

**DATE** SEPTEMBER 2014  
**ISSUE** 2

**HELPFUL NUMBERS FOR PROVIDERS**

Passport Health Plan  
PerformRx: 800-578-0898  
Bin: 600428  
Processor control: 02920000

**HELPFUL NUMBERS FOR MEMBERS**

Passport Health Plan  
800-578-0603

**WEBSITE**

[www.passporthealthplan.com](http://www.passporthealthplan.com)

**NEW IN THIS ISSUE**

- Formulary Updates
- Pharmacy Tips & Reminders
- Recent FDA Advisories
- P&T Committee Review

## Formulary Updates

Top Preferred Drug List Changes: Drugs previously preferred that are now non-preferred.

NON PDL TRADE NAME	PDL ALTERNATIVES
FOCALIN XR	GENERIC AVAILABLE FOR 15MG, 30MG, 40MG, DEXMETHYLPHENIDATE HCL IR
ADVAIR DISKUS	DULERA, SYMBICORT
NASONEX	FLUNISOLIDE, FLUTICASONE PROPIONATE, TRIAMCINOLONE ACETONIDE
INTUNIV	GUANFACINE HCL (GENERIC AVAILABLE FOR 1MG, 2MG)
FLOVENT HFA	BUDESONIDE, PULMICORT, PULMICORT FLEXHALER, QVAR
SUPRAX	CEFDINIR, CEFDITOREN PIVOXIL, CEFTIBUTEN
PREMARIN	ESTRADIOL, MENEST, ESTROPIPATE
ASMANEX	BUDESONIDE, PULMICORT, PULMICORT FLEXHALER, QVAR
CARISOPRODOL	CYCLOBENZAPRINE HCL, BACLOFEN, METHOCARBAMOL
DETROL LA	GENERIC AVAILABLE
ADVAIR HFA	DULERA, SYMBICORT
NUVARING	GENERIC ORAL CONTRACEPTIVES: NORGESTIMATE-ETHINYL ESTRADIOL
APIDRA SOLOSTAR	HUMALOG
DENAVIR	ACYCLOVIR OINTMENT, ZOVIRAX
LATUDA	OLANZAPINE, OLANZAPINE ODT, OLANZAPINE-FLUOXETINE HCL, SEROQUEL XR, QUETIAPINE FUMARATE
ELIDEL	PROTOPIC
APIDRA	HUMALOG
SAPHRIS	OLANZAPINE, OLANZAPINE ODT, OLANZAPINE-FLUOXETINE HCL, SEROQUEL XR, QUETIAPINE FUMARATE
XOPENEX HFA	VENTOLIN HFA, FORADIL
AMITIZA	GENERIC LAXATIVES, RELISTOR,
ENABLEX	TOLTERODINE TARTRATE ER, TOLTERODINE TARTRATE, OXYBUTYNIN CL ER, OXYBUTYNIN,
PROCTOFOAM-HC	PRAMOXINE HCL PLUS HYDROCORTISONE
INVEGA SUSTENNA	ABILIFY VIAL, ABILIFY MAINTENA, OLANZAPINE, RISPERDAL CONSTA

