

**DATE** DECEMBER 2018  
**ISSUE** 4

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

#### NEW IN THIS ISSUE

- Insulin Class Updates
- Sodium Glucose Cotransporter-2 (SGLT2) Inhibitor Class Updates
- Anticholinergic/Long-Acting Beta-2 Agonist (LABA) Inhaler Update
- Doxycycline Formulary Changes
- New Prior Authorization Additions
- Formulary Changes
- P&T Committee Review
- New Generics
- Line Extension Products
- Notification of Coordination of Benefits Change
- Recent FDA Safety Advisories

## Insulin Class Updates

Rapid, short and intermediate-acting insulin products were reviewed at the November Pharmacy and Therapeutics Committee meeting. Humalog®, Humalog® Kwikpen®, and Humalog® Kwikpen® U-200 products will move to a non-preferred status effective February 4, 2019. **Admelog®, Admelog Solostar®, Humalog® Mix™, and Humulin® products will remain as preferred alternatives.** Please consider transitioning members to a preferred product. Members who are currently using a medication moving to a non-preferred status will be provided a transition period to allow time to submit a prior authorization request if needed.

## SGLT2 Inhibitor Class Updates

Additional updates to diabetes medications included formulary status changes to Sodium Glucose Cotransporter-2 (SGLT2) Inhibitors. Invokana®, Inovakmet®, Invokamet® XR, Synjardy®, and Synjardy® XR will all move to non-preferred status effective February 4, 2019. Jardiance® will remain preferred but will change from a step therapy requirement to that of a prior authorization, which will require a cardiovascular indication and a step through Metformin. **Steglatro™ and Segluromet™ will be the preferred products and will require step therapy through Metformin.** Please consider transitioning members to a preferred product. Members who are currently using a medication moving to a non-preferred status will be provided a transition period to allow time to submit a prior authorization request if needed.

## Anticholinergic/Long-Acting Beta-2 Agonist (LABA) Inhaler Update

Effective February 4, 2019, Anoro Ellipta will move from preferred to non-preferred status. **The Stiolto® Respimat® device is the preferred formulary alternative in the anticholinergic/LABA combination inhaler class.** Please consider transitioning members to the preferred product. Members who are currently using a medication moving to a non-preferred status will be provided a transition period to allow time to submit a prior authorization request if needed.

## Doxycycline Formulary Changes

The P&T committee approved changes to the formulary status of several formulations of the antibiotic doxycycline. The updated formulary statuses of the doxycycline formulations are summarized in the table below. All changes are effective February 4, 2019. **The preferred formulary options are the Doxycycline Monohydrate 50mg and 100mg capsules and the 25mg/5mL suspension.** If medically necessary, non-formulary medications can be requested through a non-formulary medication request.

PREFERRED – NO PA REQUIRED	PREFERRED – PA REQUIRED	REMOVED FROM FORMULARY
<ul style="list-style-type: none"> <li>• Doxycycline monohydrate 50mg capsules</li> <li>• Doxycycline monohydrate 100mg capsules</li> <li>• Doxycycline monohydrate 25mg/5mL suspension</li> </ul>	<ul style="list-style-type: none"> <li>• Doxycycline hyclate 20 mg tablet</li> <li>• Doxycycline hyclate 50 mg capsule</li> <li>• Doxycycline monohydrate 50 mg tablet*</li> <li>• Doxycycline monohydrate 75 mg tablet*</li> <li>• Doxycycline monohydrate 100 mg tablet*</li> <li>• Doxycycline hyclate 100 mg tablet, capsule</li> <li>• Doxycycline monohydrate 150 mg tablet, capsule*</li> </ul>	<ul style="list-style-type: none"> <li>• Doxycycline hyclate delayed release 75mg, 100mg, 150mg, 200mg tablets*</li> <li>• Doxycycline hyclate delayed release 40 mg capsules*</li> <li>• Doxycycline monohydrate 75 mg capsule*</li> </ul>

\*Indicates a formulary status change approved at the November P&T Committee meeting.

## New Prior Authorization Additions

Passport Health Plan will require prior authorization review for the following medications, effective **February 4, 2019**.

- Actimmune®
- Arcalyst®
- Prolastin®-C
- Cystagon®
- Cystaran™
- Aralast
- Zemaira®

## Formulary Changes

Please note the following formulary changes that were approved at the November 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 **February 4, 2019**, unless otherwise noted.

