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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 Advantage
BIN: 004336
PCN: MEDDAVDV

HELPFUL NUMBERS FOR MEMBERS

Passport Health Plan
1-800-578-0603

WEBSITE

www.passporthealthplan.com

NEW IN THIS ISSUE

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- Opioid Overdose Prevention Coverage
- 2016-2017 Flu Vaccine Coverage
- Preferred Drug List Changes
- New Universal PA forms
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Concurrent Opioid-Benzodiazepine Safety Edit

Background

Passport Health Plan (Passport) implemented several safety edits to ensure the appropriate utilization of controlled substances, including concurrent use of benzodiazepines (BZD) and opioids. The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain states that “clinicians should avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.” Studies have shown that concurrent use of BZD and opioids have contributed to the overdose epidemic – in 2011 there were 16,917 opioid overdose deaths, and 31% were related to concurrent BZD use. Concomitant therapy with BZDs and opioids have demonstrated increased risk of respiratory depression and death, and prescribers should incorporate management plans to mitigate the risk if co-prescribing BZD and opioids is medically necessary. It is important to find alternate treatment options and minimize BZD use while on opioids.

Action Plan

- Clinicians should always **check KASPER** before prescribing an opioid or a BZD.
- If the patient is receiving BZD for **anxiety**, prescriber should consider discontinuing BZD with slow tapering. Alternatives such as **evidence-based cognitive behavioral therapy** and/or treatment with an **SSRI** to manage anxiety should be considered when appropriate.
- If the patient is receiving BZD for **muscle spasms**, prescriber should consider discontinuing BZD with slow tapering. Alternative muscle relaxers on Passport formulary, such as **cyclobenzaprine**, **baclofen**, etc. may be offered. **Carisoprodol should not be used as an alternative.**
- Prescribers should consider prescribing **naloxone** to patients who use a BZD concurrently with opioids. Products Passport currently covers are listed in the table below.
- CDC recommends to **taper opioids first** and then taper BZD; however, the prescriber’s clinical judgment should determine the tapering schedule.
- If prescribers encounter claim rejections regarding these safety edits while the patient is on a tapering plan, please **call CVS at 1-800-380-8831 to complete a PA with tapering plans or medical necessity for concurrent use.**

Concurrent Opioid-Benzodiazepine Safety Edit

Passport Health Plan covers the following naloxone products. Quantity limits and prior authorization requirements may apply.

Product	Coverage Limits	Cost
Naloxone 1mg/mL injection solution for intranasal use	Preferred with QL of 8mL (4 doses) per 30 days	\$
Nasal atomizer for use with naloxone syringe	Preferred	\$
Narcan 4mg/0.1mL nasal spray,	Preferred with QL of 2 boxes (4 sprays) per 30 days	\$\$
Evzio 0.4 mg/0.4 mL auto-injector	Non-preferred PA required with QL of 0.8 ML (two doses) per 180 day(s)	\$\$\$\$
Evzio 2 mg/0.4 mL auto-injector	Excluded from coverage; use preferred products	\$\$\$\$

2016-2017 Flu Vaccine Coverage

Passport Health Plan will reimburse pharmacies for administration of the injectable* seasonal influenza vaccines for all members age 19 and above. Flu vaccines are provided for children age 18 or under through the Vaccines for Children (VFC) Program. Pharmacy may not administer or bill for children's flu vaccines. For more information regarding the VFC program, please visit the Centers for Disease Control and Prevention (CDC) website at www.cdc.gov/vaccines/programs/vfc/index.html.

REFERRALS

Pharmacies not administering the flu vaccine should refer Passport members to their provider or local health department for the flu vaccine. The CDC's vaccine recommendations for the 2016-2017 flu season are at www.cdc.gov/flu/about/season.

CONTACT US

For questions or assistance with flu-related claims, please call the CVS Help Desk at 1-888-512-8935.

**FluMist (Live attenuated influenza vaccine) is NOT recommended for use during the 2016-2017 season because concerns of its effectiveness*

Preferred Drug List Changes

Coming soon Passport will be updating the preferred drug list as well as the searchable drug formulary tool to now only include the preferred products. We hope this change makes it easier for our members and providers to understand which products are available with the least restrictions and offer the best value for our members.

New Universal Pharmacy Prior Authorization (PA) forms

Beginning February 1, 2017, Passport will make available the Kentucky Medicaid Universal Pharmacy Prior Authorization Forms. These forms will be posted on the pharmacy page of the Passport web site and available for providers to use for pharmacy PA requests. For select drugs, you may also find an addendum that will include additional information (i.e., lab results, patient consents, etc.) to provide when submitting the universal PA forms.

