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**HELPFUL NUMBERS
FOR PROVIDERS**

Magellan: 1-800-846-7971
Bin: 016523
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**HELPFUL NUMBERS
FOR MEMBERS**

Passport Health Plan
1-800-578-0603

WEBSITE

www.passporthealthplan.com

NEW IN THIS ISSUE

- Prior-Authorization for Compounded Products
- Reminder: 90-Day Supply at Retail Pharmacy
- MTM Champion Spotlight
- Recent FDA Advisories
- P & T Committee Review

Prior-Authorization for Compounded Products

Passport Health Plan will soon implement a prior-authorization for compounded products. Our goal is to ensure compounded medications are being used for FDA approved indications and/or indications supported in medical literature. Topical compounds containing ingredients such as ketamine, baclofen, and gabapentin will no longer be covered due to lack of FDA approved indication or strong clinical evidence to support topical use. In addition, the prior-authorization for compounded products will help ensure that similar products are not commercially available and that the requested ingredients have not been withdrawn from the market due to safety reasons. For assistance with the prior-authorization process, please call the Magellan Help Desk at 1-800-846-7971.

Reminder: 90-Day Supply at Retail Pharmacy

Some generic medications used in chronic conditions require a 90-day supply to be dispensed. Our goal is to improve adherence and in turn improve overall health and quality of life of our members. If a patient receives a drug on the *90-Day Supply at Retail Medication List* for 90 or more days in the previous 180 days, the medication must be dispensed for a 90-day supply. If the prescriber or pharmacy deems a 90-day supply inappropriate for a patient, please call the Magellan Help Desk at 1-800-846-7971. For the complete *90-Day Supply at Retail Medication List* please visit <http://passporthealthplan.com/pharmacy/#resources>.

All medications may be subject to edits to limit quantities dispensed, day's supply, and drug-drug interactions at the point of service. Pharmacy and Therapeutic Committee decisions are based upon relevant medical literature that is evidence based and peer reviewed. Price(s) listed are calculated based on Wholesale Acquisition Cost (WAC) published by First Data Bank. The cost of therapy is calculated based on a 30 days' supply unless otherwise indicated. This information is to be used as a reference and/or a learning tool for providers.

MTM Champion Spotlight



Pharmacist Prevents Hospital Admission

Anthony Oswald, Walmart Pharmacy– Carrollton, KY

A TIP alerted Anthony that a patient with diabetes was not prescribed a medication, recommended by current guidelines, to help lower their cholesterol. Patients with diabetes are at an increased risk of experiencing heart events such as heart attack and stroke. Anthony reached out to the patient and learned the patient had previously taken a cholesterol-lowering therapy but thought they were taken off of the medication. Anthony consulted with the prescriber who was unaware the patient had stopped taking the medication. Anthony recommended reinitiating the cholesterol lowering therapy and the prescriber agreed. The cholesterol medication was filled and the patient was educated on the importance of taking the medication each day to receive the most benefit.

Thanks to Anthony's intervention, a hospital admission was prevented. Great work, Anthony!

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

The FDA recently issued the following advisories:

- 04/08/16** **FDA Revises Warnings Regarding Use of Metformin in Certain Patients with Reduced Kidney Function.** The FDA is requiring labeling changes regarding the recommendations for metformin use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients with impaired kidney function. From the review of studies published in the medical literature, the FDA has concluded that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function. The FDA is requiring changes to the metformin labeling to reflect this new information and provide specific recommendations on the drug's use in patients with mild to moderate kidney impairment.
- 04/26/16** **FDA to Review Study Examining Use of Oral Fluconazole in Pregnancy.** The FDA is evaluating the results of a Danish study¹ that conclude there is a possible increased risk of miscarriage with the use of oral fluconazole for yeast infections. The FDA is also reviewing other data and will communicate its final conclusions and recommendations when the review is concluded. The FDA recommends that health care professionals be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections. Until the review is complete, the FDA is advising cautious prescribing of oral fluconazole in pregnancy.
- 1. Molgaard-Nielsen, Ditte, Henrik Svanström, Mads Melbye, Anders Hviid, and Björn Pasternak. "Association Between Use of Oral Fluconazole During Pregnancy and Risk of Spontaneous Abortion and Stillbirth." *Jama* 315.1 (2016): 58*
- 05/02/16** **FDA Approves Brand Name Change for Antidepressant Drug Brintellix® (vortioxetine) to Avoid Confusion with Antiplatelet Drug Brilinta® (ticagrelor).** The new brand name of vortioxetine will be Trintellix®, and it is expected to be available starting in June 2016. No other changes will be made to the label or packaging.
- 05/03/16** **FDA Warns About New Impulse-Control Problems Associated with Aripiprazole.** The FDA is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of aripiprazole. These uncontrollable urges

were reported to have stopped when the drug was discontinued or the dose was reduced. These adverse effects are rare, but they may result in harm to the patient and others if not recognized. The FDA recommends that health care professionals educate patients of the risk of these uncontrollable urges and specifically ask patients about any new or increasing urges while they are being treated with aripiprazole. The FDA recommends monitoring for new or worsening uncontrollable urges and to consider reducing the dose or stopping the medicine if such urges develop.

