PHARMACY NEWS

PASSPORT HEALTH PLAN

SUPPORTING OUR PROVIDER PARTNERS THROUGH COMMUNICATION AND COLLABORATION.

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ISSUE 1

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

Hepatitis C Category Update

In an effort to continue aligning with the Department of Medicaid Services criteria, some updates were made to the existing general prior authorization criteria for Hepatitis C medication coverage. Additional criteria with this update include documentation that the patient does not have short life expectancy that would not be remediated through Hepatitis C treatment or liver transplant, that the patient is not pregnant, date of diagnosis, and two HCV laboratory confirmations consistent with CDC guidelines* separated by at least 6 months for patients diagnosed within the past year. Removed from the policy are the criteria requiring evidence of advanced disease and a signed treatment consent form. Modifications to the criteria related to reinfection treatment and substance abuse history were also made. These criteria updates were discussed with and deemed clinically appropriate by providers serving Passport's member population.

Oral Oncology Category Update

In the interest of consistency across all oral products used in the treatment of any type of cancer, a new "Oral Oncology Products" policy was created. This new policy is designed to ensure that a requested oral oncology agent is being prescribed by or in consultation with an oncologist or hematologist for its FDA approved or compendia-supported indication(s), and at its appropriate dosage. The new policy will subject all oral oncology agents to a required prior authorization review. 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. All current policies regarding specific oral oncology products will be retired and replaced by this new, all-encompassing policy. This change was discussed with and deemed clinically appropriate by providers serving Passport's member population.

Over-The-Counter Coverage (OTCs)

Passport Health Plan will be updating coverage of over-the-counter drugs to prefer generic products, unless a covered category has only a brand available. Clinically appropriate quantity limits will also be added to all OTC products.

Topical Corticosteroid Products Quantity Limit Update

All topical corticosteroids will have a quantity limit of 120 grams or 120 milliliters per 30 days. This addition is to promote consistency regarding proper dosing recommendations for dermatologic treatment with topical corticosteroid products. This change was discussed with and deemed clinically appropriate by providers serving Passport's member population.

Testosterone Products Quantity Limit Update

A category review was conducted for quantity limitations on testosterone products. To promote clinically safe and appropriate dosing with these products, the following quantity limitations were implemented.

DRUG NAME	RECOMMENDATION
Androderm® patch (2 mg/24 hr)	30 patches per 30 days
Androderm® patch (4 mg/24 hr)	30 patches per 30 days
Androgel® 1.62% (20.25 mg/1.25 gm)	30 packets per 30 days
Androgel® 1.62% (40.5 mg/2.5 gm)	30 packets per 30 days
Androgel® 1.62% (20.25 mg/act)	1 bottle (75 gm) per 30 days
Axiron® topical solution (30 mg/act)	1 bottle (90 ml) per 30 days
Fortesta® gel 2% (10 mg/act)	1 canister (60 gm) per 30 days
Natesto® nasal gel (5.5 mg/act)	3 tubes per 30 days
Striant® buccal system (30 mg)	60 buccal systems per 30 days

These changes were discussed with and deemed clinically appropriate by providers serving Passport's member population.

Spiriva® Products Quantity Limit Update

Spiriva® products were reviewed to ensure that the quantity limitation for each reflects the recommended dosing as supported by the manufacturer and compendia. The quantity limitation changes are listed below.

DRUG NAME	RECOMMENDATION
Spiriva® Handihaler Inhalation Capsules	1 box (90 count) per 30 days
Spiriva® Respimat	1 inhaler (4 gm) per 30 days

These changes were discussed with and deemed clinically appropriate by providers serving Passport's member population.

New Generics*

BRAND NAME	BRAND NAME	AVAILABLE	FORMULARY STATUS
Carvedilol ER	Coreg CR	11/13/2017	$0 tier with PA
Caspofungin Acetate	Cancidas®	11/14/2017	$0 tier
Timolol Maleate 0.5%	Istalol®	11/28/2017	$0 tier with PA
Tigecycline	Tygacil®	12/5/2017	$0 tier
Sildenafil Citrate	Viagra®	12/13/2017	Do Not Add – Excluded from Coverage
Tenofovir Disoproxil Fumarate	Viread®	12/18/2017	$0 tier with QL
Carbinoxamine	Ryvent™	12/20/2017	$0 tier
Efavirenz	Sustiva®	12/20/2017	$0 tier with QL
Atazanavir Sulfate	Reyataz®	12/28/2017	$0 tier with QL
Estradiol Cream	Estrace®	1/4/2018	$0 tier with PA
Testosterone 1% Gel	Androgel 1%	10/16/2017	$0 tier with QL
Dapsone Gel	Aczone	10/19/2017	$0 tier
Oseltamivir	Tamiflu Suspension	11/3/2017	$0 tier with QL and PA for members > 12

*Generic drugs will have a $0 co-pay. However, 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.