To assist providers with providing the most complete information needed to review PA requests, we also have many drug specific PA forms on our website at <http://passporthealthplan.com/pharmacy/prior-authorizations/>. These forms are categorized by therapeutic category and specialty or non-specialty drug status.

New Generics

BRAND NAME	GENERIC NAME	BRAND NAME	GENERIC NAME
8-MOP	Methoxsalen	Mirapex®	Pramipexole ER
Armour® Thyroid	NP thyroid 15 mg	Nilandron	Nilutamide
Azor®	Amlodipine and olmesartan	Nitrostat®	Nitroglycerin
Benicar®	Olmesartan	Nuvigil	Armodafanil
Benicar HCT®	Olmesartan and hydrochlorothiazide	Seroquel XR®	Quetiapine fumarate ER
Beyaz®	Drospirinone, ethinyl estradiol and levomefolate	Tikosyn®	Dofetilide
Crestor®	Rosuvastatin	Treximet®	Sumatriptan and naproxen
Edecrin	Ethacrynic Acid	Tribenzor®	Olmesartan, amlodipine and hydrochlorothiazide
Epzicom	Abacavir and lamivudine	Vagifem®	Yuvaferm
Eryped	Erythromycin ethylsuccinate 200 mg/5 ml	Valcyte® (solution)	Valganciclovir (solution)
Fenoglide® 120mg	Fenofibrate 120mg	Zemlar® (solution)	Paricalcitol (solution)
Glyset®	Miglitol	Ziana® (gel)	Clindamycin and Tretinoin (gel)

**Generic drugs will have a \$0 co-pay. However, some generic drugs may still have prior authorization or step therapy requirements, and may be subject to certain quantity limits. For details, please refer to the drug formulary on Passport 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:

- 06/14/16** **FDA strengthens kidney warnings for diabetes medicines canagliflozin (Invokana®, Invokamet®) and dapagliflozin (Farxiga®, Xigduo® XR).** FDA has strengthened their warnings of the risk of acute kidney injury for canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR). FDA encouraged health care professionals to assess patients’ kidney functions prior to initiating canagliflozin or dapagliflozin treatment. The kidney functions should also be monitored during the treatment.
- 07/26/16** **FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects.** FDA has issued label changes by adding a Boxed Warning and required education materials to be provided with systematic fluoroquinolone antibiotics due to severe permanent side effects of the tendons, muscles, joints, nerves, and central nervous. In addition, due to the potential risks outweighing the benefits, the FDA does not recommend the use of systematic fluoroquinolones for treating acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections. FDA recommended using alternative therapy options for the above indications. Health care professionals should evaluate risks and benefits for other serious infections.
- 08/31/16** **FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.** Due to the growing combined use

of opioids with benzodiazepines (BZD) or other central nervous system (CNS) depressants, FDA added Boxed Warnings regarding serious, and potential lethal, CNS side effects. FDA recommended health care professionals to limit prescribing opioids with BZD or other CNS depressants only to patients for whom alternative treatment options are inadequate. Health care professionals should use clinical judgment to minimize or limit the doses opioids and BZD when concomitant use cannot be avoided. Patients should be counseled on the potential risks of respiratory depression when more than one CNS depressants, including alcohol, were used concurrently.

- 10/04/16** **FDA warns about the risk of hepatitis B reactivating in some patients treated with direct-acting antivirals for hepatitis C.** FDA added Boxed Warnings about the risk of hepatitis B virus (HBV) reactivation in patients receiving direct-acting antiviral (DAA) treatment for hepatitis C. FDA recommends health care professionals to screen all patients for evidence of current or prior HBV infection before initiating DAA treatment, and monitor HBV flare-ups by blood tests during and post-treatment.
- 12/12/16** **Updated FDA review concludes that use of type 2 diabetes medicine pioglitazone may be linked to an increased risk of bladder cancer.** FDA has previously issued warnings regarding potential risk of bladder cancer to pioglitazone-containing medicines (Actos®, Actoplus Met®, Actoplus Met® XR, Duetact®, Oseni) in 2011. As the result of the updated review on additional studies, FDA approved label updates and warned all health care professionals not to use pioglitazone in patients with active bladder cancer. The risk and benefits of using pioglitazone in patients with a history of bladder cancer should be carefully evaluated.
- 12/14/16** **FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women.** FDA warned that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. However, anesthetic and sedation are necessary for infants, children, and pregnant women who require surgery or other painful and stressful procedures. Health care professionals should balance the benefits of appropriate anesthesia against the potential risks, especially for procedures that may last longer than 3 hours or if multiple procedures are required.
- 12/16/16** **FDA revises description of mental health side effects of the stop-smoking medicines Chantix® (varenicline) and Zyban® (bupropion) to reflect clinical trial findings.** Based on the review of a clinical trial, FDA determined the risk of serious side effects on mood, behavior, or thinking with smoking cessation medicines is lower than previously suspected. The results of the trial confirm that the benefits of stopping smoking outweigh the risks. Therefore, FDA removed the Boxed Warning for serious mental health side effects from Chantix and Zyban drug label. The patient medication guide will continue to be provided with every dispensed prescription, but the risk evaluation and mitigation strategy (REMS) program requirement will be removed. However, FDA warned that the risk of serious mental health side effects is still present, especially in those currently being treated for mental illness, such as depression, anxiety, or schizophrenia. Health care professionals should counsel patients about the benefits of smoking cessation, and should discuss the risks and benefits of using smoking cessation medicines to help them quit smoking.

