PHARMACY NEWS

PASSPORT HEALTH PLAN

SUPPORTING OUR PROVIDER PARTNERS THROUGH COMMUNICATION AND COLLABORATION.

DATE JUNE 2019
ISSUE 2

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

ADHD Products Update

Effective July 15, 2019 the medication Vyvanse® will move from the preferred formulary tier to the nonpreferred tier and will require a prior authorization for coverage. Current utilizers under the age of 18 who are stable on therapy and have not had a gap in fill will not be affected by this change at this time. All new utilizers and any current utilizers 18 years of age or older will need to have a prior authorization submitted for Vyvanse to continue therapy. The prior authorization criteria require a diagnosis of ADHD and at least a 30-day trial of a generic extended release stimulant from both the amphetamine and methylphenidate-based classes. This change was reviewed and approved by the Pharmacy and Therapeutics Committee following the May 2019 meeting.

Hepatitis C Products Update

Effective **May 28, 2019** the medication Mavyret™ for Hepatitis C treatment will become a nonpreferred product for Passport Health Plan members. The medication requires a prior authorization for coverage and a reason that the preferred product cannot be used. The preferred hepatitis C treatment for Passport Health Plan members is Sofosbuvir 400 mg-Velpatasvir 100 mg (generic for Epclusa®).

Proton Pump Inhibitors (PPI) Safety Edit

Effective **August 5, 2019** a cumulative duration of 12 weeks of therapy per previous 365 days will be applied to all proton pump inhibitor prescriptions for members age 3 and older being used to treat gastroesophageal reflux disease (GERD). This decision aligns with the safety recommendation for these medications in package labeling and the American College of Gastroenterology guidelines for the diagnosis and management of GERD. Members who have been on these medications for over 6 months will be allowed additional time to titrate off therapy with a PA request. Members who have completed 12 or more weeks of collective PPI therapy may be provided a one-time additional 4 weeks of therapy upon documentation that discontinuation is being attempted. Other diagnosis exceptions that warrant extended therapy and are outlined in the American College of Gastroenterology guidelines will be considered to continue therapy beyond 12 weeks through a PA request.

Cardiovascular Products Update

Changes to several classes of cardiovascular medications were approved at the May 2019 Pharmacy and Therapeutics Committee meeting. The exact changes to medications are listed in the table below under Formulary Changes. The classes of medications affected include antiplatelet agents, angiotensin receptor blockers (ARBs), angiotensin converting enzyme inhibitors (ACE inhibitors), beta blockers, cholesterol lowering agents, and diuretics. The changes are effective **July 15, 2019**.

New Prior Authorization Additions

Passport Health Plan will require prior authorization review for the following medications, effective **July 15, 2019.**

- Brilinta®
- Bumetanide tablets
- Dihydroergotamine spray
- Methitest™
- Riomet®
- Spiriva® Respimat®
- Vyvanse®

Formulary Changes

Please note the following formulary changes that were approved at the May P&T Committee meeting. Some formulary changes include the addition of Prior Authorizations and/or Quantity Limits only (and not a tier change). Changes will be effective July 15, 2019, unless otherwise noted in the table below.

PRODUCT	NEW FORMULARY STATUS	PREFERRED ALTERNATIVES
Miscellaneous Products		
Vyvanse® caps 10mg, 50mg	Tier 3 (non-preferred) with PA and QL	• Amphetamine • Amphetamine - Dextroamphetamine • Amphetamine - Dextroamphetamine ER • Dextroamphetamine • Dextroamphetamine ER • Methylphenidate • Methylphenidate ER
Vyvanse® caps 20mg, 30mg, 40mg, 60mg, 70mg	Tier 3 (non-preferred) with PA	
Vyvanse® chewable tabs 10mg, 20mg, 30mg, 40mg, 50mg, 60mg	Tier 3 (non-preferred) with PA	
Mavyret™ tab 100-40mg	Tier 3 (non-preferred) with PA	Sofosbuvir-Velpatasvir (generic Epclusa®)
Hydroxyprogesterone Caproate	Tier 1 (preferred) with PA requiring step through Makena Auto-injector *Effective 5/28/19*	• Makena® auto-injector
Spiriva® Respimat®	Tier 3 (non-preferred) with PA (PA does not apply to ages 6-17 yo)	• Incruse Ellipta
Actemra®	Tier 3 (non-preferred) with PA *Effective 5/28/19*	• Cosentyx® • Enbrel® • Humira® • Kevzara® • Siliq™ • Xeljanz® / Xeljanz XR®