Topical Corticosteroid Products Quantity Limit Update

The following medications will require prior authorization, effective April 23, 2018.

- Duexis®
- Vimovo®
- Buprenorphine patch
- Carbaglu®
- Vpriv®
- Sucraid®
- Zavesca®
- Absorica®
- Tretinoin microspheres
- Clindamycin-benzoyl peroxide gel 1-5%
- Signifor®
- Tolcapone
- Mozobil®
- Promacta®

These policy additions were reviewed by and deemed clinically appropriate by providers serving Passport's member population.

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

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Odactra™	House dust mite allergen extract	Treatment of allergic rhinitis induced by house dust mite allergen	Grastek®, Ragwitek®, Oralair®	Non-preferred with PA and QL
Trelegy Ellipta	fluticasone furoate/ umeclidinium/ vilanterol	Treatment of COPD for patients on a fixed-dose combination of fluticasone furoate and vilanterol desiring additional treatment to improve airflow obstruction and reduce exacerbations, or for patients already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol	Breo Ellipta, Anoro® Ellipta®, Advair® HFA, Advair Diskus®, Stiolto® Respimat® (note that these are not fixed-dose triple combination therapies like Trelegy)	Non-Preferred with PA and QL
Fiasp®	insulin aspart	Improve glycemic control in adults with diabetes mellitus	Humalog® vial/Kwikpen/ cartridge, Apidra® vial/ SoloStar®, Novolog® vial/ FlexPen®/cartridge, Afrezza®	Non-Preferred with ST and QL
Ozempic®	semaglutide	Adjunct to diet and exercise for improving glycemic control in adults with type 2 diabetes	Adlyxin®, Bydureon®, Byetta®, Tanzeum®, Trulicity®, Victoza®	Non-Preferred with ST and QL
Steglatro™, Steglujan™, Segluromet™	ertugliflozin, ertugliflozin/ sitagliptin, ertugliflozin/ metformin	Improve glycemic control in adults with type 2 diabetes mellitus, in addition to diet and exercise	Invokana®, Jardiance®, Farxiga®; Glyxambi®, Qtern®; Invokamet®/XR, Synjardy®/ XR, Xigduo®/XR	Non-Preferred with ST and QL
Calquence®	acalabrutinib	Mantle cell lymphoma (MCL), in previously-treated adult patients	Imbruvica®, Revlimid®	Preferred with PA and QL
Benznidazole	benznidazole	Pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by Trypanosoma cruzi (T. cruzi).	N/A	Preferred with PA and QL
Solosec™	secnidazole	Treatment of bacterial vaginosis in adult women	Metronidazole, Tinidazole	Non-Preferred with PA and QL
Prevymis™	letermovir	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)	N/A	Preferred with PA and QL
Gocovri™	amantadine extended-release	Treatment of dyskinesia in patients with Parkinson disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications	Amantadine immediate release	Non-Preferred with PA and QL

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Endari™	l-glutamine	Prevention of acute complications of sickle cell disease in adults and pediatric patients 5 years of age and older	Hydroxyurea	Non-Preferred with PA and QL
Vyzulta™	latanoprostene bunod	Raised intraocular pressure in open-angle glaucoma or ocular hypertension	Latanoprost, Xalatan®, Lumigan®, Zioptan™, Travatan Z®	Non-Preferred with ST
Sublocade™	buprenorphine extended-release	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days	Buprenorphine, Buprenorphine/ Naloxone, Vivitrol®	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 the CVS Help Desk at 1-888-512-8935 or call Passport Pharamacy Services at 1-844-380-8831.*

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

The FDA recently issued the following advisories:

1/10/2018 Recall: Clopidogrel Bottles May Contain Simvastatin Tablets

International Laboratories announced its voluntary recall of one lot of clopidogrel 75mg tablets in 30-count bottles after a mislabeling error may have caused the intended product to also contain simvastatin 10mg tablets. This error could lead to unintentional missed doses of clopidogrel that could cause an increased risk of heart attack and stroke, and could lead to unintentional doses of simvastatin which could cause adverse events such as myopathy and allergic reactions, as well as fetal harm in pregnant women. The affected lot is listed below.

