PROVIDER *Update*

CalViva HEALTH

Health Net COMMUNITY SOLUTIONS

CONTRACTUAL | NOVEMBER 27, 2019 | UPDATE 19-917sum | 3 PAGES

Summary Update: Medication Trend Updates and *Preferred Drug List* Changes – 4th Quarter 2019

Review changes for oral, inhalable and injectable drugs

Stay up to date with information about:

- Requirements for brand-name overrides.
- Alternative sites for infusion care.
- A new boxed warning on Xeljanz® and Xeljanz XR®.
- Long-term use of proton pump inhibitors (PPIs).
- Changes to the CalViva Health Medi-Cal *Preferred Drug List* (formulary) for the fourth quarter of 2019.

Requirements for brand-name overrides

The health plan pharmacy benefits require generic medications to be used when a U.S. Food and Drug Administration (FDA)-approved generic version is available. The intent of this program is to promote utilization of appropriate generic alternatives as first-line therapies when medically appropriate.

CalViva Health Medi-Cal members may have different plan benefits for brand drugs used in place of generics. Some plans may allow the brand-name drug when medically necessary and when indicated on the prescription. Other plans will charge more for the brand version or require pre-approval for coverage.

To approve a brand-name drug, coverage requires the physician to provide medical necessity. Criteria for approval include:

- Has there been failure of an adequate trial or clinically significant adverse effects for at least two different generic manufacturers?
- A description of the unsatisfactory therapeutic response or clinically significant adverse drug reaction.

If clinically significant adverse reactions were experienced, a copy of the Form FDA 3500 that was submitted to MedWatch must be provided. Form FDA 3500 may be used by health professionals or consumers for voluntary reporting of adverse events, product use errors, product quality problems, and therapeutic failures. The form is available at www.fda.gov/media/76299/download.

A manufacturer's copay card or coupon is not a medical necessity. Members cannot use a copay card or manufacturer's coupon when a lower cost generic is available, with some

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- ● Physicians
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exceptions. See Health and Safety Code SECTION 1. Division 114 (commencing with Section 132000).

Prior authorization may be granted after the above medical necessity information has been approved. Some members may still have to pay an additional amount over their normal copay.

Note, many pharmaceutical companies are providing authorized generics. Authorized generics are the brand company's own product repackaged and marketed as a generic drug either through a subsidiary or a third party. **An authorized generic is a brand-name drug**, already approved as a New Drug Application (NDA) by the FDA, and marketed as a generic product under a private label.

Alternative sites of infusion care

The plan always looks for ways to help our members better manage and obtain medication therapies. Patients being treated with any of the infusion products listed in the below table of products eligible for an alternate site of infusion care have the option to transition infusions from the hospital to the home or an ambulatory infusion suite (AIS). Alternate site of infusion care is part of a member's standard benefits.

Health Net,* on behalf of CalViva Health, has partnered with Coram® CVS Specialty™ Infusion Services as the designated provider for these infusions. Coram provides:

- **Experience.** More than 30 years of experience in specialized infusion care and demonstrated expertise in the delivery and administration of complex specialty infused medications.
- **Safety.** Clinicians are certified and specialize in delivery of chronic and complex drug therapy and careful patient monitoring. Experienced nurses stay for the entire infusion duration ensuring patients receive high-level care.
- **Convenience.** In-home and AIS-based infusions are scheduled directly with patients, enabling flexibility, independence and enhanced quality of life. Clinical support is available to patients 24 hours a day, seven days a week.
- **Lower cost.** Infusions may be provided at a lower cost to patients promoting compliance to therapy and ultimately improve outcomes and reduce health costs.

For patient referrals or additional information, contact Peter Tran, PharmD, at (714) 934-3362, Monday through Friday, from 9:00 a.m. to 4:00 p.m., and reference the Site of Care Optimization of Therapeutic Infusion (SCOTI) Program.

The following table lists products eligible for alternate site of infusion care.

