PROVIDER *Update*

CalViva HEALTH

Health Net COMMUNITY SOLUTIONS

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Medication Trend Updates and Formulary Changes – 3rd Quarter 2018

This update includes information regarding the potential risk of neural tube birth defects associated with the active ingredient dolutegravir in Juluca,® Tivicay® and Triumeq,® and changes to the CalViva Health formulary for the third quarter of 2018.

POTENTIAL RISK OF NEURAL TUBE BIRTH DEFECTS ASSOCIATED WITH ACTIVE INGREDIENT DOLUTEGRAVIR IN JULUCA, TIVICAY AND TRIUMEQ

Serious cases of neural tube birth defects involving the brain, spine and spinal cord have been reported in babies born to women treated with dolutegravir used to treat HIV. Neural tube defects are birth defects that can occur early in pregnancy when the spinal cord, brain and related structures do not form properly. Approved in 2013, dolutegravir has been on the market for five years and is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medications under the brand names Juluca and Triumeq.

Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects. To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. The U.S. Food and Drug Administration (FDA) is investigating this new safety issue and will update the public when more information is available.

Patients should not stop taking dolutegravir without first talking to their health care professionals (HCPs). HCPs should weigh benefits and risks of the drug and inform women of childbearing age about the potential risk of neural tube defects when a dolutegravir-containing regimen is used at the time of conception and early in pregnancy. Alternative antiretroviral medications should be considered. If women of childbearing age continue to use dolutegravir, HCPs should reinforce the consistent use of effective birth control. Pregnancy testing should be performed before initiating a dolutegravir-containing regimen in women of childbearing age to exclude pregnancy.

For further information, visit the FDA's safety alerts page at: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm608168.htm.

THIS UPDATE APPLIES TO MEDI-CAL PROVIDERS:

- ● Physicians
- ● Participating Physician Groups
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PROVIDER SERVICES

1-888-893-1569
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CHANGES TO THE CALVIVA HEALTH FORMULARY

The Pharmacy and Therapeutics Committee, which comprises practicing physicians, pharmacists and other health care professionals, reviews the medications on the
CalViva Health formulary each quarter to determine which medications should remain on the formulary and which should be moved to a different status. A list of some recent changes is provided in the table below. The list contains prescription medications, their status, alternatives, and comments for the third quarter of 2018. The complete CalViva Health formulary and other pharmacy-related provider updates, revised prior authorization criteria and pharmacy forms are available at provider.healthnet.com under *Pharmacy Information*.

CALVIVA HEALTH FORMULARY CHANGES

Medication	Status	Formulary Alternative(s)	Comments
ORAL MEDICATIONS			
Bevyxxa® (betrixaban) capsule	F (QL)**	enoxaparin	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE Quantity limit is 42 capsules per 42 days. For Medicare, quantity limit is 1 capsule per day
Calquence® (acalabrutinib) capsule	F*, **		Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
Erleada™ (apalutamide) tablet	F*, **	bicalutamide (Casodex®),** flutamide	Treatment of patients with non-metastatic castration-resistant prostate cancer (CRPC)
Prevymis™ (letermovir) tablet	NF**	valacyclovir (Valtrex®) tablet	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
Verzenio® (abemaciclib) tablet	NF	anastrozole (Arimidex®), exemestane (Aromasin®), letrozole (Femara®), Fareston,® Ibrance®	In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
OPHTHALMIC PREPARATIONS			

Medication	Status	Formulary Alternative(s)	Comments
Vyzulta® (latanoprostene bunod) ophthalmic solution	NF**	latanoprost (Xalatan®), timolol (Timoptic®), brimonidine (Alphagan® P), dorzolamide (Trusopt®)	Reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
INJECTABLE PREPARATIONS			
Fasenra™ (benralizumab) prefilled syringe	F*, **	Inhaled corticosteroid: budenoside (Pulmicort), Aerospan,® Arnuity® Ellipta,® Asmanex,® Flovent,® Qvar® Long-acting beta agonist (LABA): Serevent® Combination products: fluticasone/ salmetrol (Airduo RespiClick®), Advair,® Breo Ellipta,® Dulera,® Symbicort® Leukotriene modifier: montelukast, zafirlukast	Add-on maintenance treatment of patients with severe asthma ages 12 and older, and with an eosinophilic phenotype Limitation(s) of use: Fasenra is not indicated for treatment of other eosinophilic conditions Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus
Hemlibra® (emicizumab-kxwh) vial	Medical benefit		Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors
Mepsevii™ (vestronidase alfa-vjbk) vial	Bill Medi-Cal Fee for Service directly		Treatment of mucopolysaccharidosis VII (MPS VII, Sly syndrome) in pediatric and adult patients Limitation(s) of use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined

Medication	Status	Formulary Alternative(s)	Comments
Ozempic® (semaglutide) prefilled pen	NF**	metformin GLP-1 receptor agonists: Adlyxin® *, **, Bydureon® *, **, Byetta,® Soliqua® *, **, Trulicity,® *, **, Victoza,® *, **, Xultophy® *, **	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Electronic step therapy (EST) requires a trial of metformin first For commercial line of business, coverage of Ozempric requires a trial of Victoza and Trulicity
INJECTABLE PREPARATIONS, CONTINUED			
Prevymis (letermovir) single-dose vial	Bill Medi-Cal Fee for Service directly	valacyclovir (Valtrex) tablet	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
THE FOLLOWING CHANGES TO THE FORMULARY ARE EFFECTIVE AS OF NOVEMBER 1, 2018			
Admelog®	F		Admelog is currently on the formulary; however it will be the preferred rapid-acting insulin for CalViva Health, effective as of November 1, 2018
Humalog®	NF	Admelog	Removed from formulary. Admelog is the preferred rapid-acting insulin
Apidra®	NF	Admelog	Removed from formulary. Admelog is the preferred rapid-acting insulin

*Prior authorization (PA) is required to verify member eligibility and that the member satisfies clinical protocols to ensure appropriate use of the medication.

**CCS = California Children's Services: Refer to www.dhcs.ca.gov for the local telephone number to determine member's coverage eligibility.

- F indicates formulary.
- NF indicates nonformulary.

ADDITIONAL INFORMATION

If you need additional information regarding the CalViva Health formulary, contact CalViva Health at 1-888-893-1569 or the pharmacy department by telephone at 1-800-867-6564, press #, or by fax at 1-800-977-8226.

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Summary Update: Medication Trend Updates and Formulary Changes – 3rd Quarter 2018

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A list of recent changes to the CalViva Health formulary is available in the complete provider update 18-584, *Medication Trend Updates and Formulary Changes – 3rd Quarter 2018*. The list contains brand-name prescription medications, status, alternatives, and comments. A complete listing of the formulary is available on the provider website at provider.healthnet.com by selecting *Pharmacy Information*.

ADDITIONAL INFORMATION

To obtain a comprehensive description of the above topics, the complete update, 18-584, is available on the provider website at provider.healthnet.com in the Provider Library under *Updates and Letters > 2018;* search for provider update 18-584. Providers who do not have access to the Internet may request a print copy of update 18-584 by contacting the Provider Communications Department by fax at 1-800-937-6086 or by email at provider.communications@healthnet.com.

If you need additional information regarding the CalViva Health formulary, contact CalViva Health at 1-888-893-1569 or the pharmacy department by telephone at 1-800-867-6564, press #, or by fax at 1-800-977-8226.

For the most current version of the formulary, visit the provider website at provider.healthnet.com > *Pharmacy Information* > *Drug Lists*.