PRODUCT	NEW FORMULARY STATUS
<b>TOPICAL CORTICOSTEROIDS</b>	
Flurandrenolide 0.05% cream, lotion, ointment	Non-Formulary
Cordran® (flurandrenolide) 4 mcg/cm tape	Non-Formulary
Diflorasone diacetate 0.05% cream	Non-Formulary

PRODUCT	NEW FORMULARY STATUS
Diflorasone diacetate 0.05% ointment	Non-Formulary
<b>ANTIPSORIATICS</b>	
Calcitriol 3 mcg/gm ointment	Non-Formulary
Calcipotriene 0.005% solution	Tier 1 (preferred) with QL of 60 ml/30 days
Calcipotriene 0.005% ointment	Tier 1 (preferred) with QL of 120 grams/30 days
Calcipotriene 0.005% cream	Tier 1 (preferred) with PA and QL of 120 grams/30 days
Calcipotriene-betamethasone dipropionate ointment 0.005-0.064%	Tier 1 (preferred) with QL of 60 grams/30 days
<b>POSITIVE FORMULARY CHANGES – EFFECTIVE IMMEDIATELY</b>	
Steglatro™	Tier 2 (preferred) with ST
Segluromet™	Tier 2 (preferred) with ST
Trulance®	Tier 2 (preferred)
Xeljanz®	Tier 2 (preferred) with PA
Siliq™	Tier 2 (preferred) with PA
Oxytrol® Patch (OTC)	Tier 2 (preferred) with QL of 8 patches / 28 days

## The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications in November 2018

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Mektovi®	binimetinib	In combination with encorafenib (Braftovi™), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	Tafinlar® (P) Mekinist® (P) Cotellic® (P) Zelboraf® (P)	Preferred with PA and QL
Braftovi™	encorafenib	In combination with binimetinib (Mektovi®) for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	Tafinlar® (P) Mekinist® (P) Cotellic® (P) Zelboraf® (P)	Preferred with PA and QL
Copiktra™	duvelisib	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies	Imbruvica® (P) Zydelig® (P)	Preferred with PA and QL

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Vizimpro®	dacomitinib	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test	Tarceva® (P) Iressa® (P) Gilotrif® (P) Tagrisso® (P)	Preferred with PA and QL
Tibsovo®	ivosidenib	To treat patients with refractory acute myeloid leukemia who also have an IDH1 mutation	Mitoxantrone (G) Cytarabine (G) Daunorubicin (G) Idarubicin (G)	Preferred with PA and QL
Epidiolex®	cannabidiol	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older	N/A	Preferred with PA
Diacomit®	stiripentol	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking Onfi® (clobazam)	N/A	Preferred with PA and QL
Ajovy™	fremanezumab-vfrm	Preventative treatment of migraine in adults	Aimovig™ (NP) Emgality™ (NP)	Non-preferred with PA and QL
Emgality™	galcanezumab-gnlm	Preventative treatment of migraine in adults	Aimovig™ (NP) Ajovy™ (NP)	Non-preferred with PA and QL
Olumiant®	baricitinib	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies	Xeljanz® (P) Xeljanz® XR (P)	Non-preferred with PA and QL
Orilissa™	elagolix	Management of moderate to severe pain associated with endometriosis	Danazol (G) Lupron® (P) Synarel® (NP) Norethindrone (G) Depo-Provera® (P)	Non-preferred with PA and QL
Galafold™	migalasta	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant	Fabrazyme® (P)	Preferred with PA and QL
Mulpleta®	lusutrombopag	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	Doptelet® (P)	Preferred with PA and QL
TPOXX®	tecovirimat	Treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg	N/A	Non-formulary with QL
Krintafel	tafenoquine	Malaria prophylaxis - Radical cure (prevention of relapse) of Plasmodium vivax malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection.	Primaquine (NP)	Non-preferred with PA and QL

BRAND NAME	GENERIC NAME	INDICATIONS	FORMULARY ALTERNATIVES	PASSPORT HEALTH PLAN STATUS
Pifeltro™	doravirine	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history	Efavirenz (G) Intelence™ (P) Edurant® (P) Nevirapine (G) Rescriptor® (P) Viramune® (NP) Viramune XR® (P)	Preferred with QL
Delstrigo™	doravirine/lamivudine/tenofovir	For the treatment of HIV-1 infections in adult patients with no prior antiretroviral treatment history	Atripla® (P) Complera® (P) Odefsey® (P)	Preferred with QL
Tahkzyro™	lanadelumab-flyo	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years of age and older	Cinryze® (P) Haegarda® (P)	Preferred with QL
Xofluza™	baloxavir marboxil	Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours	Oseltamivir (G) Relenza® (P)	Preferred with 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](http://www.passporthealthplan.com) or call Pharmacy Services at 844-380-8831.

