PHARMACY NEWS

PASSPORT HEALTH PLAN

SUPPORTING OUR PROVIDER PARTNERS THROUGH COMMUNICATION AND COLLABORATION.

DATE MARCH 2019
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

Acne Products Update

Effective **May 6, 2019** Passport Health Plan will only cover medications used to treat acne for members 18 and younger. Medications used to treat acne for members aged 19 years and older will move to non-formulary. Additional changes to acne products that apply to members aged 18 years and younger are outlined below in the formulary changes chart. The additional formulary changes for acne medications applicable to members 18 years old and younger are also effective May 6, 2019. These changes were reviewed and approved at the February P&T Committee meeting.

Nasal Steroid Medication Updates

The over-the-counter (OTC) nasal steroid products: Budesonide nasal suspension, fluticasone nasal spray, and triamcinolone nasal spray will be the preferred products beginning **April 15, 2019**. Prescription nasal steroid products will move to non-formulary effective April 15, 2019. The prescription products affected are outlined in the table below. Please note, the prescription product mometasone spray will continue to be covered for patients under 4 years of age and for the indication of nasal polyps with a prior authorization. These changes were approved at the February P&T Committee meeting.

Inhaler Product Updates

The preferred long-acting bronchodilator and glucocorticoid combination products are salmeterol-fluticasone (generic for AirDuo™ RespiClick®) and Breo Ellipta. Advair HFA products and generic Advair Diskus® products (Wixela™ Inhub™ and fluticasone-salmeterol) will move to non-preferred status and require prior authorization, effective April 15, 2019. Please note that a PA will not be required for members under the age of 18 years old for the generic Diskus products.

The preferred inhaled corticosteroid products are QVAR® RediHaler™ and Arnuity® Ellipta®. Asmanex® and Asmanex HFA products will remain on Tier 3 (non-preferred) and require a prior authorization; however, the age edit will be removed, effective April 15, 2019. All members, regardless of age, will need a prior authorization to receive these products. Current utilizers younger than 12 years old will be given a period of time to transition to a

preferred product. These changes were reviewed and approved at the February P&T Committee meeting.

Anticoagulants Update

Effective **April 15, 2019**, Eliquis® will remain on Tier 2 as the preferred agent and Xarelto will move to Tier 3 (non-preferred) and will require a prior authorization for all new users.. These changes were reviewed and approved at the February P&T Committee meeting.

Diabetic Supply Changes

Effective June 3, 2019, BD Brand pen needles and syringes will be the preferred brand, and all other brands of pen needles and syringes will move to non-formulary. Please consider transitioning members to BD brand as soon as possible. A non-formulary product will require prior authorization.

Also effective June 3, 2019, formulary diabetic testing products will be updated. Please consider transitioning members to one of the products listed below as soon as possible. A non-formulary drug will require prior authorization. **Accu-Chek® offers a free diabetic meter program**. To inquire about this program, please call 1-800-588-4456.

Formulary Diabetic Testing Products (effective June 3, 2019):

- Accu-Chek Care Kits: Aviva Plus, Guide and Nano SmartView
- Accu-Chek Test Strips: Aviva Plus, Guide, SmartView (for Nano), Compact Plus
- FreeStyle Meters: InsuLinx®, Lite, Freedom Lite, Precision Neo Meter
- FreeStyle Test Strips: InsuLinx, Lite, Precision Neo
- Precision Xtra Meter
- Precision Xtra Test Strips

Insulin Delivery Devices Update

Effective **June 3, 2019**, the following insulin infusion products should be billed through the medical benefit only and will be removed from the pharmacy benefit.

- Minimed™
- Omnipod®
- T:Slim
- Varisoft®
- V-Go®

For coverage of these products under the medical benefit, please contact Passport Medical UM Department at 1-800-578-0636 (phone) or 502-585-7989 (fax).

New Prior Authorization Additions

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

- Advair® HFA, Advair Diskus® and generic Advair Diskus products
- Atripla®
- L-methylfolate
- Santyl®
- Xarelto®
- Xiidra®

Quantity Limit Updates

Quantity limits were added for the following products, effective April 15, 2019.

PRODUCT	NEW QUANTITY LIMIT
Diclofenac Diclofenac Gel 1% Gel 1%	200 gra Non-Formulary ms/30 days
Diclofenac Ge Adapalene Gel 0.1% l 3%	100 gr OTC covered, RX version requires PA ams/30 days

Formulary Changes

Please note the following formulary changes that were approved at the February 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 **April 15, 2019**, unless otherwise noted.

