PHARMACY NEWS

PASSPORT HEALTH PLAN

SUPPORTING OUR PROVIDER PARTNERS THROUGH COMMUNICATION AND COLLABORATION.

DATE OCTOBER 2018
ISSUE 3

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

Compounds Update

Topical compounded products for adults will now require a prior authorization for coverage determination. This includes but is not limited to the following: topical compounded creams, ointments, emulsions, lotions, gels and solutions. Products for the pediatric population will remain as is. The intent of this change is to address potential fraud, waste, and abuse with compounded drug products, while allowing the pharmacy network to remain unchanged. As a reminder, all topical compounds used for a pain-related diagnosis will continue to be excluded from coverage. These changes were discussed with and deemed clinically appropriate by providers serving Passport's member population.

Controlled Substance Safety Edits

As a reminder, new controlled substance safety edits were approved at the May 2018 Pharmacy and Therapeutics (P&T) Committee meeting. These safety edits, effective **September 25, 2018**, are being made 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.

- Maximum morphine equivalent dose (MED) of 80 per day for chronic opioid users
- Maximum morphine equivalent dose (MED) of 50 per day and maximum 7-day supply for new opioid users

Other new safety policies will go into effect in future months:

- Claims for an extended release opioid formulation without a history of therapy with an immediate release opioid product
- Opioid prescriptions from dentists (and other acute pain specialties) that exceed 3 days of therapy and/or 50 MED per day

DESI Products

Please remember that DESI products are not covered by Passport Health Plan. Drug Efficacy Study Implementation (DESI) is a program that requires all drugs be efficacious, as well as safe. Please consider safer, more effective alternatives to any DESI drugs which may be prescribed. Specific

member and provider letters have been sent to anyone who is prescribed/prescribes one of these medications with recommended formulary alternatives.

Update to Durable Medical Equipment (DME), Intravenous Medications and other Medical Products

Please note that DME- and medical-like products as well as some intravenous medications were removed from the Passport pharmacy formulary. After discussion with the P&T Committee members, it was deemed clinically appropriate that these products should be billed to the member's medical or DME benefit. For coverage of these products under the medical benefit, please contact Passport Medical UM Department at 1-800-578-0636 (phone) or 502-585-7989 (fax). For inquiries regarding DME product coverage, please contact Passport DME department at 800-578-0603 (phone).

New Prior Authorization Additions

Passport Health Plan will require prior authorization review for the following medications, effective **October 15, 2018.**

- Oxycodone ER tablet 15mg, 30mg, 60mg
- EURAX® Cream 10%
- EURAX® Lotion 10%
- Malathion Lotion 0.5%
- Stimate® Solution 1.5 mg/ml
- Colchicine
- Hizentra®
- Terbinafine tablets

Formulary Changes

Please note the following formulary changes that were approved at the August P&T Committee meeting.

PRODUCT	NEW FORMULARY STATUS
Admelog® (insulin lispro)	Tier 2 (preferred) with QL
Korlym® (mifepristone)	Tier 3 (non-preferred) with PA
Xatmep™ (methotrexate oral solution)	Tier 2 (preferred) with PA
Ceramax cream	Non-formulary

Quantity Limit Updates

Quantity limits were updated for the following medications, effective **October 15, 2018.**

PRODUCT	NEW QUANTITY LIMIT
Eucrisa® 2% Ointment	60 gm/60 days
Ingrezza® 40 mg	30 capsules/30 days

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in August 2018

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Aimovig®	erenumab-aooe	Preventive treatment of migraine in adults	Beta-blockers, Anti-epileptics, Anti-depressants, Botox	Non-preferred with PA and QL
Doptelet®	avatrombopag	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	Promacta® Nplate®	Preferred with PA and QL
Jynarque™	tolvaptan	Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	N/A	Preferred with PA and QL
Ilumya™	tildrakizumab-asmn	Treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Humira®, Enbrel®, Remicade®, Tremfya®, Stelara®, Siliq™, Taltz®, Cosentyx®	Non-preferred with PA and QL
Lucemyra™	lofexidine	Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.	Clonidine	Non-preferred with PA and QL
Lokelma™	sodium zirconium cyclosilicate	Treatment of hyperkalemia in adults	Sodium polystyrene sulfonate, Veltassa®	Non-preferred with PA and QL
Tavalisse™	fostamatinib disodium hexahydrate	Treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	Danazol, Rituxan®, Promacta®, Nplate®	Non-preferred with PA and QL
Palynziq™	pegvaliase-pqpz	Reduce blood phenylalanine concentrations in adult patients with concentrations greater than 600 micromol/L on existing management	Kuvan®	Non-preferred with PA 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
Miglustat	Zavesca®	4/24/2018	Tier 1 with PA
Phytonadione	Mephyton tablets	5/15/2018	Tier 1
Colesevelam	Welchol® tablets	5/17/2018	Tier 1 with PA
Methylergonovine	Methergine®	5/25/2018	Tier 1
Hydroxyprogesterone caproate	Makena oil	6/28/2018	Tier 1 with PA
Clindamycin	Clindagel®	7/5/2018	Tier 1
Luliconazole	Luzu® cream	7/5/2018	Tier 1 with PA
Clindamycin-benzoyl peroxide	Acanya® 1.2-2.5%	7/5/2018	Tier 1 with PA
Budesonide	Uceris® 9mg	7/9/2018	Tier 1 with ST
Colesevelam	Welchol® powder	7/9/2018	Tier 1 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:

