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3rd QUARTER NEWSLETTER ● 2022

WEST VIRGINIA Department of Health & Human Resources
BUREAU FOR MEDICAL SERVICES

MARSHALL
SCHOOL OF PHARMACY

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Newsletter Published Quarterly by:

The Marshall DUR Coalition

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INSIDE THIS ISSUE

Medications and the Inflation Reduction Act (IRA) of 2022

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On August 12, 2022, President Biden signed the Inflation Reduction Act (IRA) into law. This legislation focuses on climate, taxes, energy, and healthcare. Most of the healthcare reform involves Medicare which include the following provisions[1]:

a. Medicare Drug Price Negotiation Program beginning in 2026 for 10 medications eligible under Medicare Part B or Part D. The number of medications considered for price negotiations increases annually.[1] This negotiation provision to control drug costs for Medicare could be compared to the Medicaid Drug Rebate Program (MDRP) created by the Omnibus Reconciliation Act of 1990. In this program, drug manufacturers enter into a rebate agreement with the Secretary of Health and Human Services that they will rebate a portion of the Medicaid payment back to the states who share part of the rebate with the Federal government.[2]
b. Rebate provision for medications costs rising higher than inflation for medications eligible under Medicare Parts B or D.[1]
c. Cap insulin price at $35 for years 2023-2025. In 2026, cap could change to lesser of $35, the MFP or Medicare negotiated price.[1]
d. Cap on out-of-pocket costs for Part D medication at $2,000 per year beginning in 2025.[1]

Top 10 Medicare medications (2020)[3] compared to top 10 Medicaid medications (2017)[4] ranked by cost

	Medicare	Use	Medicaid	use
1	Eliquis	anticoagulant	Abilify	antipsychotic
2	Revlimid	chemotherapy	Sovaldi	antiviral
3	Xarelto	anticoagulant	Vyvanse	ADHD
4	Januvia	antidiabetic	Harvoni	antiviral
5	Trulicity	antidiabetic	Truvada	antiviral
6	Imbruvica	chemotherapy	Lantus	antidiabetic
7	Jardiance	antidiabetic	Methylphenidate	ADHD
8	Humira	RA/psoriasis	Atripla	antiviral
9	Ibrance	chemotherapy	Advair	asthma/COPD
10	Symbicort	Asthma/COPD	Seroquel XR	antipsychotic

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Where are my Patient's Drugs?
DUR Newsletter September 2022

Tyler B. Clay, PharmD, BCPS

Pharmacists and pharmacies have managed drug shortages before, however the problems we are facing today are accelerating at an alarming rate. At the height of the COVID-19 pandemic, supply shortages such as PPE and Ventilators where the headlines of news articles and local news broadcasts across the country. Fortunately, these shortages quickly resolved, however drug shortages across the country were already present and have persisted over the last 2 years. As of September 23, 2022, the American Society of Health-System Pharmacists (ASHP) has 209 medications listed on their active drug shortage list. These medication shortages span all sectors of healthcare and

almost all patient populations. Weight loss clinics are facing shortages of semaglutide, hospitals are facing shortages of medications used in the operating room such as aminocaproic acid, community practitioners are being forced to change therapy for stable patients because dextroamphetamine salts are in short supply, and community pharmacists are unable to keep common OTC items such as guaifenesin on their shelves. These are just a few examples that highlight the drug shortage issue.

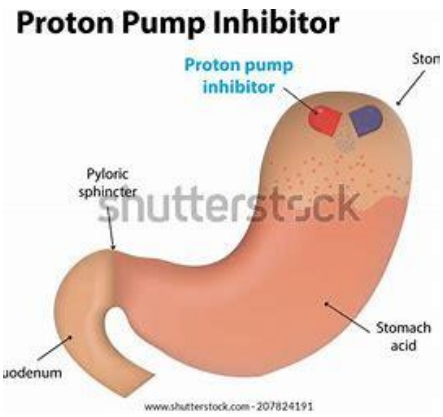
This begs the question, why have these issues persisted for so long? The Food and Drug Administration (FDA) lists typical causes of shortages including manufacturing quality problems, production delays, and product discontinuation as several factors that commonly cause drug shortages, though the issues we are currently facing seem to be taking a different turn. Following the economic impacts of the COVID-19 pandemic, most Americans are aware of supply chain issues causing delays in manufacturing and logistics and many of these same factors are hitting drug manufactures. Of the 209 active drug shortages listed, many are tied to these very issues including trouble obtaining the needed resin and plastic products for IV solution containers, as well as shipping delays related to raw materials. So how do we begin to correct this?