Products eligible for alternate site of infusion care

Disorder	Product	Disorder	Product
Alpha-1 antitrypsin deficiency	Aralast™ NP	Immune deficiencies and related conditions	Bivigam®
	Glassia®		Carimune® NF
	Prolastin®-C		Cuvitru®
	Zemaira®		Cytogam®
Asthma	Cinqair®		Flebogamma® Dif
Autoimmune	Actemra®		Gammagard® liquid
	Cimzia® lyophilized powder		Gammagard® S/D
	Entyvio®		Gammaked™
	Inflectra®		Gammaplex®
	Orencia®		Gamunex®-C
	Remicade®		Hyqvia®
	Renflexis®		Hizentra®
	Rituxan®		Octagam®
	Simponi Aria®		Privigen®
	Stelara®	Lysosomal storage	Aldurazyme®
Gout	Krystexxa®		Cerezyme®
Hereditary angioedema	Berinert®		Elaprase®
	Cinryze®		Elelyso®
	Kalbitor®		Fabrazyme®

Products eligible for alternate site of infusion care, continued

Disorder	Product	Disorder	Product
Hereditary angioedema	Ruconest®	Lysosomal storage	Kanuma®
Movement	Radicava®		Lumizyme®
Multiple sclerosis	Lemtrada®		Naglazyme®
	Ocrevus®		Vimizim®
	Tysabri®		Vpriv®
Paroxysmal nocturnal hemoglobinuria	Soliris®	Systemic lupus erythematosus	Benlysta®

New boxed warning on Xeljanz and Xeljanz XR

On July 26, 2019, the FDA approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of Xeljanz and Xeljanz XR (tofacitinib) for patients with ulcerative colitis (UC). The 10 mg twice daily dose of tofacitinib is not approved for rheumatoid arthritis (RA) or psoriatic arthritis (PsA). This dose is only approved for UC for initial treatment and for long-term use in limited situations. While the cardiovascular risks showed up in RA patients taking the 10 mg dose in a post-marketing study, these risks may also apply to those taking tofacitinib for UC.

Please discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Counsel patients about the risks and advise them to seek medical attention immediately if they experience any unusual symptoms. Symptoms include sudden shortness of breath, chest pain that worsens with breathing, swelling of a leg or arm, leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm. Tofacitinib used for UC should be reserved in patients who have had inadequate response or who are intolerant to tumor necrosis factor (TNF) blockers. Tofacitinib should be avoided in patients who may have a higher risk of thrombosis. For the treatment of UC, use tofacitinib at the lowest effective dose and limit the use of the 10 mg twice daily dosage to the shortest duration needed.

Reference: FDA Drug Safety and Availability on Xeljanz and Xeljanz XR.

Long-term use of proton pump inhibitors

Proton pump inhibitors (PPIs) are widely used to prevent and treat various gastroesophageal-related conditions. Although generally considered safe and proven to be effective, long-term use may result in uncommon but serious adverse effects including increased risk of kidney disease, hypomagnesemia, Clostridium difficile-associated diarrhea, vitamin B12 deficiency, and fractures. According to the American Gastroenterological Association (AGA), the dose of long-term PPIs should be periodically reevaluated so that the lowest effective PPI dose can be prescribed to manage the condition. When appropriately indicated, consider decreasing to a lower dose or stop and use on-demand strategies in addition to lifestyle modifications. Patients should also have a follow-up appointment after each de-prescribing step to assess symptoms.

Patients with the following diagnoses should continue long-term use of PPIs, as the benefits of treatment outweigh the risks:

- Barrett's esophagus
- Chronic non-steroidal anti-inflammatory (NSAIDs) use
- Severe esophagitis
- History of bleeding gastrointestinal (GI) ulcer

CalViva Health Medi-Cal *Preferred Drug List* changes

A list of recent changes to the CalViva Health Medi-Cal *PDL* is available in the complete provider update 19-917, *Medication Trend Updates and Preferred Drug List Changes – 4th Quarter 2019*. The list contains brand-name prescription medications, status, alternatives, and comments. A complete CalViva Health Medi-Cal *Preferred Drug List* is available on the provider website at provider.healthnet.com under *Pharmacy Information*.

To obtain a comprehensive description of the above topics, the complete update, 19-917, is available on the provider website at provider.healthnet.com in the Provider Library under *Updates and Letters > 2019*; search for provider update 19-917. You may request a print copy of update 19-917 by contacting the Provider Communications Department by email at provider.communications@healthnet.com.

If you need additional information regarding the CalViva Health Medi-Cal *Preferred Drug List,* contact the Pharmacy Department by telephone at 1-800-867-6564, press option #2, or by fax at 1-800-977-8226. For all other questions contact CalViva Health at 1-888-893-1569.