7/9/2018 **Blister Packs for Several Meds Recalled Due to Risk of Harm to Children**

Novartis and Sandoz have issued a voluntary recall due to products failing to meet child-resistant closure requirements as per the Poison Prevention Packaging Act. This recall affects approximately 470,000 units that include drugs packaged with 3 to 10 tablets per blister card. These blister packs were developed for use in hospitals, however some were sent to retail pharmacies and were likely dispensed for in-home use. At this time, 1 report of a child consuming haloperidol from a blister pack has been received. Consumers in possession of the affected blister cards should keep them out of sight and reach of children. Once the packages are secured, patients should continue to take their medications as directed.

7/10/2018 **Fluoroquinolone Antibiotics: FDA Requires Labeling Changes Due to Low Blood Sugar Levels and Mental Health Side Effects**

The FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects. The new label changes will add that low blood sugar levels can lead to coma and the new label will also make the mental health side effects warning more prominent and more consistent across the systemic fluoroquinolone drug class. Health care professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. Health care 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.

7/19/2018 Valsartan-Containing Products: Update Health Professional and Consumer on Recent Recalled Products

Multiple manufacturers are voluntarily recalling their Valsartan containing products due to possible contamination. The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the API manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. The presence of the potentially cancer-causing NDMA was unexpected, and the agency believes the NDMA is related to changes in the way the active substance was manufactured. Some levels of the impurity may have been in the valsartan-containing products for as long as four years. Recalled manufacturers include:

- Teva Pharmaceuticals USA labeled as Major Pharmaceuticals
- Prinston Pharmaceuticals Inc. Labeled as Solco Healthcare LLC
- Teva Pharmaceuticals labeled as Actavis LLC
- Camber pharmaceuticals, Inc.
- Torrent Pharmaceuticals
- Torrent Pharmaceuticals Limited

Patients should be aware that not all valsartan-containing medications are affected and being recalled and if you have questions, you should ask your pharmacist or health care provider. Health 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.

8/18/2018 Product Quest Manufacturing LLC Recalls All Nasal Products and Baby Oral Gels Manufactured at Florida Facility Due to Possible Microbial Contamination

Product Quest has decided to expand the recall to include all lots of nasal products and baby oral gels currently within expiration that were manufactured at the company's Florida facility. Repetitive use of a nasal spray or other nasal product containing a gram-negative pathogen can potentially lead to colonization and subsequent infection which can be life threatening in certain patient populations, such as those with cystic fibrosis or immune-compromised individuals. Similarly, repetitive use of an oral gel product containing a pathogen can potentially lead to colonization and subsequent infection which can be life threatening in certain patient populations, including babies or very young children. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

8/27/2018 Accord Healthcare Inc. Issues Voluntary nationwide recall of Hydrochlorothiazide Tablets USP 12.5 Mg Due to Labeling Mix-up

Accord Healthcare Inc. is voluntarily recalling one lot of Hydrochlorothiazide Tablets USP, 12.5 mg, to the consumer level. A 100-count bottle of Hydrochlorothiazide Tablets USP 12.5 mg has been found to contain 100 Spironolactone Tablets USP 25 mg. Use of spironolactone instead of hydrochlorothiazide tablets, poses the risk of contracting hyperkalemia in certain individuals resulting in adverse events that range from limited health consequences to life threatening situations in certain individuals.

- NDC: 16729-182-01, Lot PW05264

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

8/27/2018 Pfizer, Inc. Issues a Voluntary Nationwide Recall of One Lot of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle

Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling one lot of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ due to customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described as milliliters (mL). Pfizer concluded that the use of the product with an unmatched dosage cup marked in teaspoons rather than milliliters has a chance of being associated with potential overdose.

- NDC: 0573-0207-30, Lot R51129, Exp: 11/20

Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

8/29/2018 FDA Warns About Rare Occurrences of a Serious Infection of the Genital Area with SGLT2 Inhibitors for Diabetes

The FDA is warning that cases of a rare but serious infection of the genitals/genital area have been reported with sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. Patients should seek medical attention immediately if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum and have a fever above 100.4 F or a general feeling of being unwell. To help FDA track safety issues with medicines, the FDA urges patients and health care professionals to report side effects involving SGLT2 inhibitors or other medicines to the FDA MedWatch program.

8/31/2018 FDA Announces Voluntary Recall of Montelukast Tablets by Camber Pharmaceuticals Due to Incorrect Drug in Bottles

Camber Pharmaceuticals, Inc. has issued a voluntary recall of one lot of Montelukast Sodium Tablets. Sealed bottles labeled as montelukast sodium tablets, 10 milligram, 30-count bottle from Camber were found to instead contain 90 tablets of Losartan Potassium Tablets, 50 mg. This tablet mix-up may pose a safety risk as taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels and low blood pressure.

- NDC: 31722-726-30, Lot MON17384, Exp: 12/31/19

The FDA encourages health care professionals and consumers to report adverse events to the FDA's MedWatch Adverse Event Reporting program.