the medication at all.

Pro's and Con's of each bag for Specialty Prescriptions

Brown Bagging:

Pro's:

- No delay in administering medication as member picks up and brings medication to facility.

Con's:

- Potential incorrect storage or treatment of medication by patient prior to bringing medication to the specialty facility.

White Bagging:

Pro's:

- Patients do not have to be concerned with handling medications because the medications are shipped directly to administering facility.

Con's:

- Potential delay in treatment, as medication needs to be shipped from an eligible specialty pharmacy to the specialty facility.
- Patient must also make sure specialty facility has a contractual agreement with the specialty pharmacy.[1]

Overall, it is important to reach out to the PBM affiliated with the health plan to determine how they incorporate white bagging and brown bagging, and which would be most beneficial for the health plan and patients.

Sources:

1. *"What color bag? Three emerging practices pharmacists should know," Pharmacy Today, accessed October 20, 2022, https://www.pharmacytoday.org/article/S1042-0991(22)00132-3/fulltext*

Market trends

Drug Supply Shortages

Cheap and effective drugs, but in increasingly short supply.

One of the longstanding challenges of the US healthcare system is the continuing risk of various drug shortages. While most patients are unlikely to encounter one, for those impacted the effects can be devastating.

Drug Shortage Trends

Currently, there are two primary categories of drugs in shortage. The first and largest being drugs that are being discontinued by manufacturers. This is primarily caused by low profit margins on drug lines, of which there are currently 261 according to the FDA. The second drug shortage category are those drugs impacted by supply chain challenges, unexpected increases in demand, or manufacturing problems.

According to historical data provided by the FDA,

- As of October 2022, 165 drugs have been reported to have a supply shortage. This is double the amount of reported drug shortages for 2021.[1]
- While COVID-19 did cause significant disruption in drug supply chains, there is still notable unrelated COVID annual drug shortages being reported and averages to about 30-50 new drugs per year.[1]
- Through the executive intervention of the FDA and other partner agencies, an additional 317 drug shortages were prevented in 2021.[1]

Surprisingly, the primary drugs typically reported to be in shortage are not high cost, orphan condition drugs, but are instead low cost, generic therapeutics.

"Economic Forces are the Root Causes of Drug Shortages"[1]

According to the FDA, the primary driver of drug shortages in the US are business decisions revolving around economic forces.

- Due to the enormous price pressure, referred to generic manufacturers as the "race to the bottom" on pricing, there is little to no incentive to continue to manufacture older, generic, low-cost therapies.
  - Between 2013 and 2017, 163 drugs in shortage were sampled by the FDA. They found that the median per dose price was $8.73 for all shortage drugs.[2]
  - Injectables reflect the higher end of the spectrum with a median per dose price of $11.05.[2]
  - Orally administered drugs had a significantly lower median with $2.27 per dose ($68 for a 30 day supply).[2]

Unfortunately, this low-cost alternative shortage trend does not appear to be easing anytime soon. Until the incentive and pricing structures change, the FDA's ability to intervene via executive authority will continue to be the primary impediment against drug shortages.

**Orphan condition drugs are defined as drugs used to treat rare diseases that affect less than 200,000 people in the United States, making sponsors reluctant to develop such drugs under usual marketing conditions since these drugs are not profitable to produce without government assistance.[3]*

Sources:

1. *"Drug Shortages for calendar Year 2021," Food and Drug Administration, accessed October 18, 2022, https://www.fda.gov/media/159302/download*
2. *"2019 Drug Shortages Report," Food and Drug Administration, accessed October 18, 2022, https://www.fda.gov/media/131130/download*
3. *"About Orphan Drugs," Orphanet, accessed November 30, 2022, https://www.orpha.net/consor/cgi-bin/Education_AboutOrphanDrugs.php?lng=EN*

Disease Spotlight

Sleep and its impact on your health

Why is sleep important?

To keep your heart healthy, you need a good night's rest, and it is well documented that 7-8 hours of sleep is vital to your overall health. People who sleep for shorter periods, 5 hours or less, are more likely to be at risk of chronic diseases later in life.