Duexis® Vimovo®	Non-formulary	• Ibuprofen • Naproxen • Famotidine • Esomeprazole • Omeprazole
Dihydroergotamine Mesylate Nasal Spray	Tier 1 (preferred) with PA	• Triptans
Tizanidine Capsules	Non-formulary	• Tizanidine tablets
Oxandrolone	Non-formulary	• Testosterone
Methitest™	Tier 2 (preferred) with PA	• Testosterone
Riomet® solution	Tier 2 (preferred) with PA	• Metformin tablets
Prescription Anti-seborrheic Products		
Selenium Sulfide Sulfacetamide Sodium Miscellaneous Creams/Kits	Non-formulary	• Over-the-counter Selenium Sulfide
Cardiovascular Agents		
Brilinta® tabs 60mg, 90mg	Tier 3 (non-preferred) with PA	• Clopidogrel • Prasugrel
Bystolic® Nadolol Pindolol	Non-formulary	• Acebutolol • Atenolol • Bisoprolol • Metoprolol • Propranolol • Sotalol
Captopril Enalapril Moexipril	Non-formulary	• Lisinopril • Quinapril • Ramipril
Nadolol-Bendroflumethiazide	Non-formulary	• Atenolol-Chlorthalidone • Bisoprolol-HCTZ • Metoprolol-HCTZ • Propranalol-HCTZ
Trandolapril-Verapamil	Non-formulary	• Amlodipine-Benazapril • Prestalia (Perindopril-Amlodipine) (requires PA)
Candesartan Olmesartan Telmisartan	Non-formulary	• Irbesartan • Losartan • Valsartan
Fenofibrate • Capsules (43, 50, 67, 130, 134, 150 and 200 mg) • DR Capsules (45, 135 mg) • Tablet (105 mg) • Antara Capsules (30, 90 mg) • Triglide Tablets (160 mg)	Non-formulary	• Fenofibrate Tablets (40, 48, 54, 120, 145, 160 mg)
Fluvastatin	Non-formulary	• Atorvastatin • Lovastatin • Pravastatin • Rosuvastatin (requires PA) • Simvastatin
Bumetanide	Tier 1 (preferred) with PA	• Furosemide • Torsemide

Quantity Limit Updates		
Stimulants	QL in line with FDA-labeled dosing	N/A
Positive Formulary Changes – Effective Immediately		
Praluent®	Tier 2 (preferred) with PA	N/A
Makena® Auto-injector	Tier 2 (preferred) with PA	N/A
Miscellaneous		
Mircera	Moved to be billed on the medical benefit	N/A