PRODUCT	NEW FORMULARY STATUS
ACNE AGENTS, 18 YEARS OF AGE AND YOUNGER – EFFECTIVE MAY 6, 2019	
ADAPALENE	
Adapalene Cream 0.1%, Gel 0.3%, Lotion 0.1%	Non-Formulary
Adapalene Gel 0.1%	OTC covered, RX version requires PA
AZELAIC ACID	
Azelaic Acid Cream, Foam	Non-Formulary
BENZOYL PEROXIDE	
Benzoyl Peroxide Liquid 4%, 5%, 10%	Tier 1 (preferred) with QL
Benzoyl Peroxide Cream 10%	Tier 1 (preferred) with QL
Benzoyl Peroxide Gel 2.5%, 5%, 1haha l0%	Tier 1 (preferred) with QL
Benzoyl Peroxide Foam 5.3%, 5.5%, 9.5%, 9.8%	Non-formulary
Benzoyl Peroxide Liquid 5.25%, 7%	Non-Formulary
Benzoyl Peroxide Gel 2.75%, 5.25%	Non-formulary
Benzoyl Peroxide Cloth 6%	Non-formulary

PRODUCT	NEW FORMULARY STATUS
CLINDAMYCIN	
Clindamycin Phosphate Soln 1%	Tier 1 (preferred)
Clindamycin Phosphate Swab, 1%	Tier 1 (preferred)
Clindamycin Phosphate Gel1%, Lotion 1%	Tier 1 (preferred) with PA
Clindamycin Phosphate Foam 1%	Non-formulary
DAPSONE	
Dapsone Gel 5%	Non-formulary
ERYTHROMYCIN	
Erythromycin Solution 2%	Tier 1 (preferred)
Erythromycin Gel, Pads 2%	Non-formulary
SULFACETAMIDE SODIUM AND SULFACETAMIDE SODIUM WITH SULFUR	
All Products	Non-formulary
BRIMONIDINE	
Brimonidine Tartrate Gel 0.33%	Non-formulary
TAZAROTENE	
Tazarotene Cream 0.1 %	Tier 1 (preferred) with PA
Tazarotene Cream 0.05%	Tier 2 (preferred) with PA
Tazarotene Gel 0.05%, 0.1%, Foam 0.1%	Non-formulary
TRETINOIN	
Tretinoin Cream 0.025%, 0.05%, 0.1%	Tier 1 (preferred) with PA
Tretinoin Gel 0.1%	Tier 1 (preferred) with PA
Tretinoin Gel 0.05%	Non-formulary
Tretinoin Microsphere Gel 0.04%, 0.1%	Non-formulary
ACNE COMBINATION AGENTS	
Adapalene-Benzoyl Peroxide Gel - 0.1-2.5%, 0.3-2.5%	Non-formulary
Benzoyl Peroxide-Erythromycin Gel – 5-3%	Tier 1 (preferred) with PA
Benzoyl Peroxide-Erythromycin Gel Pack 5-3%	Non-formulary
Clindamycin Phosphate/Benzoyl Peroxide (Refrig) Gel 1.2-5.0%	Tier 1 (preferred) with PA
Clindamycin Phosphate-Benzoyl Peroxide Gel 1.2-2.5%, 1.2-3.75%, 1-5%	Non-formulary
Clindamycin Phosphate/Tretinoin Gel-1.2-0.025%	Non-formulary
ORAL ISOTRETINOIN AGENTS	
Isotretinoin Capsules - 10mg, 20mg, 30mg, 40mg (Amnesteem®, Claravis®, Isotretinoin, Myorisan™, Zenatane™)	Tier 1 (preferred) with PA
Absorica® Capsules - 10mg, 20mg, 25mg, 30mg, 35mg, 40mg	Non-formulary