Please visit www.fda.gov/opa/com/7alerts.html for more information.

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in August and November 2016*

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Adlyxin™ Trulicity® Victoza®	Lixisenatide Dulaglutide Liraglutide	Type 2 diabetes	Victoza, Trulicity	Adlyxin: Non-Preferred, PA Trulicity, Victoza: Preferred, ST (metformin)
Alecensa®	Alectinib	Anaplastic lymphomakinase (ALK) positive, metastatic non-small cell lung cancer	Xalkori®, Zykadia®	Preferred, PA QL 8/day
Basaglar®	Insulin Glargine	Type 1 and type 2 diabetes	Lantus®, Levemir®	Preferred, QL 45mL/month
Bevespi	Glycopyrrolate and formoterol	Chronic obstructive pulmonary disease (COPD)	Stiolto™ Respimat®, various COPD medications	Non-Preferred, ST (2 preferred agent)
Briviact®	Brivaracetam	Partial onset seizure	Various generic anticonvulsants	Non-Preferred, PA, QL 10mg tablets: 60/lifetime, oral solution: 600/month, all other tablet strengths: 60/month
Cabometyx™	Cabozantinib	Advanced renal cell carcinoma (RCC)	Cometriq®, Inlyta®, Sutent®, Votrient®, Nexavar®	Non-Preferred, PA, QL 1/day
Cotellic®	Cobimetinib	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	Mekinist®	Non-Preferred, PA, QL 63/month
Descovy®	Emtricitabine and tenofovir alafenamide	HIV	Various antiretroviral drugs	Preferred, QL 1/day
Epclusa®	Sofosbuvir and velpatasvir	Hepatitis C	Harvoni®, Zepatier™	Preferred, PA, QL 1/day
Inflectra®	Infliximab-dyyb	Crohn's disease, Ulcerative colitis, Rheumatoid arthritis, Ankylosing spondylitis, Psoriatic arthritis, and Plaque psoriasis	Remicade®, Humira®, Enbrel®	Preferred, PA
Neupogen® Zarxio®	Filgrastim	Neutropenia	Leukine®, Neulasta® syringes	Neupogen: Non-Preferred, PA Zarxio: Preferred, PA
Nuplazid™	Pimavanserin	Multiple myeloma	Kyprolis®	Preferred, PA, QL 3/28 days
Ocaliva™	Obeticholic acid	Hallucinations and delusions associated with Parkinson disease psychosis	Various generic antipsychotics	Non-Preferred, PA, QL 60/month
Royaldee®	Calcifediol	Primary biliary cholangitis (PBC)	Ursodiol	Non-Preferred, PA QL 1/day

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Symbicort®	Budesonide and formoterol	Asthma and COPD	Breo® Ellipta®, Dulera®	Non-Preferred, ST (2 preferred agents for asthma, 1 preferred agent for COPD)
Tagrisso™	Osimertinib	Metastatic epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer	Tarceva®, Iressa®, Gilotrif®	Non-Preferred, PA, QL 1/day
Venclexta™	Venetoclax	Chronic lymphocytic leukemia (CLL) in patients with 17p deletion	Imbruvica®, Zydelig®	Non-Preferred, PA, QL Starter pak: 1/lifetime 10mg: 60/month 50mg: 30/month 100mg: 120/month
Vraylar™	Caripazine	Schizophrenia and bipolar I disorder	Various generic antipsychotics	Non-Preferred, ST (2 preferred agents), QL 1/day
Xiidra®	Lifitegrast	Chronic dry eyes	Artificial teras, Restasis®	Non-Preferred, PA, QL 60/month
Xuriden™	Uridine triacetate	Hereditary orotic aciduria	N/A	Non-preferred, PA
Zurampic®	Lesinurad	Hyperuricemia associated with gout	Probenecid, Allopurinol, Febuxostat	Non-Preferred, ST, QL 1/day

**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.*