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ISSUE 2

HELPFUL NUMBERS FOR PROVIDERS

CVS: 1-888-512-8935
Primary: 004336
Secondary Commercial: 013089
Secondary Part D: 012114
Passport Pharmacy Services:
1-844-380-8831

Passport Advantage
BIN: 004336
PCN: MEDDAVDV

HELPFUL NUMBERS FOR MEMBERS

Passport Health Plan
1-800-578-0603

WEBSITE

www.passporthealthplan.com

NEW IN THIS ISSUE

- Controlled Substance Edits Update
- Compounds Update
- Human Immunodeficiency Virus (HIV) Category Update
- New Prior Authorization Additions
- Quantity Limit Updates
- P&T Committee Review
- New Generics
- Recent FDA Safety Advisories

Controlled Substance Edits Update

In an effort to more accurately reflect Kentucky Board of Medical Licensure guidance with respect to promoting safety and curbing abuse potential with acute opioid prescribing, a number of controlled substance drug utilization review (DUR) edits will be updated to include the following:

- The morphine equivalent dosing (MED) of greater than 120 milligrams (mg) per day will be reduced to MED exceeding 80 mg/day.
- New policies to reduce limits for *new* opioid users that meet any of the following criteria:
 - Medication supplies exceeding 7 days of therapy
 - Claims for an extended release opioid formulation without a history of therapy with an immediate release opioid product
 - MED exceeding 50 mg/day.
- Opioid prescriptions from dentists that meet the following criteria: medication supplies exceeding 3 days of therapy and/or a MED exceeding 50 mg/day.

These DUR policy revisions and additions fall in line with the most recent acute pain management treatment recommendations and are in accordance with numerous state level prescribing restrictions of opioids and controlled substances. These DUR policies will require prior authorization in which the prescriber must demonstrate the medical necessity for the requested therapy. These changes were discussed with and deemed clinically appropriate by providers serving Passport's member population.

Compounds Update

The maximum dollar threshold for compounds prepared for adults will be reduced from \$250 to \$50, while the maximum dollar threshold for compounds prepared for pediatric members will be reduced from \$250 to \$100. The intent of this reduction is to address potential fraud, waste, and abuse with compounded drug products, while allowing the pharmacy network to remain unchanged. These changes were discussed with and deemed clinically appropriate by providers serving Passport's member population.

Human Immunodeficiency Virus (HIV) Category Update

In the interest of establishing consistency across all products used in the treatment human immunodeficiency virus (HIV), a categorical review of these therapies was conducted. This review was designed to ensure that a requested HIV agent is being prescribed in accordance with the most updated Center for Disease Control (CDC) treatment guidelines and at its appropriate dosage. The updates to this therapeutic category include the following stipulations: all generics and brands that do not have a generic available will be placed on a preferred tier with no required prior authorization; drugs that are not considered first-line therapies based on clinical guidelines will be subject to a prior authorization review consisting of a trial and failure of two preferred alternatives. Members currently on therapy will not be impacted by this change. Additionally, quantity limitations have been added in accordance with FDA and compendia-supported dosing guidelines. Quantity limits are excluded from the grandfathering that is granted for prior authorization requirements. Any current policies regarding specific HIV products will be retired, and all products that require prior authorization will be encompassed by the Non-Preferred Medications policy. This update was discussed with and deemed clinically appropriate by providers serving Passport's member population.

New Prior Authorization Additions

Passport Health Plan will require prior authorization review for the following medications, effective July 23, 2018.

- Mupirocin 2% Cream
- Zovirax® 5% Cream and 5% Ointment
- Adapalene 0.1% Gel, 0.1% Cream, 0.1% Lotion, 0.3% Gel
- Sumatriptan/naproxen (Treximet®)
- Almotriptan**
- Frovatriptan**
- Fluoxetine tablets**
- Venlafaxine ER tablets**
- Chorionic gonadotropin, Novarel®, Pregnyl®
- Triкло

***Please note that members currently on almotriptan, frovatriptan, fluoxetine tablets, and venlafaxine ER tablets will be allowed to continue therapy for the duration of their membership with Passport Health Plan.*

Quantity Limit Updates

Quantity limits were added for the following medications, effective July 23, 2018.