According to the CDC, heart disease is the leading cause of death in the United States.[1] In June of 2022, the American Heart Association added sleep deprivation to its cardiovascular health checklist. The checklist comprises eight items that can help manage cardiovascular health, they include: quitting tobacco, eating better, being active, managing weight, managing blood pressure, controlling cholesterol, reducing blood sugar, and getting healthy sleep.[2]

Sleep Deprivation Research

Researchers from Columbia University's Mailman School of Public Health performed a study that had 2,000 middle-age or older adults fill out sleep surveys, wear devices that measured sleep for seven days, and take part in an overnight observation.[2]

It was found that about 63% of the participants slept less than seven hours a night and that 30% slept for less than six hours. Those "who slept less than seven hours had a higher chance of 'low sleep efficiency," irregular sleep patterns, excessive daytime sleepiness, and sleep apnea.' In addition to these sleep disruptions, individuals that slept for less than seven hours had a higher risk of heart disease factors including, obesity, type 2 diabetes, and high blood pressure.[2]

It is not just your physical health that can be impacted but also your mental health. Poor sleep lowers the chance of physical activity throughout the day, increases poor diet cravings, can raise stress levels, and increase depression.

Tips to Improve your Sleep

By knowing the health risks associated with sleep deprivation, you can begin to mitigate those risks with some best practices.

Stick to a sleep schedule

- Go to bed and wake up the same time each day, be consistent with your schedule.
- If you can't fall asleep within the first 20 minutes, go do something relaxing and then go back to bed when you're tired.[3]

Pay attention to what you eat

- Don't overeat or go to bed hungry.
- Monitor your nicotine, caffeine, and alcohol as they can disrupt your sleep.[3]

Create a restful environment

- Keep the room cool, dark, and quiet. Blackout shades and white noise machines may be effective.
- Limit time in front of screens such as a tv, computer, or phone.[3]

Limit daytime naps

- Prolonged naps during the day can interfere with nighttime sleep. Avoid naps longer than an hour.[3]

Add physical activity to your day

- Exercise can promote better sleep as long as it is not too close to bedtime.[3]

Manage stress

- Try to resolve your worries prior to bedtime. Write down what's on your mind and set it aside for the next day.[3]

If you've tried combinations of the above tips and are still having trouble sleeping, it's best to consult with your health care provider. A professional may be able to help identify the root cause and help you get back to the sleep you deserve.

Sources:

1. *"About Multiple Cause of Death, 1999–2020," Centers for Disease Control and Prevention, accessed October 24, 2022, https://wonder.cdc.gov/mcd-icd10.html*
2. *Christensen, Jen (2022, Oct. 21) "Sleep may be just as important to heart health as diet and physical activity, research finds," KSL.com, accessed October 24, 2022, https://www.ksl.com/article/50498223/sleep-may-be-just-as-important-to-heart-health-as-diet-and-physical-activity-research-finds*
3. *"Sleep tips: 6 steps to better sleep," Mayoclinic.org, accessed October 24, 2022, https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/sleep*

Clinical Spotlight

Gene Therapy for Degenerative Brain Disorder Wins FDA Approval

Bluebird Bio sets a new pricing record with Skysona – a $3M gene therapy.

The FDA granted accelerated approval to Bluebird Bio's new gene therapy, Skysona. Skysona treats a rare neurological disorder called childhood cerebral adrenoleukodystrophy (CALD). Skysona is a one-time treatment and the first and only gene therapy to treat CALD. Bluebird will have to provide confirmatory long-term clinical data to the FDA as a condition of the accelerated approval granted. This includes the results of an ongoing study that will follow patients treated in the clinical trials over 15 years. Bluebird plans to make Skysona available by the end of 2022. Skysona will initially be available only at Boston Children's Hospital and the Children's Hospital of Philadelphia.[1]

Childhood Cerebral Adrenoleukodystrophy (CALD)

CALD is a rare, debilitating form of adrenoleukodystrophy that generally occurs in boys ages 4 to 17 years.[1] The disease is caused by a genetic mutation in the ABCD1 gene. This leads to a buildup of long chain fatty acids that destroy the protective myelin sheath around nerve cells. The destruction of myelin causes relentless progressive deterioration leading to permanent disability and death usually within four to eight years of symptom onset.[2] CVS estimates 700 potential candidates in the United States for Skysona.[3]