*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.*

NON PDL TRADE NAME	PDL ALTERNATIVES
HUMATROPE	TEV-TROPIN*
ASTEPRO	AZELASTINE HCL
DALIRESP	BETA-2 AGONISTS, ANTICHOLINERGIC, METHYLXANTHINES, INHALED CORTICOSTEROIDS, COMBINATION BETA2-AGONISTS/ANTICHOLINERGIC, COMBINATION BETA2-AGONISTS/CORTICOSTEROIDS
VOLTAREN 1% TOPICAL GEL	IBUPROFEN, MELOXICAM, NAPROXEN, DICLOFENAC SODIUM 3 % TOPICAL GEL
TOBRADEX 0.3 %-0.1% OPHTHALMIC OINTMENT	TOBRAMYCIN-DEXAMETHASONE 0.3 %-0.1% OPHTHALMIC SUSPENSION
VIVELLE- DOT	ESTRADIOL (TRANSDERMAL)
VYTORIN	SIMVASTATIN PLUS ZETIA (PA required unless history of treatment with Vytorin)
AVELOX	CIPROFLOXACIN, CIPROFLOXACIN ER, OFLOXACIN
PATADAY	EPINASTINE HCL, AZELASTINE HCL
VERAMYST	FLUNISOLIDE, FLUTICASONE PROPIONATE, TRIAMCINOLONE ACETONIDE
ESTRACE (Cream)	VAGIFEM
CLEOCIN PHOSPHATE (VAGINAL CREAM)	CLINDAMYCIN PHOSPHATE (VAGINAL CREAM)
FLOVENT DISKUS	PULMICORT FLEXHALER, QVAR,
SINGULAIR	MONTELUKAST SODIUM
NOVOLOG	HUMALOG
PEG-INTRON REDIPEN	PEGASYS, PEGASYS PROCLICK
BILTRICIDE	ALBENZA, STROMECTOL, PIN-X, REESE PINWORM
NOVOLOG FLEXPEN	HUMALOG
MEPERIDINE HCL	HYDROCODONE/ACETAMINOPHEN, MORPHINE SULFATE, OXYCODONE
SEREVENT DISKUS	FORADIL,PERFOROMIST
CORTISPORIN-TC	NEOMYCIN/POLYMYXIN B SULF/HC,CORTOMYCIN
ARANESP	PROCRIT
LAMICTAL	LAMOTRIGINE
KOMBIGLYZE XR	JENTADUETO, JANUMET, JANUMET XR

\* *Tev-tropin, our preferred agent for growth hormone deficiency, is currently on manufacturer back order. While this product is on back order, the preferred agent is Norditropin.*

For additional drug formulary changes, please visit [www.passporthealthplan.com/pharmacy/formulary/index.aspx](http://www.passporthealthplan.com/pharmacy/formulary/index.aspx).

## Pharmacy Tips and Reminders

### Important Information on Using Web PA

#### How to submit Prior Authorization Requests Online

In addition to phone and fax submissions, prescribers may submit prior authorizations, as well as determine if a drug requires PA, through an online web portal application called Pharmacy Web Prior Authorization (Web PA). To access Web PA, prescribers and their staff will need to register with the User Administration Console (UAC) located in the Magellan pharmacy portal at [www.passporthealthplan.com/pharmacy](http://www.passporthealthplan.com/pharmacy).

If you have any questions regarding the copay or formulary status of a drug please call Magellan Pharmacy at the number listed below.

Health Plan	Bin	PCN	State	Pharmacy Help Desk #
Passport	016523	747	KY	(800) 846-7971

To view the Passport Health Plan drug formulary, visit [www.passporthealthplan.com/pharmacy/formulary/index.aspx](http://www.passporthealthplan.com/pharmacy/formulary/index.aspx).