- NDC# 54458-888-16 Lot 117099A

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.

1/11/2018 FDA: Prescription Opioid Cough/Cold Meds No Longer Indicated for Children

The FDA is now requiring changes to the labeling of prescription cough and cold medicines containing the opioids codeine and hydrocodone that include limiting the use of these agents to adults, as well as the addition of new safety information to the Boxed Warning regarding the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death. The requirement comes after FDA's Pediatric Advisory Committee's evaluation of opioid antitussive use in pediatric patients that deemed the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medications to outweigh the benefits in patients less than 18 years of age. Given this change, the FDA is recommending that alternative treatments for children (i.e., dextromethorphan, prescription benzonatate) be considered when treatment of cough is necessary.

1/19/2018 Magno-Humphries Laboratories, Inc., Issues Voluntary Nationwide Recall of Basic Drugs Brand of Senna Laxative Due to Mislabeling

Magno-Humphries Laboratories, Inc. has voluntarily recalled one of its lots of the Basic Drugs Brand of Senna Laxative tablets after finding that the lot of 8.6mg Sennosides mistakenly contained naproxen instead. Unintentional dosing of the naproxen could lead to potentially fatal adverse events in the event of drug allergy or cardiac, gastrointestinal, hepatic, and renal conditions, as well as patients having recently undergone cardiac bypass graft surgery. Specific adverse events include: myocardial infarction, stroke, congestive heart failure, renal toxicity, bleeding, ulceration, or perforation of the stomach or intestines. High risk populations for adverse events include: children, pregnant women, nursing mothers, and surgical patients. While no adverse events have yet been reported relating to this mislabeling, any that do occur should be immediately reported to a patient's physician or health care provider. The lot of concern is listed below.

- Lot# 352300, Exp: 01/2019

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.

1/29/2018 Kareway Products, Inc. Issues Voluntary Nationwide Recall of Gericare Eye Wash due to Complaints Received on Potential Product Contamination that Compromises Sterility

The FDA announced that Kareway Products, Inc. has voluntarily recalled 60,000 units of its 4 fluid ounce formulation of the Gericare Eye Wash, Sterile Eye Irrigation Solution after potential microbial contamination was found that could compromise product sterility. While the manufacturer has not yet received any reports of adverse events related to the recall, the contamination does increase the risk of potentially sight-threatening eye infection or impairment. The lot of concern is listed below.

- UPC 3-57896-18604-3 Lot 86041601, Exp: 09/2019.

It is recommended that any sale or use of this lot of this product be stopped immediately, and that adverse reactions or quality problems experienced with the use of this product be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

1/30/2018 Imodium® (loperamide) for Over-the-Counter Use: Drug Safety Communication - FDA Limits Packaging to Encourage Safe Use

The FDA is working with manufacturers to use blister packs or other single dose packaging and to limit the number of doses in a package. The FDA has received reports of serious heart problems and deaths due to loperamide doses exceeding the recommended quantity – usually associated with intentional misuse and abuse. The FDA had issued a Drug Safety Communication regarding this safety concern previously in 2016 and added heart problems as a warning to prescription and over-the-counter loperamide products.

Patients should only take the recommended dose of loperamide according to health care professionals or the OTC Drug Facts label. Medical attention should be sought immediately if patients taking loperamide experience fainting, rapid or irregular heartbeat, or unresponsiveness. Health care professionals are advised to be aware of the cardiac effects with exceedingly high doses of loperamide and to counsel patients to take loperamide only as prescribed or in accordance with the OTC Drug Facts label. Adverse events and side effects related to loperamide use should be reported by health care professionals to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

2/13/2018 Acyclovir 400mg Tablets by Apace Packaging: Recall - Product Mix-up

The FDA announced that Apace Packaging LLC has voluntarily recalled one lot of acyclovir tablets. This lot, intended to contain acyclovir 400mg tablets in a 50 tablet blister card, may contain torsemide 20mg tablets. This potential dosing mix-up could cause viral reactivation from the missed dose of acyclovir or excessive urination from the unintentional torsemide dose, or both. Other serious adverse events that cannot be ruled out from a potential unintentional error in medication taken include: atrial fibrillation, chest pain, diarrhea, digitalis intoxication, gastrointestinal hemorrhage, hyperglycemia, hyperuricemia, hypokalemia, hypotension, hypovolemia, shunt thrombosis, rash, rectal bleeding, syncope, and ventricular tachycardia. The affected lot of the acyclovir is listed below.

- NDC # 50268-061-15 Lot 19900, 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.