The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in June 2019

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES (G)- generic (P)- preferred (NP)- nonpreferred	PASSPORT HEALTH PLAN STATUS
Motegrity™	prucalopride	Treatment of Chronic Idiopathic Constipation (CIC) in adults	Linzess® (P-QL) Trulance® (P-QL) Amitiza (NP- PA,QL)	Non-preferred with PA and QL
Cablivi®	caplicizumab-yhdp	Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy	N/A	Preferred with PA and QL
Egaten™	triclabendazole	Treatment of fascioliasis in patients 6 years of age and older	Alinia® (P) *Off-label*	Preferred
Spravato™ *reviewed in May 2019	Esketamine	Treatment-resistant depression (in conjunction with an oral antidepressant)	Oral antidepressants Aripiprazole	Non-preferred with PA and QL
Sunosi	Solriamfetol	Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)	Dextroamphetamine (G) Amphetamine (G- PA, QL) Amphetamine/ Dextroamphetamine (G- QL) Modafinil (G- PA, QL) Armodafinil (G- ST, QL) Xyrem® (P- PA, QL)	Nonformulary
Mayzent®	Siponimod	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	Gilenya® (P- PA, QL) Aubagio® (P- PA, QL) Tecfidera® (P- PA, QL)	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	FORMULARY STATUS
Fluticasone-Salmeterol / Wixela Inhub 100/50, 250/50, 500/50	Advair Diskus®	T1 with PA
Toremifene Citrate Tablet 60 mg	Fareston®	T1 with PA
Minocycline ER Tablet 80 mg, 150 mg	Solodyn®	T1 with PA
Acyclovir Cream 5%	Zovirax®	T1 with PA and QL
Vigabatrin Tablet 500 mg	Sabril®	T1 with PA and QL
Sevelamer Tablet 800 mg	Renalgel®	T1 with PA
Buprenorphine-Naloxone Sublingual Film 2-0.5 mg, 4-1 mg, 8-2 mg, 12-3 mg	Suboxone®	T1 with PA and QL
Cyclobenzaprine ER Capsule 15 mg, 30 mg	Amrix®	T1 with PA
Ranolazine ER Tablet 500 mg, 1,000 mg	Ranexa®	T1 with PA
Aliskiren Tablet 150 mg, 300 mg	Tekturna®	T1 with PA
Pyridostigmine Bromide 60 mg Tablet, 60 mg/5 ml Syrup	Mestinon®	T1 with PA
Diclofenac Topical Patch 1.3%	Flector®	T1 with PA
Deferasirox Tablet 125 mg, 250 mg, 500 mg	Exjade®	T1 with PA
Albuterol Sulfate 0.09 mg/actuation	Proventil®	T1 with PA
Ambrisentan Tablet 5 mg, 10 mg	Letairis®	T1 with PA and QL
Solifenacin Tablet 5 mg, 10 mg	VESIcare®	T1 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.*

Line Extension Products

GENERIC NAME	BRAND NAME	RECOMMENDATION
Erenumab-Aooe Subcutaneous Solution Auto-Injector 140 mg/ml	Aimovig®	T3 with PA and QL
Tafenoquine Succinate Tablet 200 mg	Krintafel	T3 with PA and QL

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

The FDA recently issued the following advisories:

April 22, 2019: Fentanyl Transdermal Patches Recalled Due to Product Mislabeling

Alvogen recalled two lots for fentanyl transdermal patches due to the strength on carton not matching the patches in the box. The labeled 50mcg/h transdermal patches were misplaced in the 12mcg/h boxes. The products affected by this recall included lot 180060 expiring on 05/2020 and lot 180073 expiring on 06/2020. Although no adverse events have been reported to date, potential life-

threatening side effects may occur such as respiratory depression, especially opioid-naive patients and the elderly. Physicians are advised to stay cautious of patients on fentanyl transdermal patches due to the mislabeling.

April 29, 2019: Teva Pharmaceuticals USA, Inc. Issues Voluntary Nationwide Recall of Losartan Potassium 25 mg and 100 mg Tablets USP, Sold Exclusively to Golden State Medical Supply

Teva Pharmaceuticals USA, Inc. has initiated a voluntary recall of 35 lots of bulk Losartan Potassium USP Tablets, due to the detection of an impurity NMBA (– N-Nitroso-N-methyl-4-aminobutyric acid). Teva Pharmaceuticals USA, Inc., had stated the impurity exposure limit was above FDA's interim acceptable exposure limit of 9.82ppm, however the risk of developing cancer in patients who use the product long-term cannot be ruled out. Hetero Labs manufactured 6 lots of the active pharmaceutical ingredient (API) in which the impurity was found. It has been reported that the lots containing impurities were exclusively sold to Golden State Medical Supply of Camarillo, California. No adverse events have been reported to date and patients taking Losartan Potassium tablets are advised to continue taking their medication. If there are any concerns or questions Teva Medical Information has advocated to call them by phone at: 888-838-2872 or by email at druginfo@tevapharm.com.