PRODUCT	NEW FORMULARY STATUS
ANTICOAGULANTS	
Xarelto® tabs 2.5mg, 10mg, 15mg, 20mg	Tier 3 (non-preferred) with PA
HIV COMBINATION THERAPY	
Atripla® tab	Tier 3 (non-preferred) with PA
INHALED MEDICATIONS	
Asmanex®, Asmanex® HFA	Tier 3 (non-preferred) with PA for all members (age edit removed)
Advair® HFA	Tier 3 (non-preferred) with PA
Wixela™ Inhub™, Fluticasone-Salmeterol (generics for Advair Diskus®)	Tier 3 (non-preferred with PA
MEDICATIONS FOR PAIN	
Nalfon® capsules 400mg	Non-formulary
Zipsor® capsules 25mg	Non-formulary
Zorvolex® capsules 18mg, 35mg	Non-formulary
Fenoprofen capsules 200mg, 400mg, tabs 600mg	Non-formulary
Cambia powder packets 50mg	Non-formulary
Tramadol extended-release capsules 100mg, 150mg, 200mg, 300mg	Non-formulary
NASAL STEROIDS	
Beconase AQ, Qnasl and Qnasl Child, Budesonide (prescription), Omnaris, Flunisolide, Veramyst, Fluticasone (prescription), Triamcinolone AQ (prescription)	Non-formulary
OTHER PRODUCTS	
Innopran XL® caps	Non-formulary
Veltassa®	Non-formulary
Xiidra®	Tier 3 (non-preferred) with PA
Restasis®	Non-formulary
Omeprazole 20mg tablet (OTC)	Non-formulary
Intrarosa®	Exclusion (dyspareunia)
POSITIVE FORMULARY CHANGES – EFFECTIVE IMMEDIATELY	
Symfi™, Symfi Lo tablet	Tier 2 (preferred)
Ozempic® Pen 2mg/1.5mL	Tier 2 (preferred) with ST
QVAR® RediHaler™ 40mcg, 80mcg	Tier 2 (preferred)
Soliqua® Injection 100 unit/33mcg/mL	Tier 2 (preferred) with PA
DIABETIC SUPPLIES	
BD Brand Pen Needles and Syringes	Tier 1 (preferred) with QL
All other brands of Pen Needles and Syringes	Non-formulary

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

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES (G)- generic (P)- preferred (NP)- nonpreferred	PASSPORT HEALTH PLAN STATUS
Yupelri™	revefenacin	Maintenance treatment of chronic obstructive pulmonary disease (COPD)	Spiriva® Respimat® (P) Incruse Ellipta (P) Atrovent® HFA (P) Spiriva® HandiHaler® (NP) Tudorza® Pressair® (NP) Seebri® Neohaler® (NP)	Preferred with PA and QL
Nuzyra™	omadacycline	Treatment of adult patients with community-acquired bacterial pneumonia Treatment of adult patients with acute bacterial skin and skin structure infections	Azithromycin (G) Clarithromycin (G) Doxycycline (G) Minocycline (G) Clindamycin (G) TMP-SMX (G) Levofloxacin (G) Moxifloxacin (G) Linezolid (G) Baxdela (NP) Sivextro (NP)	Non-preferred with PA and QL
Seysara™	sarecycline	Treatment of inflammatory lesions of moderate to severe, non-nodular Acne vulgaris in patients 9 years of age and older	Azithromycin (G) Tetracycline (G) Erythromycin (G) Doxycycline (G) Minocycline (G) TMP-SMX (G)	Non-formulary
Aemcolo™	rifamycin	Treatment of adult patients with travelers' diarrhea caused by noninvasive strains of Escherichia coli (E. coli) not complicated by fever or blood in the stool	Azithromycin (G) Ciprofloxacin (G) Xifaxan (NP)	Non-preferred with PA and QL
Tegsedi™	inotersen	Treatment of adults with polyneuropathy related to hereditary transthyretin mediated amyloidosis (hATTR).	Onpattro® (medical)	Preferred with PA and QL
Revcovi™	elapagademase-lvlr	Treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients	Adagen® (nonformulary)	Preferred with PA
Firdapse®	amifampridine	Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults	None	Preferred with PA and QL
Oxervate™	cenegermin-bkbi	Treatment of neurotrophic keratitis	None	Preferred with PA and QL