The High Cost of Gene Therapies

Skysona has earned the title of the world's most expensive treatment at $3 million. Until the approval of Skysona, Bluebird Bio's Zynteglo was the most expensive drug on that market at $2.8 million. Pharmaceutical companies can charge such high prices for these gene therapies due to their one-time use and limited competition when it comes to treatment options. Some companies are offering money-back guarantees due to the high price tag, however, Bluebird will not be offering that type of refund for Skysona due to the rarity and complexity of the brain disease it treats. According to the FDA, there is a surge of cell and gene therapy products coming to market and with approvals ranging from 10 to 20 annually by 2025. CVS estimates that the United States could spend anywhere from $14.8 billion to $45 billion between 2020 and 2024 on gene therapies.[5]

Sources:

1. *"A $3M gene therapy: Bluebird bio breaks its own pricing record with FDA approval of Skysona," Fierce Pharma, accessed October 31, 2022, https://www.fiercepharma.com/pharma/3m-gene-therapy-bluebird-breaks-own-record-fda-approval-skysona*
2. *"Adrenoleukodystrophy," Boston Children's Hospital, accessed October 31, 2022, https://www.childrenshospital.org/conditions/adrenoleukodystrophy-ald*
3. *"Gene Therapy Pipeline," CVS Health, accessed October 31, 2022, https://payorsolutions.cvshealth.com/sites/default/files/q3-2022-gene-therapy-treatments-approval-timelines.pdf*
4. *"Statement from FDA Commissioner," U.S. Food & Drug Administration, accessed October 31, 2022, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics*
5. *"Gene Therapy Keeping Costs from Negating Its Unprecedented Potential," CVS Health, accessed October 31, 2022,https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-gene-therapy-keeping-costs-from-negating-its-unprecedented-potential-white-paper-january-2020.pdf*

Pipeline

Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
etranacogene dezaparvovec	CSL Behring	Hemophilia B	Nov 2022
sparsentan	Travere/Bristol-Myers Squibb	Immunoglobulin A (IgA) nephropathy (IgAN)	11/17/2022
mirvetuximab soravtansine	Immunogen	Ovarian cancer	11/28/2022
Omaveloxolone	Reata/Abbvie	Friedreich's ataxia (FA)	11/30/2022
adalimumab 100 mg/mL (biosimilar to Abbvie's Humira)	Alvotech	RA; AS; PSO; PsA; JIA; CD; UC	December 2022
Adagrasib	Mirati	NSCLC	12/14/2022
trastuzumab (biosimilar to Genentech's Herceptin	Novartis	Breast cancer; Gastric/ gastroesophageal cancer	12/20/2022
toripalimab	Coherus	Nasopharyngeal cancer	12/23/2022
Mosunetuzumab	Genentech	Follicular lymphoma	12/29/2022
Palovarotene	Ipsen	Fibrodysplasia ossificans progressiva	12/29/2022
lecanemab	Eisai/Biogen	Alzheimer's disease (early)	1/6/2023
Filgastim (biosimilar to Amgen's Neupogen)	Tanvex	Neutropenia/leukopenia	February 2023
elacestrant	Menarini	Breast cancer	2/17/2023
fezolinetant	Astellas	VMS	2/22/2023
efanesoctocog alfa	Sanofi	Hemophilia A	2/28/2023

Brands Losing Patent

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Oravig	miconazole	Antifungal	September 2022
Yondelis	trabectedin	Liposarcoma/ leiomyosarcoma	October 2022
Lumason	sulfur hexafluoride lipid-type a microspheres	Ultrasound of the liver	November 2022
Xerese	acyclovir; hydrocortisone	Herpes labialis	November 2022
Xofigo	radium ra-223 dichloride	Castration-resistant prostate cancer	November 2022
Goprelto	cocaine hydrochloride	Nasal solution local anesthesia	December 2022
Giapreza	angiotensin ii acetate	Hypotension; shock	December 2022
Humira	adalimumab	RA; AS; PSO; PsA; JIA; CD; UC	January 2023
Numbrino	cocaine hydrochloride	Local anesthesia	January 2023

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