PRODUCT	NEW QUANTITY LIMIT
Mupirocin 2% Cream	15 gm/30 days
Mupirocin 2% Ointment	132 gm/30 days
Zovirax® 5% Cream	5 gm/30 days
Zovirax® 5% Ointment	30 gm/30 days
Adapalene 0.1% Gel	45 gm/30 days
Adapalene 0.1% Cream	45 gm/30 days
Adapalene 0.1% Lotion	59 mL/30 days
Adapalene 0.3% Gel	45 gm/30 days
Sumatriptan/Naproxen (Treximet®) 10mg-60mg	9 tablets/30 days

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in May 20188

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Xepi™	Ozenoxacin	Treatment of impetigo due to Staphylococcus aureus and Streptococcus pyogenes	Mupirocin 2% ointment, Altabax® ointment	Non-preferred with QL
Rhopressa®	Netarsudil	Reduction of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension	Bimatoprost 0.03%, Latanoprost 0.005%, Brimonidine 0.15% or 0.2%, Betaxolol 0.5%, Timolol maleate 0.25% or 0.5%, Dorzolamide HCl 2%, Pilocarpine 1% or 2%	Non-Preferred with ST
Biktarvy®	Bictegravir / emtricitabine / tenofovir alafenamide	HIV-1 Infection in adults without antiretroviral treatment history or to replace the current antiretroviral regimen in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least 3 months without history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy®	Genvoya®, Stribild®, Juluca®, Triumeq®, Isentress®, Tivicay, Descovy®, Truvada®	Preferred with QL
Symdeko™	Tezacaftor / ivacaftor	Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor	Kalydeco®, Orkambi®	Non-Preferred with PA and QL
Erleada™	Apalutamide	Treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC)	Bicalutamide, Nilutamide, Flutamide, Xtandi®, Zytiga®	Preferred with PA and QL
Admelog®	Insulin lispro	To improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus	Humalog®, Novolog®, Apidra®, Fiasp®	Non-preferred with ST and QL

**The Pharmacy and Therapeutics committee also reviewed updates to quantity limits, prior-authorization durations, and other clinical criteria requirements. For specific questions about the clinical criteria please visit www.passporthealthplan.com or call Pharmacy Services at 844-380-8831.*

New Generics*

GENERIC NAME	BRAND NAME	AVAILABLE	FORMULARY STATUS
Efavirenz	Sustiva® 600mg	2/2/2018	\$1 tier with QL
Memantine XR	Namenda® XR	2/23/2018	\$1 tier
Sumatriptan/Naproxen	Treximet® 85-500mg	2/23/2018	\$1 tier with QL
Minocycline	Solodyn®	2/23/2018	\$1 tier with PA
Trimipramine Maleate	Surmontil®	3/9/2018	\$1 tier
Praziquantel	Biltricide® 600mg	4/27/2018	\$1 tier with PA

**Some generic drugs may still be subject to prior authorization or step therapy requirements, and certain quantity limits. For details, please refer to the drug formulary on Passport Health Plan website www.passporthealthplan.com*

Recent U.S. Food and Drug Administration (FDA) Drug Safety Advisories Affecting Network Pharmacies and Providers

The FDA recently issued the following advisories:

3/15/2018 Bayer Issues Voluntary Recall of Alka-Seltzer Plus® Products

Bayer is voluntarily recalling Alka-Seltzer Plus® packages that were sold in the U.S. at Walmart, CVS, Walgreens and Kroger (including Dillons Food Stores, Fred Meyer, Fry's Food Stores, Ralphs, King Soopers and Smith's Food and Drug) after February 9, 2018. If the logo in the lower left corner of the front of the carton has an orange or green background, the product is included in the recall. These products are being recalled because the ingredients on the front sticker may not match the actual product in the carton. Ingestion of this product by a consumer can lead to an allergic or anaphylactic reaction. Additionally, consumers may ingest an ingredient which they should avoid due to their medical conditions. Overall, there may be potential for serious health consequences. Consumers who have purchased this recalled product should stop using the product and report any issues to their physician or healthcare provider. Adverse events or side effects may also be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

4/25/2018 Lamictal® (lamotrigine): Drug Safety communication—serious Immune System Reaction

The FDA is warning that the medicine Lamictal® (lamotrigine) for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body's infection-fighting immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, the FDA is requiring a new warning about this risk be added to the prescribing information in the lamotrigine drug labels. Evaluate patients who develop fever or rash promptly, and discontinue lamotrigine if HLH or another serious immune-related adverse reaction is suspected and an alternative etiology for the signs and symptoms cannot be established. Advise patients to seek immediate medical attention if they experience symptoms of HLH during lamotrigine treatment. Patients or their caregivers should contact their health care professionals right away if they experience any symptom of HLH while taking lamotrigine. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

- 5/21/2018** **Apotex Corp. Issues Voluntary Nationwide Recall of Fluticasone Propionate Nasal Spray USP 50 mcg Per Spray 120 Metered Sprays Due to Potential for Small Glass Particles**
- Apotex Corp. has issued a voluntary recall of one lot of Fluticasone Propionate Nasal Spray to the consumer level. The lot has been found through a customer complaint to contain small glass particles, which could block the actuator and impact the functionality of the pump. Patients can also be exposed to the glass particles in the nasal spray, causing mechanical irritation or local trauma to the nasal mucosa. Customers, retailers, or any entity with an existing inventory of the lot subject to the recall should stop use and distribution of the remaining units and quarantine immediately.
- NDC: 60505-0829-1, Lot NJ4501, Exp: 07/2020
- Health care professionals should be contacted if patients experience any health concerns related or potentially related to using the product. Adverse events or side effects should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.
- 5/29/2018** **Allergan Issues Nationwide Voluntary Recall of TAYTULLA™ Softgel Capsules 1mg/20mcg Sample Packs Due to Out of Sequence Capsules**
- Allergan has issued a voluntary recall in the US market on one lot of Taytulla™ sample packs. It has been identified through a physician report that the first four days of therapy capsules were placed out of order, containing placebo capsules instead of active capsules. This potential mix-up could place the user at risk for contraceptive failure and unintended pregnancy. This error may not be apparent to both new users and previous users of Taytulla™, increasing the likelihood of taking the capsules out of order.
- Lot 5620706, Exp: 05/2019
- Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.
- 6/4/2018** **Hospira Issues a Voluntary Nationwide Recall for Two Lots of Naloxone Hydrochloride Injection, USP, in the Carpuject™ Syringe System due to the Potential Presence of Particulate Matter**
- Hospira is voluntarily recalling two lots of Naloxone Hydrochloride Injection, USP, 0.4mg/mL, 1mL in 2.5mL, Carpuject™ Single-use cartridge system due to the potential presence of embedded and loose particulate matter on the syringe plunger. Upon administration of this impacted product, the patient could possibly experience adverse events ranging from local irritation, allergic reactions, phlebitis, end-organ granuloma, tissue ischemia, pulmonary emboli, pulmonary dysfunction, pulmonary infarction, and toxicity.
- Box/Carton NDC 0409-1782-69, Lot 72680LL, Exp 12/01/2018
 - Box/Carton NDC 0409-1782-69, Lot 76510LL, Exp 04/01/2019
- Retailers, hospitals, or any entity with an existing inventory of these lots should stop use of the medication and quarantine it immediately. The occurrence of adverse events or side effects related to the use of these products is encouraged to be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.