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES (G)- generic (P)- preferred (NP)- nonpreferred	PASSPORT HEALTH PLAN STATUS
Talzenna™	talazoparib	Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative locally advanced or metastatic breast cancer	Lynparza® (P)	Preferred with PA and QL
Lorbrena®	lorlatinib	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on 1) crizotinib and at least one other ALK inhibitor for metastatic disease; or 2) alectinib as the first ALK inhibitor therapy for metastatic disease; or 3) ceritinib as the first ALK inhibitor for metastatic disease.	Xalkori® (P) Alecensa® (P) Zykadia® (P) Alunbrig® (P)	Preferred with PA and QL
Daurismo™	glasdegib	Acute myeloid leukemia in newly diagnosed adult patients ≥75 years old (or who have comorbidities that preclude use of intensive induction chemotherapy) in combination with low-dose cytarabine	Venclexta® (P)	Preferred with PA and QL
Xospata®	gilteritinib	Adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test	Nexavar® (P)	Preferred with PA and QL
Vitrakvi®	larotrectinib	Treatment of solid tumors (in adult and pediatric patients) that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have no satisfactory alternative treatments or that have progressed following treatment.	None	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
Silodosin Capsule 4 mg, 8 mg	Rapaflo®	Preferred with PA
Buprenorphine Transdermal Patch 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr	Butrans®	Preferred with PA

GENERIC NAME	BRAND NAME	FORMULARY STATUS
Mesalamine Suppository 1,000 mg	Canasa®	Preferred
Pimecrolimus Cream 1%	Elidel®	Preferred with PA and QL (30/30)
Cinacalcet HCl Tablet 60 mg, 90 mg	Sensipar®	Preferred with PA and QL (60/30)
Alogliptan 6.25 mg, 12.5 mg, 25 mg	Nesina	Preferred with ST and QL (30/30)
Aminocaproic Acid Tablet 500 mg, 1,000 mg	Amicar®	Preferred, Preferred with PA
Albuterol Sulfate	Ventolin®	Preferred
Albuterol Sulfate	ProAir®	Preferred 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
Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg tablet	Symtuza™	Tier 3 with PA and QL
Lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg tablet	Cimduo™	Tier 2 with QL
Adalimumab prefilled syringe kits and pen-injector kits (multiple strengths)	Humira®	Tier 2 with PA and QL
Epinephrine solution auto-injector 0.1 mg/0.1 ml	Auvi-Q®	Tier 3 with PA and QL
Pimavanserin tartrate 10 mg tablet and 34 mg capsule	Nuplazid®	Tier 3 with PA and QL
Lumacaftor-ivacaftor granules packet 150-188 mg and 100-125 mg	Orkambi®	Tier 3 with PA, QL and Age Edit
Etanercept subcutaneous solution cartridge 50 mg/ml	Enbrel®	Tier 2 with PA and QL
Rivaroxaban 2.5 mg tablet	Xarelto®	Tier 2 with QL

Preferred Insulin Products

As a reminder, Admelog®, Basaglar®, Humulin® and Tresiba® are the preferred insulin products. All other non-preferred products (Lantus®, Levemir®, Humalog®, NovoLlog®, and Novolin® products) require a prior authorization.

Member Copays

Member copays at the pharmacy are generally $1 for generic product and $4 for brand product. This may change if the member is in an excluded group or has reached their quarterly cost share. Once a member has reached their cost share, the copay will be $0.

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

The FDA recently issued the following advisories:

January 22, 2019: Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium and Hydrochlorothiazide Tablets, USP
March 1, 2019: Updated

Torrent Pharmaceuticals Limited is expanding its voluntary recall from 10 lots of Losartan potassium tablets to include 6 lots of Losartan potassium and hydrochlorothiazide tablets. This has been further expanded to 60 total lots of Losartan potassium tablets USP and 54 lots of Losartan potassium/hydrochlorothiazide tablets, USP on March 1. This is due to the detection of trace amount of an unexpected impurity in the active pharmaceutical ingredient, N-nitrosodiethylamine (NDEA). This agent is a substance classified as a probable human carcinogen by the international Agency for Research on Cancer. Torrent is recalling specified lots of losartan containing NDEA amounts above the acceptable daily intake levels released by the FDA. For all affected lot numbers, please visit: www.fda.gov/Safety/Recalls/ucm632509.htm.

Additional Recalls due to NDEA/NMBA by company and products affected are listed below:

AurobindoPharma USA, INC: Amlodipine Valsartan Tablets USP and Valsartan Tablets, USP. For affected lot numbers, please visit www.fda.gov/Safety/Recalls/ucm632442.htm.

Camber Pharmaceuticals, INC: Losartan Potassium Tablets, USP, 25mg, 50mg, and 100mg. For affected lot numbers, please visit www.fda.gov/Safety/Recalls/ucm632395.htm.