## New Generics\*

GENERIC NAME	BRAND NAME	AVAILABLE	FORMULARY STATUS
Desoximetasone spray 0.25%	Topicort®	7/27/18	Tier 1 with PA
Succinylcholine chloride injection 20 mg/ml	Quelicin™	7/27/18	Tier 1 with PA
Crotamiton lotion 10%	Eurax	7/27/18	Tier 1 with PA
Dorzolamide HCl-timolol maleate PF ophthalmic solution	Cosopt® PF	8/3/18	Tier 1 with ST
Loratadine 5 mg chewable tablet	Claritin®	8/3/18	Tier 1 with Age Edit and QL
Dexamethasone tablet therapy pack (multiple strengths)	DexPak® (multiple strengths)	8/3/18	Tier 1 with PA
Urea cream 47%	Keralac®	8/10/18	Tier 1 with PA
Tadalafil 20 mg tablet	Adcirca®	8/17/18	Tier 1 with PA and QL
Nevirapine 50 mg/5 ml suspension	Viramune®	8/17/18	Tier 1 with QL
Imiquimod cream 3.75%	Zyclara® Pump	8/24/18	Tier 1 with PA
Dalfampridine ER 12-hour 10 mg tablet	Ampyra®	9/14/18	T1 with PA and QL
Itraconazole 10 mg/ml oral solution	Sporanox®	9/21/18	Tier 1 with QL
Albendazole 200 mg tablet	Albenza®	9/28/18	Tier 1
Lactulose 10 gram oral crystal packet	Kristalose®	9/28/18	Tier 1 with PA
Morphine sulfate ER 40 mg capsule	Kadian®	9/28/18	Tier 1 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](http://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

## Coordination of Benefits Change

Primary	Secondary
RXBIN: 004336	RXBIN: 012114
RXPCN: MEDDADV	RXPCN: ADV
RXGRP: RX8627	RXGRP: RX3218

Passport Health Plan is an existing plan sponsor with CVS Caremark®. Effective January 1, 2019, Passport will make changes to how Coordination of Benefits are processed. Currently, pharmacies only need to submit one transaction and CVS Caremark automatically processes the claim to secondary and returns the final response. Effective January 1, 2019, pharmacies will need to submit two separate transactions.

Please use the information below to assist with claims processing:

IF THE PRIMARY IS...	IF THE SECONDARY IS...	RXBIN	RXPCN	RXGRP	OTHER COVERAGE CODE
Medicare Part D Plan*	Medicaid	012114	COBADV	RX3218	03.08
Commercial Insurance Plan	Medicaid	013089	COMSEGADV	RX6432	03.08

CODE	DESCRIPTION
03	Claim Not Covered: Indicates secondary coverage; primary plan denied or rejected the claim.
08	Claim Billing for Copay: Indicates secondary coverage; primary claim pays part of the claim and plan member has a copay.

\*Member may have other Medicare Part D coverage. Please submit to primary using the information provided on member's ID card.

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

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The FDA recently issued the following advisories:

### **September 13, 2018: Roche Diagnostics Recalls CoaguChek® XS PT Test Strips Due to Inaccurate INR Test Results**

CoaguChek® XS PT 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: [https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm624822.htm?utm\\_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20CoaguChek%20XS%20PT%20Test%20Strips%20by%20Roche%20Diagnostics&utm\\_medium=email&utm\\_source=Eloqua](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm624822.htm?utm_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20CoaguChek%20XS%20PT%20Test%20Strips%20by%20Roche%20Diagnostics&utm_medium=email&utm_source=Eloqua)

### **November 1, 2018: The FDA Warns Against the use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications: FDA Safety Communication**

The FDA is alerting patients and health care providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA and may not have the scientific or clinical evidence to support this use for most medications. Changing drug treatment based on the results from such a genetic test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient. Do not change or stop taking any medicine based on a report from a genetic test you took on your own. Discuss the results of the genetic test with your health care provider, including whether the medication label includes information on how to use genetic information to determine dosage, and whether your health care provider recommends changes to your treatment. Medicine should always be taken as prescribed by your health care provider. Be aware that most genetic tests that make claims about the effects of a specific medicine are not supported by enough scientific information or clinical evidence.