- 05/10/16** **FDA Warns About Rare but Serious Skin Reactions with Olanzapine.** The FDA is warning that olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. The FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). The FDA recommends that health care professionals immediately discontinue olanzapine if DRESS is suspected. It is also recommended to educate patients on the signs and symptoms of severe skin reactions and when to seek immediate medical care.
- 05/12/16** **FDA Advises Restricting Fluoroquinolone Antibiotic Use for Certain Uncomplicated Infections.** The FDA is advising that the serious side effects (involving the tendons, muscles, joints, nerves, and central nervous system) associated with fluoroquinolones generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. The FDA is requiring the drug labels and Medication Guides for all fluoroquinolones to be updated to reflect this new safety information.
- 05/19/16** **FDA Warns that Prescribing of Nizoral® (Ketoconazole) Oral Tablets for Unapproved Uses Including Skin and Nail Infections Continues.** The FDA is warning health care professionals to avoid prescribing ketoconazole oral tablets to treat skin and nail fungal infections due to risk of serious liver damage, adrenal gland problems, and harmful interactions with other medicines. The FDA approved label changes for oral ketoconazole tablets in 2013 to reflect these serious risks and to remove the indication for treatment of skin and nail fungal infections.
- 06/02/16** **FDA Evaluating the Risk of Burns and Scars with Zecuity® (Sumatriptan) Patch.** The FDA is investigating the risk of serious burns and potential permanent scarring with the use of Zecuity® (sumatriptan iontophoretic transdermal system) patch for migraine headaches and will update the public with new information when the review is complete. The FDA recommends health care professionals advise patients who report moderate to severe pain at the application site to remove the Zecuity® patch immediately and to consider a different formulation or alternative migraine medicine.
- 06/06/16** **FDA Warns About Serious Bleeding Risk with Over-The-Counter Antacid Products Containing Aspirin.** These widely used products already contain warnings about the risk of bleeding on their labels; however, the FDA continues to receive reports of this serious safety issue. The FDA will continue to evaluate this safety concern and plans to assemble an advisory committee of external experts to provide input regarding whether additional FDA actions are required.
- 06/07/16** **FDA Warns About Serious Heart Problems with High Doses of Loperamide.** The FDA is warning that taking higher than recommended doses of loperamide (Imodium®) can cause serious heart problems that can lead to death. The risk of these cardiac issues, including

abnormal heart rhythms, may also be increased when high doses of loperamide are taken with interacting medicines. The bulk of reported cases occurred in patients who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria. The FDA will continue to evaluate this safety issue and will determine if additional actions are required.

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

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in May 2016:

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Advair® Diskus®	Fluticasone/salmeterol	Asthma, chronic obstructive pulmonary disease (COPD)	Breo® Ellipta®, Dulera®, Symbicort®	Ages 4-11 years (if controlled, may continue ≥ age 12): preferred New starts ≥ 12 years: nonpreferred
Aerospan® Qvar®	Flunisolide, beclomethasone dipropionate	Asthma	Arnuity® Ellipta®, budesonide, Pulmicort Flexhaler®	Aerospan®: preferred Qvar®: nonpreferred
Asmanex®	Mometasone furoate	Asthma	Arnuity® Ellipta®, budesonide, Pulmicort Flexhaler®	Preferred
Byetta® Bydureon® Tanzeum®	Exenatide, exenatide, albiglutide	Type 2 diabetes	Various oral and injectable anti-diabetic agents	Byetta® and Bydureon®: nonpreferred Tanzeum®: preferred with step therapy: trial and failure of metformin, sulfonyleurea, or DPP4-inhibitor
Daklinza™	Daclatasvir	Chronic hepatitis C genotypes 1 or 3	Harvoni®, Sovaldi®	Nonpreferred; PA; QL of 1/day; maximum treatment duration of 12 weeks
Durlaza® ER	Aspirin	Reduce the risk of death and myocardial infarction	Aspirin-dipyridamole, cilostazol, clopidogrel, dipyridamole, Brilinta®, Effient®, Zontivity®	Nonpreferred; PA; QL 1/day
Dyanavel™ XR	Amphetamine sulfate ER	Attention deficit/hyperactivity disorder (ADHD)	Dextroamphetamine sulfate oral solution	Nonpreferred; PA; QL 24mL/day