Macleods Pharmaceuticals Limited: Losartan Potassium/Hydrochlorothiazide 100mg/25mg. Only one lot, lot # BLM715A. NDC 33342-0052-10. Expiration Date: Jul 2019.

January 29, 2019: Tris Pharma Expands Its Voluntary Nationwide Recall of Infants' Ibuprofen Oral Suspension Drops, USP, (NSAID) 50 mg per 1.25 mL, Due to Higher Concentration of Ibuprofen

A total of six lots of infants' ibuprofen are being recalled after having been found to potentially have higher concentrations of ibuprofen. The products were sold to a single distributor who distributed to the US market. All products were distributed to Wal-Mart, CVS, or Family Dollar Services stores. There is a possibility that infants, who may be more susceptible to a higher potency level of drug, would therefore be more vulnerable to permanent NSAID-associated renal injury. This recall is an FDA approved class II retail level recall, a situation in which use of, or exposure to the requested product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. For affected lot numbers, please visit www.fda.gov/Safety/Recalls/ucm627780.htm

February 1, 2019: Terrific Care, LLC. / Medex Supply Recalls CoaguChek® XS PT Test Strips Used to Monitor Blood Thinner Warfarin Due to Inaccurate Test Results

This recall is a follow-up to the Roche Diagnostics recall of CoaguChek® XS PT Test Strips from November 2018. These strips were also manufactured by Roche, were distributed by Terrific Care/ Medex Supply, and include catalog numbers that were not included in the recent Roche recall. These test strips are used with Roche INR Test Meters to monitor patient response to warfarin, a blood thinner prescribed to prevent and treat blood clots. Roche Diagnostics, the manufacturer of CoaguChek® meters and test strips, is recalling the CoaguChek® XS PT Test Strips due to inaccurate INR test results, when compared to laboratory results. Use of affected products may increase the risk of serious adverse health consequences, including death. This is a class I recall by the FDA, the most serious kind of recall they issue. A full list of the products and lot numbers affected can be found at: www.fda.gov/Safety/Recalls/ucm628976.htm

February 22, 2019: Uloric Labeling Updated with New Indication, Boxed Warning After Review of CV Safety Data

The prescribing information for Uloric (Febuxostat) is being updated to include a Boxed Warning regarding an increased risk of CV death and all-cause mortality with Uloric. This is based on the CARES (Cardiovascular Safety of Febuxostat and Allopurinol in Patients with Gout and Cardiovascular Morbidities) trial showing febuxostat had an a statistically significant increase in cardiovascular death and all-cause mortality. The FDA is now limiting its approved use for only those patients who have failed or cannot tolerate maximally titrated allopurinol doses. A new Medication Guide, which discusses the cardiovascular risks, should be provided to all patients who receive Uloric prescriptions.

February 26, 2019: Increased Risk of Pulmonary Embolism, Death in RA Patients Reported in Tofacitinib Post-marketing Study

According to data from an ongoing post-marketing study, tofacitinib dosed at 10mg twice daily was associated with an increased risk of pulmonary embolism and overall mortality in patients with rheumatoid arthritis (RA). The safety study is currently evaluating the risk of CV events, cancer, and opportunistic infections associated with 2 dosing regimens, 5mg twice daily and 10mg twice daily, in combo with methotrexate, compared with tumor necrosis factor inhibitor use. The 10mg twice-daily dose is not approved for the treatment of RA but is approved for patients with ulcerative colitis. The FDA still believes the benefits of tofacitinib outweigh the risks and all patients on tofacitinib should monitored for signs and symptoms of pulmonary embolism.

March 4, 2019: Oral Contraceptive Product Recalled Due to Packaging Error

Apotex announced a voluntary recall of 4 lots of Drospirenone and Ethinyl Estradiol Tablets 3mg/0.03mg, due to a possibility of defective blisters and incorrect tablet arrangements. The correct arrangement should be 21 active yellow tablets followed by seven white placebo tablets. The following lots have been recalled: 7DY008A, 7DY009A, 7DY010A, and 7DY011A. The outer carton displays NDC# 60505-4183-3 and contains 3 inner cartons (NDC# 60505-4183-1) with expiration date 8/2020. These impacted products were manufactured by Oman Pharmaceutical Products Co., LLC and recall letters have been sent to affected parties. Loss of efficacy and pregnancy is possible if patients do not take the appropriate tablet or miss a dose. For more information on this recall, consumers can call (800) 706-5575 or visit Apotex.com.