### **November 02, 2018: FDA alerts patients and health care professionals that some EpiPen® auto-injectors may not readily slide out of carrier tube**

FDA is alerting patients, caregivers and health care professionals that the labels attached to some EpiPen® 0.3mg and EpiPen Jr® 0.15mg auto-injectors, and the authorized generic versions, may block access to the auto-injector and prevent the ability to access the product easily. It is vital for lifesaving products to work as designed in an emergency, and patients and caregivers should inspect their epinephrine auto-injector prior to needing it to ensure they can quickly access the product. The auto-injector device and the epinephrine it delivers are not affected by this issue and can be used as prescribed.

**November 2, 2018: Janssen Issues Voluntary Nationwide Recall for one lot of ORTHO-NOVUM® 1/35 and two lots of ORTHO-NOVUM® 7/7/7 Due to Incorrect Veridate® Dispenser Instructions**

The potential risk of taking ORTHO-NOVUM® without the appropriate instructions for correct use of the Veridate® dispenser pack is that the consumer could take the pills in the incorrect order (still receiving an effective dose) or could take an inactive “reminder” pill instead of an “active” pill which could lead to breakthrough bleeding or an unintended pregnancy. Consumers with ORTHO-NOVUM® product from the affected lots can access the correct instructions for the Veridate® dispenser pack at <https://www.janssen.com/us/our-products> and talk to their prescribing medical professional if they have any concerns. Consumers should not stop taking the product and if they do miss a dose, they should follow the instructions included in the packet.

**November 7, 2018: Kadesh Incorporation Issues Voluntary Nationwide Recall of Puriton® Eye Relief Drops Due to Non-Sterile Production Conditions**

Kadesh, Inc. of Garden Grove, CA is voluntarily recalling all lots of Puriton Eye Relief Drops, 0.5 oz. (15ml) bottle to the consumer level. During a recent FDA inspection, investigators observed that ophthalmic drugs, which are required to be sterile, are manufactured without necessary production controls and conditions to assure sterility. Use of a non-sterile eye drop is potentially vision-threatening due to the risk of an eye infection. This product is an over-the-counter homeopathic eye drop for the temporary relief of burning and irritation due to dryness of the eye and discomfort due to minor irritations of the eye or to exposure to wind or sun. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Adverse reactions or quality problems associated with the use of this product may be reported to FDA’s MedWatch Adverse Event Reporting program.

**November 27, 2018: Teva Pharmaceuticals USA Issues Voluntary Nationwide Recall of All Amlodipine/Valsartan Combination Tablets and Amlodipine/Valsartan/Hydrochlorothiazide Combination Tablets That Are Within Expiry**

Teva Pharmaceuticals has initiated a voluntary recall in the United States, to the patient level, of all lots of Amlodipine / Valsartan combination tablets and Amlodipine / Valsartan / Hydrochlorothiazide combination tablets due to an impurity detected above specification limits in an active pharmaceutical ingredient (API) manufactured by Mylan India. The impurity found in Mylan’s valsartan API is known as N-nitrosodiethylamine (NDEA), which has been classified as a probable human carcinogen. This chemical is typically found in very small amounts in certain foods, drinking water, air pollution, and certain industrial processes. A full list of the products and lot numbers affected can be found at: [https://www.fda.gov/Safety/Recalls/ucm626802.htm?utm\\_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20All%20Amlodipine%2FValsartan%20Combination%20Tablets&utm\\_medium=email&utm\\_source=Eloqua](https://www.fda.gov/Safety/Recalls/ucm626802.htm?utm_campaign=FDA%20MedWatch%20Recall%20Notice%20-%20All%20Amlodipine%2FValsartan%20Combination%20Tablets&utm_medium=email&utm_source=Eloqua).