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Asthma	Cinqair®		Flebogamma® Dif
Autoimmune	Actemra®		Gammagard® liquid
	Cimzia® lyophilized powder		Gammagard® S/D
	Entyvio®		Gammaked™
	Inflectra®		Gammaplex®
	Orencia®		Gamunex®-C
	Remicade®		Hyqvia®
	Renflexis®		Hizentra®
	Rituxan®		Octagam®
	Simponi Aria®		Privigen®
	Stelara®	Lysosomal storage	Aldurazyme®
Gout	Krystexxa®		Cerezyme®
Hereditary angioedema	Berinert®		Elaprase®
	Cinryze®		Elelyso®
	Kalbitor®		Fabrazyme®

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Resources for more information:

- deprescribing.org/resources/deprescribing-patient-decision-aids/
- gastro.org/press-release/aga-releases-best-practice-advice-on-long-term-ppi-use
- uspharmacist.com/article/proton-pump-inhibitors-considerations-with-long-term-use

CalViva Health Medi-Cal *Preferred Drug List* changes

The Pharmacy and Therapeutics (P&T) Committee, which includes practicing physicians, pharmacists and other health care professionals, reviews medications on the CalViva Health Medi-Cal *Preferred Drug List* each quarter to determine medications to stay on or be moved to a different status. A list of some recent changes is provided in the table beginning on page 4. A complete CalViva Health Medi-Cal *Preferred Drug List* is available on the provider website at provider.healthnet.com under *Pharmacy Information*.

CalViva Health Medi-Cal *Preferred Drug List* changes

Medication	Status	Formulary alternative(s)	Comments
Oral medications			
Balversa® (erdafitinib) tablet	NF		Treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has: • Susceptible fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations and • Progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
Diacomit® (stiripentol) capsule and powder for oral suspension	NF	clonazepam, ethosuximide (Zarontin®), levetiracetam (Keppra®), phenobarbital, topiramate (Topamax®), valproic acid** (Depakene®), divalproex sodium (Depakote®), zonisamide (Zonegran®)	Treatment of seizures associated with Dravet syndrome in patients ages 2 and older taking clobazam For commercial, quantity limit is 6 per day (for 500 mg capsule) and 12 per day (for 250 mg capsule).
Mavenclad® (cladribine) tablet	NF	Oral formulation: Gilenya™*,**, Tecfidera®*,** Injectable formulation: glatiramer (Copaxone)*,**, Glatopa*,**, Avonex®*, Plegridy®*,**	Mavenclad is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitation(s) of use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Motegrity™ (prucalopride) tablet	NF	Bulk-forming laxative [e.g., psyllium (Metamucil®), methylcellulose powder (Citrucel®), calcium polycarbophil (FiberCon®)] stimulant laxative (e.g., bisacodyl) polyethylene glycol (MiraLax)	Treatment of chronic idiopathic constipation (CIC) in adults

Medication	Status	Formulary alternative(s)	Comments
Inhalation preparations			
Yupelri™ (revefenacin) nebulized vial	NF	Long-acting muscarinic antagonists (LAMAs): Incruse® Ellipta,® Spiriva® HandiHaler®, Spiriva Respimat®, Tudorza® Pressair® Long-acting beta agonists (LABAs): Serevent® Diskus®, Striverdi® Respimat	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). For commercial, quantity limit is 3 ml per day.
Injectable preparations			
Cablivi® (caplacizumab-yhdp) single-dose vial	NF		Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy
Epogen® (epoetin alfa) vial	F	Retacrit	Retacrit is now preferred Effective as of January 1, 2020, Epogen will be nonformulary
Procrit® (epoetin alfa) vial	F	Retacrit	Retacrit is now preferred Effective as of January 1, 2020, Procrit will be nonformulary
Retacrit™ (epoetin alfa-epbx) single-dose vial	F		Retacrit is now preferred
Zolgensma® (onasemnogene abeparvovec-xioi) infusion kit	Medical benefit*	Spinraza®*, **	Treatment of pediatric patients less than age 2 with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. Limitation of use: • The safety and effectiveness of repeat administration of Zolgensma have not been evaluated. • The use of Zolgensma in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.

Medication	Status	Formulary alternative(s)	Comments
Zulresso™ (brexanolone) single-dose vial	Medical benefit*	Selective serotonin reuptake inhibitor (SSRI): citalopram, escitalopram, fluoxetine, paroxetine, sertraline Serotonin-norepinephrine reuptake inhibitor (SNRI): duloxetine, venlafaxine, desvenlafaxine Tricyclic antidepressant (TCA): amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline Other antidepressants: buproprion, mirtazapine	Treatment of postpartum depression (PPD) in adults

*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.gov for the local telephone number to determine member's coverage eligibility.

- F indicates formulary.
- NF indicates nonformulary. These medications require member-specific medical reasons why formulary medications cannot be considered. Requests are reviewed via the plan's prior authorization process.

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