## Recent Federal Drug Administration (FDA) Advisories Affecting Network Pharmacies and Providers

### The FDA recently issued the following advisories:

- 6/26/14**      **FDA recommends not using lidocaine to treat teething pain and requires a new Boxed Warning:** The FDA warns that prescription oral viscous lidocaine two percent solution should not be used to treat infants and children with teething pain. A new Boxed Warning, the FDA's strongest warning, will be added to the drug label to emphasize this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death.
- 6/25/14**      **FDA warns of rare but serious hypersensitivity reactions with certain over-the-counter topical acne products:** The FDA is warning that certain over-the-counter (OTC) topical acne products can cause rare but serious and potentially life-threatening allergic reactions or severe irritation. Consumers should discontinue their topical acne product and seek emergency medical attention immediately if hypersensitivity reactions are experienced, such as throat tightness; difficulty breathing; feeling faint; or swelling of the eyes, face, lips, or tongue. Product should also be discontinued if consumers develop hives or itching.
- 6/24/14**      **FDA review of cardiovascular risks for diabetics taking hypertension drug olmesartan not conclusive; label updates required:** The FDA has completed its safety review and has found no clear evidence of increased cardiovascular risks associated with use of the blood pressure medication olmesartan in diabetic patients. Recommendations for use of olmesartan (Benicar, Benicar HCT, Azor, Tribenzor, and generics) remain the same, but information about some of the studies is required to be included in the drug labels.
- 6/20/14**      **FDA warns that cancer drug docetaxel may cause symptoms of alcohol intoxication after treatment:** The FDA is warning that the intravenous chemotherapy drug docetaxel contains ethanol, also known as alcohol, which may cause patients to experience intoxication or feel drunk during and after treatment. The FDA is changing the labels of all docetaxel drug products to warn about this risk. Health care professionals should consider the alcohol content of docetaxel when prescribing or administering to patients, especially in conjunction with other medications where alcohol intake should be avoided or minimized.
- 5/15/14**      **FDA warns of next-day impairment with sleep aid Lunesta (eszopiclone) and lowers recommended dose:** The FDA is warning that the insomnia drug Lunesta (eszopiclone) has the

potential to cause next-day impairment of driving and other activities that require alertness. The FDA has decreased the recommended starting dose of Lunesta to 1 mg at bedtime. New dosing recommendations should be followed when starting patients on Lunesta.

- 5/13/14**      **FDA study of Medicare patients finds risks lower for stroke and death but higher for gastrointestinal bleeding with Pradaxa (dabigatran) compared to warfarin:** The FDA recently completed a new study in Medicare patients comparing Pradaxa to warfarin (Coumadin, Jantoven, and generics), for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. Pradaxa and warfarin are used to reduce the risk of stroke and blood clots in patients with non-valvular atrial fibrillation (AF). Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death, but associated with an increased risk of major GI bleeding when compared to warfarin. The MI risk was similar for the two drugs.
- 4/23/14**      **FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain:** The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. These injections are given to treat neck and back pain, and radiating pain in the arms and legs. A Warning to the drug labels of injectable corticosteroids is now required to describe these risks.
- 3/31/14**      **FDA clarifies Warning about Pediatric Use of Revatio (sildenafil) for Pulmonary Arterial Hypertension:** The FDA is clarifying its prior recommendation related to prescribing Revatio (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio is FDA approved for treating adults only, not children. In August of 2012, the FDA revised the warning label stating that “use of Revatio, particularly chronic use, is not recommended in children.” This was based on observations of increasing mortality with increasing Revatio doses in a long term clinical trial in pediatric patients with PAH.
- 3/6/14**      **FDA approves label changes for antibacterial Doribax (doripenem) describing increased risk of death for ventilator patients with pneumonia:** The FDA has determined that Doribax (doripenem), an antibacterial drug used to treat patients who develop pneumonia while on ventilators, carries a high risk of death and lower clinical cure rates compared to use of imipenem and cilastatin injection. The FDA has changed the Doribax drug label to describe these risks.
- 2/11/2014**      **FDA to review heart failure risk with diabetes drug saxagliptin (marketed as Onglyza and Kombiglyze XR):** The FDA has requested data from the manufacturer of saxagliptin to examine a potential association among use of the type 2 diabetes drug and heart failure. The manufacture is expected to provide the trial data to the FDA by March 2014, then the FDA will conduct a thorough analysis and report findings.
- 1/31/2014**      **FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products:** The FDA is studying the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. The FDA is monitoring the risk and reconsidering the safety issue based on the recent publication of two separate studies that suggest an increased risk of cardiovascular events among groups of men prescribed testosterone therapy.

Please visit <http://www.fda.gov/Drugs/DrugSafety/ucm380236.htm> for more information.