Clearly a systemic problem exists. One attributing factor has been the "just in time" approach to manufacturing where drug manufactures have transitioned to last-minute drug manufacturing at their facilities. Although these strategies lower overhead costs and minimize waste from excessive inventory, they also cripple the integrity of market sustainability when challenges such as staffing shortages arise. One step to begin facing these issues is assessing the management of the Strategic National Stockpile. ASHP has called for improvements in how the Strategic National Stockpile creates and manages supply of critical medications and makes them available in response to emergencies. ASHP has advocated for the FDA to rate manufacturers' quality management process so purchasers can better predict supply chain and manufacturing vulnerabilities as well as calling for supporting regulatory changes that would require manufacturers to disclose the sources of active pharmaceutical ingredients and manufacturing sites. These actions may enhance our ability to predict market disruptions, but other forces are likely needed to enhance the overall stability of drug acquisition.

Once such change may be supply redundancy and outsourcing such as contracting with 503B facilities. Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) outlines the definition and regulations surrounding outsourcing facilities that manufacture large batches of sterile products sold to healthcare facilities. Partnering with these companies may alleviate some challenges such as current supply with normal saline and dextrose solutions needs to compound intravenous

"One step to begin facing these issues is assessing the management of the Strategic National Stockpile. ASHP has called for improvements in how the Strategic National Stockpile creates and manages supply of critical medications and makes them available in response to emergencies."

medications. When obtained through 503B sources, medications arrive in a ready to use state minimizing the need for onsite admixture and decreasing demand on the limited supply a facility is able to maintain. Unfortunately, these solutions only offer relief to a small segment of healthcare facilities. The US is in clear need of reform surrounding pharmaceutical manufacturing transparency and regulatory practices.



Adverse Drug Events Associated with Proton Pump Inhibitors

Kenneth Canipe, PharmD, BCCCP

The first approved proton pump inhibitor was omeprazole (Prilosec®), which came to the drug market in 1988. These medications have revolutionized the way we treat several disease states from peptic ulcer disease to the eradication of Helicobacter pylori. These medications are easily recognizable among patients and are currently available as both prescription and over the counter options. In 2012 this drug class accounted for approximately $9.5 billion in medication costs alone.[2] When PPIs were first brought to market, they were considered generally very safe with a limited number of side effects with short term use (headaches, rash, and dizziness). This ease of availability and generally safe drug profile has led to an overuse of PPIs with 70% of use being without an approved indication.[3,5] Since these medications have been so widely used over the past 34 years, there has been a great deal learned about PPI induced adverse drug reactions, especially with long term use.

In 2011 the FDA released a drug safety communication for a possible increased risk of fractures of the hip, wrist, and spine with the use of PPIs.[1] This safety communication was in response to the findings of two studies that were published looking at the impact of long-term PPI use and an association with increased risk of fractures.[1] The first study by Yang and colleagues was a retrospective study that was published in JAMA in 2006.[7] The study demonstrated that patients greater than the age of 50 that used PPIs for more than a year had a higher risk of fracture compared to those who did not use PPIs long term. The second study was published by Corley and colleagues in 2010 in Gastroenterology demonstrated an increased fracture risk in patients who used PPIs long term and had one additional risk factor.[8] The risk factors that lead to increased risk in association with PPI use were alcohol abuse, arthritis, diabetes, kidney disease, and glucocorticoid steroid use. There are a few proposed mechanisms as to how this increased risk occurs, once of which is hypochlorhydria-associated malabsorption of calcium. The inhibition on bone resorption due to the blocking of H+/K+ ATPase is another proposed

mechanism. The increase in gastric pH also has an impact on the bioavailability of calcium supplementation and the use of calcium citrate formulations may have the best bioavailability compared to carbonate formulations.[3]

The use of PPIs has also been linked to an increased risk of both pneumonia as well as Clostridium (C. diff) infections. The increased risk in pneumonia has been associated with the short term use of PPIs, and is thought to be overestimated based on more recent meta-analysis data.[10,13] The proposed mechanism is thought to be due to an increased gastric pH increasing micro-aspirations leading to lung colonization and eventually pneumonia.[6,12] The increased risk of C. diff has a greater amount of evidence linking it strongly to the misuse/use of PPIs.[10] The proposed mechanism is through hypochlorhydria generated by PPI associated gastric suppression increases the risk of bacterial colonization and alteration of intestinal flora, ultimately increasing the risk of C. diff infections.[10] A study published in the American Journal of Gastroenterology in 2020 identified that PPI use may be associated with an increased risk of coronavirus (COVID-19).[9] The use of PPIs was not necessarily linked with increased susceptibility to severe acute respiratory syndrome, however it was associated with poor outcomes in patients infected with COVID-19.[9]

Proton pump inhibitors have also been associated with a host of drug-drug interactions. These interactions are multifactorial both from a metabolism standpoint through CYP interactions as well as alterations in drug absorption and bioavailability due to alterations of gastric pH. Several agents that require an acidic environment for absorption include: ketoconazole, itraconazole, isoniazid, ferrous sulfate, and several protease inhibitors.[11] Conversely the absorption of some medications may be enhanced such as: digoxin and nifedipine.[11] Since these medications are impacted by the alteration of gastric pH and PPIs tend to cause sustained pH increases there are few options to mitigate these interactions. Increased drug monitoring and avoidance of PPIs if possible, should be considered.