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Enstilar®	Calcipotriene/ betamethasone	Plaque psoriasis	Calcipotriene, calcipotriene/ betamethasone, calcitrene, calcitriol topical preparations	Nonpreferred; PA
Envarsus™ XR	Tacrolimus ER	Prophylaxis of organ rejection in kidney transplant recipients	Azothioprine, mycophenolate mofetil, cyclosporine, tacrolimus IR, Azasan®, sirolimus, Rapamune®, Cellcept®, Zortress®	Nonpreferred; PA
Fortamet® Glumetza®	Metformin ER	Type 2 Diabetes	Metformin ER (generic Glucophage XR; generic Fortamet 1000 mg)	Glumetza (brand & generic non- preferred). Fortamet brand and generic 500 mg non preferred; Keep generic 1000 mg Fortamet as preferred.
Genvoya®	Elvitegravir/ cobicistat / emtricitabine/ tenofovir alafenamide	HIV	Various antiretrovirals	Preferred
Invokana®, Invokamet®, Jardiance®	Canagliflozin, canagliflozin/metformin, empagliflozin	Type 2 diabetes	Various oral and injectable anti-diabetic agents	Preferred with step therapy: trial and failure of metformin
Mybetriq®, Vesicare®	Mirabegron, solifenacin	Overactive bladder	Oxybutynin, tolterodine, trospium	Preferred with step therapy: trial and failure of generic alternative
Narcan™ nasal spray	Naloxone HCl	Emergency treatment of known or suspected opioid overdose	Naloxone injection	Preferred; QL 2 packs/ fill
Odefsey®	Emtricitabine /rilpivirine / tenofovir alafenamide	HIV	Various antiretrovirals	Preferred
Prestalia®	Perindopril/ amlodipine	Hypertension	Various anti-hypertensive agents	Nonpreferred; PA
QuilliChew™ ER	Methylphenidate HCl	Attention deficit/hyperactivity disorder (ADHD)	Dextroamphetamine/ amphetamine ER, methylphenidate CD, dextroamphetamine ER	Nonpreferred; PA; QL 1/day
Strensiq®	Asfotase alfa	Perinatal/infantile and juvenile onset hypophosphatasia (HPP)	None	Nonpreferred; PA; QL 6mg/kg/week

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Synjardy®	Empagliflozin/ metformin	Type 2 diabetes	Various oral and injectable anti-diabetic agents	Nonpreferred; PA
Tresiba®	Insulin degludec	Type 1 or 2 diabetes	Lantus®, Levemir®	Nonpreferred; PA
Uptravi®	Selexipag	Pulmonary arterial hypertension (PAH)	Adcirca®, Letairis®, Tracleer®, Tyvaso®, sildenafil	Nonpreferred; PA
Veltassa®	Patiomer	Hyperkalemia	Kayexalate®, sodium polystyrene sulfate (SPS)	Nonpreferred; PA; QL 30 packets/month
Zarxio®	Filgrastim-sndz	Decrease the incidence of infection in patients with nonmyeloid malignancies; reduce the duration of neutropenia and neutropenia-related events in patients with nonmyeloid malignancies; mobilization of autologous hematopoietic progenitor cells; reduce the incidence and duration of neutropenic complications	Neulasta®, Neupogen®, Leukine® (covered under medical benefit)	Nonpreferred; PA
Zepatier™	Grazoprevir/ elbasvir	Chronic hepatitis C genotypes 1 or 4	Harvoni®	Preferred (requires medical exception for why Harvoni® cannot be used); QL 1/day

Step Therapy Updates

Proton-Pump Inhibitor (PPI) Step Therapy:

- Step 1 (preferred): omeprazole, pantoprazole
- Step 2 (preferred with trial and failure of step 1): lansoprazole, rabeprazole, omeprazole/sodium bicarbonate
- Step 3 (nonpreferred with trial and failure of step 1 and step 2): esomeprazole magnesium, branded prescription products

COX-2 Inhibitor Step Therapy:

- Step 1 (preferred): generic NSAIDs
- Step 2 (preferred with trial and failure or contraindication to step 1): celecoxib
- Step 3 (nonpreferred with trial and failure or contraindication to step 1 and step 2): Celebrex®

**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 Magellan Help Desk at 1-800-846-7971.*