## The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in March 2014

BRAND NAME	GENERIC NAME/ DOSAGE FORMS	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Sovaldi	Sofosbuvir 400mg Tablets	<p>Sofosbuvir (Sovaldi) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Efficacy has been established in subjects with HCV genotype 1, 2, 3, or 4 infections, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.</p> <p>Monotherapy with sofosbuvir is not recommended for treatment of CHC. Treatment regimen and duration are dependent on both viral genotype and patient population and treatment response varies based on baseline host and viral factors.</p>	Peg-interferon (Pegasys, Pegasys Proclick), plus Ribavirin, Ribasphere, Ribapak, Moderiba	Preferred with prior authorization
Olysio	Simeprevir 150mg Capsules	Simeprevir (Olysio), a NS3/4A protease inhibitor, is indicated for treatment of chronic hepatitis C (CHC) genotype 1 in combination with peginterferon alpha and ribavirin in patients with compensated liver disease. Patients with hepatitis C virus (HCV) genotype 1a infection should be screened for the presence of virus with the NS3 Q80K polymorphism at baseline. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.	Incivek, Victrelis	Preferred with prior authorization
Adempas	Riociguat 0.5mg, 1mg, 1.5mg, 2mg, and 2.5mg Tablets	<p>Riociguat (Adempas), an oral soluble guanylate cyclase (sGC) stimulator, is indicated for the treatment of adults with:</p> <ul style="list-style-type: none"> <li>• Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (World Health Organization [WHO] Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.</li> <li>• Pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.</li> </ul>	Opsumit	Preferred with prior authorization
Opsumit	Macitentan 10mg Tablets	Macitentan (Opsumit) is an endothelin receptor antagonist (ERA) indicated for pulmonary arterial hypertension (PAH) to delay disease progression which includes death, initiation of intravenous (IV) or subcutaneous (SC) prostanooids, or clinical worsening of PAH.	Letairis, Tracleer	Preferred with prior authorization

BRAND NAME	GENERIC NAME/ DOSAGE FORMS	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Imbruvica	Ibrutinib 140mg Capsules	Imbruvica is indicated for Mantle cell lymphoma (MCL), which is a very rare and aggressive mature B-cell non-Hodgkin's lymphoma (NHL), with poor prognosis. MCL comprises only about six percent of newly diagnosed NHL cases. There are nearly 11,000 patients with MCL in the U.S. with approximately 3,000 new cases diagnosed each year. At MCL diagnosis, patients typically present with advanced disease, are in their 60s, and are predominantly male. It is incurable with conventional chemotherapy and most patients will have relapsed or refractory disease.	Velcade, Revlimid	Preferred with prior authorization
Gazyva	Obinutuzumab injection for intravenous (IV) infusion	Gazyva is a CD20-directed cytolytic antibody that is indicated, in combination with Leukeran (chlorambucil tablets), for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).	Rituxan, Leukeran	Preferred with prior authorization
Duavee	Conjugated estrogens/ bazedoxifene	Indicated in women with a uterus for treatment of moderate to severe vasomotor symptoms associated with menopause; and prevention of postmenopausal osteoporosis.	Conjugated estrogen (Prempro, Premphase) plus a bisphosphonate (alendronate)	Remain nonpreferred
Mirvaso	Brimonidine tartrate	Brimonidine (Mirvaso), is an alpha-adrenergic agonist topical gel indicated for the treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years and older.	Antibiotics such as metronidazole, erythromycin, clindamycin, and azelaic acid in the form of creams and other topical applications. In some cases, systemic antibiotics such as doxycycline, tetracycline, and amoxicillin have been used.	Remain nonpreferred
Velphoro	Sucroferric Oxyhydroxide 500mg Chewable Tablet	Sucroferric oxyhydroxide (Velphoro), an iron-based, calcium-free phosphate binder, is indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis.	Renvela, Eliphos	Remain nonpreferred
Otrexup	Methotrexate 10mg, 15mg, 20mg, 25 mg/0.4mL single dose auto-injector	Methotrexate preservative-free (PF) sterile solution for subcutaneous injection (Otrexup) is a folate analog metabolic inhibitor indicated for the management of severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA) in patients who are intolerant of or had an inadequate response to first-line therapy. It is also indicated for symptomatic control of severe, recalcitrant, disabling psoriasis in adults who do not respond adequately to other forms of therapy. It is not indicated for the treatment of neoplastic diseases.	Methotrexate tablets, vials	Remain nonpreferred