These are just some examples of the adverse drug reactions and interactions that PPIs have been linked to since they were first approved in the late 1980s. While they have been a cornerstone in the treatment of several acid-related disease states with superior efficacy and overall, a safe drug profile their use should not be taken lightly. The use of PPIs should routinely be evaluated for appropriate use in patients and discontinued if they are no longer clinically indicated.

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Summary of select innovative drugs approved by the FDA as of September 2022

Tiffany Davis, PHARMD, R.PH.,TTS

*The indication, CI/BBW, and Warnings and Precautions lists on this chart are for presentation purposes only. See the most recent FDA-approved Prescribing Information to find the FDA-approved conditions of use [e.g., indication(s), population(s), dosing regimen(s)] for each product.

Disease State	Brand Name	Active Ingredient	Indication	Most Common ADRs	Notes	CI/BBW	Warnings and Precautions
Acid Sphingomyelinase Deficiency (ASMD)	Xenpozyme	olipudase alfa	To treat Acid Sphingomyelinase Deficiency	Most common adverse reactions in adult patients (incidence ≥10%) are headache, cough, diarrhea, hypotension, and ocular hyperemia. Most common adverse reactions in pediatric patients (incidence ≥20%) are pyrexia, cough, diarrhea, rhinitis, abdominal pain, vomiting, headache, urticaria, nausea, rash, arthralgia, pruritus, fatigue, and pharyngitis.	First FDA approved treatment for ASMD	• BBW: Severe hypersensitivity reactions including anaphylaxis • No CI	• Infusion-Associated Reactions • Elevated Transaminases • Risk of Fetal Malformations During Dosage Initiation or Escalation in Pregnancy
Atopic dermatitis	Cibinqo	abrocitinib	To treat refractory, moderate-to-	Most common adverse reactions (≥1%) in subjects receiving 100 mg and 200 mg include:		• BBW: Serious infections, mortality, malignancy, major	• Laboratory Abnormalities (platelets,

			severe atopic dermatitis	nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis. Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.		adverse cardiovascular events, and thrombosis • CI: Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment.	lymphocytes, and lipids) • Immunizations (avoid live vaccines prior to, during, and immediately after Cibinqo treatment)
Cancer	Kimmtrak	tebentafusp-tebn	To treat unresectable or metastatic uveal melanoma	The most common adverse reactions (occurring in ≥ 30%) are cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common laboratory abnormalities (occurring in ≥50%) are decreased lymphocyte count, increased creatinine, increased glucose, increased aspartate aminotransferase, increased alanine aminotransferase, decreased hemoglobin, and decreased phosphate		• BBW: Cytokine Release Syndrome which requires monitoring for at least 16 hours following the first three infusions and then as clinically indicated • No CI	• Skin reactions • Elevated liver enzymes • Embryo-Fetal toxicity

	Opdualag	nivolumab and relatlimab-rmbw	To treat unresectable or metastatic melanoma	The most common adverse reactions (≥20%) are musculoskeletal pain, fatigue, rash, pruritus, and diarrhea. The most common laboratory abnormalities (≥20%) are decreased hemoglobin, decreased lymphocytes, increased AST, increased ALT, and decreased sodium.		• No BBW • No CI	• Immune-Mediated Adverse Reactions • Infusion-related reactions • Complications of allogeneic HSCT • Embryo-Fetal toxicity
	Pluvicto	lutetium (177Lu) vipivotide tetraxetan	To treat prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer following other therapies	Most common adverse reactions (≥ 20%) are fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Most common laboratory abnormalities (≥ 30%) are decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.		• No BBW • No CI	• Risk from radiation exposure • Myelosuppression • Renal toxicity • Embryo-Fetal toxicity • Infertility
Cardiomyopathy	Camzyos	mavacamten	To treat certain classes of obstructive hypertrophic cardiomyopathy	Adverse reactions occurring in >5% of patients and more commonly on CAMZYOS than on placebo were dizziness (27%) and syncope (6%).	Use requires REMS (Camzyos REMS Program)	• BBW: Risk of Heart Failure • CI: Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors • CI: Moderate to strong CYP2C19 inducers or	• Heart Failure • Drug Interactions Leading to Heart Failure or Loss of Effectiveness • Embryo-Fetal Toxicity