April 30, 2019: Certain Prescription Insomnia Medicines: New Boxed Warning - Due to Risk of Serious Injuries Caused by Sleepwalking, Sleep Driving and Engaging in Other Activities While Not Fully Awake

FDA is advising serious injuries to have occurred with certain common prescription insomnia medicines, especially with sedative-hypnotics. These effects have been seen commonly in Lunesta® (eszopiclone), Sonata® (zaleplon), Ambien®, Ambien CR®, Edluar®, Intermezzo®, and Zolpimist™ (zolpidem). Although rare, these side effects include sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. Health care professionals are advised to monitor patients on insomnia medications and to discontinue these medicines if they experience an episode of complex sleep behavior. FDA also encourages to report these events on www.fda.gov/MedWatch/report. It is encouraged that if these side effects are seen to change therapy regimens, as the side effects may cause more harm than benefit from taking these select medications.

May 1, 2019: Mavyret Approved to Treat All 6 Genotypes of HCV in Pediatric Patients

The FDA has approved Mavyret™ (glecaprevir and pibrentasvir; AbbVie) for children ages 12-17 or weighing at least 45kg for the treatment of all 6 genotypes of hepatitis C virus (HCV). Mavyret is a once-daily medication and works by targeting and inhibiting proteins that replicate HCV. The approval for the pediatric indication was deemed appropriate based on data from an open-label clinical trial (DORA [Part 1]). This trial included 47 HCV patients aged 12 to 17 years. It must be noted these patients were all without cirrhosis. The genotypes were tested for all participants and majority had genotype HCV1 with 79%. The other patients had either HCV 2,3 or 4. All patients received Mavyret for 8 or 16 weeks in which 77% were treatment-naïve. Results concluded that after a minimum of 12 weeks, all 47 patients had HCV RNA less than the lower limit of quantification (LLOQ). Mavyret is the first drug be able to help patients with any HCV genotypes. Additionally, no dosage adjustment is required in pediatric patients ≥12 years old or weighing ≥45kg. For more information visit: www.mavyret.com

May 1, 2019: Injectable Pain Med Recalled Due to Possible Microbial Contamination

Due to discovery of microbial growth, Sagent Pharmaceuticals has recalled one lot of Ketorolac Tromethamine Injection 60mg/2mL. This medication is supplied in a 2ml vial and has the lot M813513 with an expiration date of 02/2020. No adverse events have been reported and currently, no microorganisms have been identified in the distributed batches.

May 3, 2019: Par Pharmaceutical, Inc., Issues Voluntary Nationwide Recall of One Lot of Mycophenolate Mofetil for Injection, USP Due to the Presence of a Glass Fragment Observed in One Vial of Reconstituted Product

After finding a vial of Mycophenolate Mofetil for Injection, USP containing a glass fragment after reconstitution, Endo International plc, announced a recall of the product from hospital and retail pharmacies. Par Pharmaceutical, Inc., an operating company for Endo International plc, has notified the public that the affected product has the lot AD812, expiring 09/2020. To date, no reports of adverse events related to this recall have been reported. It is important to note that this product was distributed nationwide between January 23, 2019, and February 11, 2019. This product with the select lot number should be immediately stopped and any adverse reactions should be reported through the FDA's Medwatch Adverse Event Reporting program. Par Pharmaceutical, Inc. is arranging for return of all recalled product through Inmar, Inc. Physicians and pharmacists are advised to recheck vials for any visible glass remnants of all products to prevent any adverse events from taking place. Adverse events may include irritation while administering the drug due to the glass particles in the medication solution. Serious adverse events may lead to blood clots or excessive bleeding, potentially leading to death.

May 11, 2019: Promacta® (eltrombopag) 12.5 Oral Suspension by Novartis: Recall - Due to Potential Peanut Contamination

Three lots of Promacta® (eltrombopag) 12.5 mg for oral suspension to the consumer level. The oral suspension lots are being recalled because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site. Affected lot numbers include: 8H57901589, 9H57900189, and 9H57900289.