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications on June 19, 2014.

BRAND NAME	GENERIC NAME/ DOSAGE FORMS	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Anoro Ellipta®	umeclidinium 62.5 mcg/vilanterol 25 mcg	Indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). It is NOT indicated for the treatment of asthma or acute bronchospasms.	Tudorza Pressair, Spiriva, Symbicort, Atrovent Hfa, Combivent Respimat, Foradil	Nonpreferred. Prior authorization criteria: trial and failure of 2 preferred agents, diagnosis of COPD. Patients must be 18 years and older. No concurrent use of another LABA. Quantity Limit: One unit/30 days (0.48/day )
Aptiom®	Eslicarbazepine acetate, Tablets: 200 mg, 400 mg, 600 mg, and 800 mg	Adjunctive treatment for adult partial-onset seizures associated with epilepsy. This medication is structurally similar to carbamazepine and oxcarbazepine	Carbamazepine, Carbamazepine ER, Carbamazepine XR, Gabapentin, Lamotrigine, Lamotrigine ER, Levetiracetam, Levetiracetam ER, Oxcarbazepine, Topiramate	Nonpreferred. Prior Authorization criteria: trial of 2 preferred agents. Quantity limit: 1200mg/day (any combination of various strengths available).
Farxiga®	dapagliflozin propanediol, Tablets: 5 mg, 10 mg	Dapagliflozin (Farxiga) is a sodium-glucose cotransporter (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. SGLT2 inhibitors reduce renal glucose reabsorption in the proximal convoluted tubule, leading to increased urinary glucose excretion.	Invokana	Nonpreferred, Prior authorization criteria: trial and failure of Invokana. Patients must be ≥18 years with a diagnosis of type 2 diabetes; patient does not have severe renal impairment, end-stage renal disease and not receiving hemodialysis. Quantity limit: 30 tablets/month (1 tab/day)
Luzu®	Luliconazole, Topical cream: 1% (each gram contains 10 mg of luliconazole in a white cream base)	Luliconazole 1% topical cream (Luzu) is an azole antifungal to be applied topically for treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by Trichophyton rubrum and Epidermophyton floccosum in patients 18 years of age and older.	Topical azoles include econazole, ketoconazole, clotrimazole, miconazole, oxiconazole, sulconazole, and sertaconazole. Topical allylamines include naftifine and terbinafine and the benzylamine, butenafine	Nonpreferred. Prior authorization criteria: trial and failure of 2 preferred products, such as ciclopirox. Nystatin, and miconazole.

BRAND NAME	GENERIC NAME/ DOSAGE FORMS	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Fycompa®	Perampanel Tablets: 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg	Perampanel (Fycompa), a non-competitive AMPA glutamate receptor antagonist, is a Schedule III controlled substance, indicated as adjunctive therapy for the treatment of partial- onset seizures, with or without the presence of generalized seizures, in patients diagnosed with epilepsy 12 years of age and older.	Carbamazepine, Carbamazepine ER, Carbamazepine XR, Gabapentin, Lamotrigine, Lamotrigine ER, Levetiracetam, Levetiracetam ER, Oxcarbazepine, Topiramate	Nonpreferred, Prior authorization criteria: trial of 2 preferred products. Quantity Limit: 30 tablets/month (1 tab/day)

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