						moderate to strong CYP3A4 inducers	
Diabetes	Mounjaro	tirzepatide	To improve blood sugar control in diabetes (in addition to diet and exercise)	The most common adverse reactions reported in ≥5% of patients treated with MOUNJARO are nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.		• BBW: Risk of Thyroid C-Cell Tumors • CI: Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 • CI: Known serious hypersensitivity to tirzepatide or any of the excipients in MOUNJAR	• Pancreatitis • Hypoglycemia with Concomitant use of Insulin Secretagogues or Insulin • Hypersensitivity Reactions • Acute Kidney Injury • Severe Gastrointestinal Disease • Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy • Acute Gallbladder Disease
H. Pylori infection	Voquezna Triple Pak	vonoprazan, amoxicillin, and clarithromycin	To treat *Helicobacter pylori* infection	<u>VOQUEZNA TRIPLE PAK</u>: Most common adverse reactions (≥ 2%) were dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension. <u>VOQUEZNA DUAL PAK</u>: Most common adverse reactions (≥ 2%) were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis.	Dual Pak does not contain clarithromycin; however, the Triple Pak does contain clarithromycin.	• No BBW <u>CI: VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK</u>: • Known hypersensitivity to vonoprazan, amoxicillin or any other beta-lactams, clarithromycin or any other macrolide antimicrobial or	<u>VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK</u>: • Hypersensitivity Reactions: • Severe Cutaneous Adverse Reactions (SCAR) • *Clostridioides difficile*-associated diarrhea (CDAD) <u>VOQUEZNA TRIPLE PAK Due to the Clarithromycin Component</u>:

						any component of VOQUEZNA TRIPLE PAK. • Known hypersensitivity to vonoprazan, amoxicillin or any other beta-lactams or any component of VOQUEZNA DUAL PAK. • Rilpivirine-containing products. <u>CI: VOQUEZNA TRIPLE PAK Due to the Clarithromycin Component</u>: • Pimozide. • Lomitapide, lovastatin, and simvastatin. • Ergot alkaloids (ergotamine or dihydroergotamine). • Colchicine in renal or hepatic impairment. • History of cholestatic jaundice/hepatic dysfunction	• QT Prolongation: Avoid • Hepatotoxicity: Discontinue if • Serious adverse reactions due to concomitant use with other drugs • Embryo-Fetal Toxicity • Myasthenia Gravis:

						with use of clarithromycin.	
Insomnia	Ouviviq	daridorexant	To treat insomnia	The most common adverse reactions (reported in ≥ 5% of patients treated with QUVIVIQ and at an incidence ≥ than placebo) were headache and somnolence or fatigue	Newest orexin receptor antagonist	• No BBW • CI: QUVIVIQ is contraindicated in patients with narcolepsy	• CNS-Depressant Effects and Daytime Impairment • Worsening of Depression/Suicidal Ideation • Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms • Complex Sleep Behaviors • Compromised Respiratory Function • Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days.
Macular Degeneration	Vabysmo	faricimab-svoa	To treat neovascular (wet) aged-related macular degeneration and diabetic macular edema	The most common adverse reaction (≥ 5%) reported in patients receiving VABYSMO was conjunctival hemorrhage (7%).	Also indicated for Diabetic Macular Edema (DME)	• No BBW • CI: Ocular or periocular infection • CI: Active intraocular inflammation • CI: Hypersensitivity	• Endophthalmitis and retinal detachments may occur following intravitreal injections • Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection • There is a potential risk of arterial

							thromboembolic events (ATEs) associated with VEGF inhibition
Psoriasis	Spevigo	spesolimab-sbzo	Generalized pustular psoriasis flares	Most common adverse reactions (≥5%) are asthenia and fatigue, nausea and vomiting, headache, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.		• No BBW • CI: Severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO	• Infections: SPEVIGO may increase the risk of infections. Do not initiate SPEVIGO during any clinically important active infection. • Tuberculosis (TB): Evaluate patients for TB prior to initiating treatment with SPEVIGO • Hypersensitivity and Infusion-Related Reactions: Hypersensitivity including drug reaction with eosinophilia and systemic symptoms (DRESS) and infusion-related reactions may occur. • Vaccinations: Do not administer live vaccines concurrently with SPEVIGO
	Vtama	tapinarof	Plaque psoriasis	Most common adverse reactions (incidence ≥ 1%) in subjects treated with VTAMA cream were		• No BBW • No CI	• No listing for Warnings and Precautions

				folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza			
Vulvovaginal candidiasis (recurrent)	Vivjoa	oteseconazole	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	The most frequently reported adverse reactions (incidence > 2%) were headache and nausea		• No BBW • CI: Females of reproductive potential • CI: Pregnant/lactating women • CI: Hypersensitivity to oteseconazole	• Embryo-Fetal Toxicity

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