Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q1 2022

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The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Pharmacy Director Anne Freese, at afreese@goldchp.org or 1-805-437-5652.

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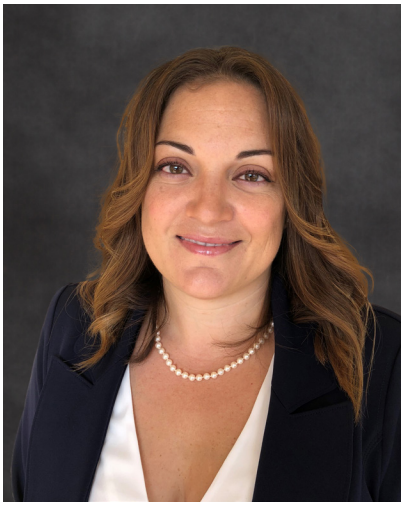
A Message from the Gold Coast Health Plan Pharmacy Director



Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to GCHP's formulary, new drug approvals, and safety labeling changes.

Our goal is to provide all medically necessary pharmaceuticals in the most economical way possible. GCHP's formulary was developed by the Pharmacy & Therapeutics (P & T) Committee. It is reviewed and updated quarterly due to advances in therapeutic treatment regimens and newly-approved products by the U.S. Food and Drug Administration (FDA).

We want to ensure that all drugs are available to our members when the drugs are indicated. To help manage drug utilization, the formulary employs several mechanisms: Step therapy protocols, prior authorizations, quantity limits, and age restrictions. Any drug that is limited or is not listed may be available via prior authorization.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and our members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me.

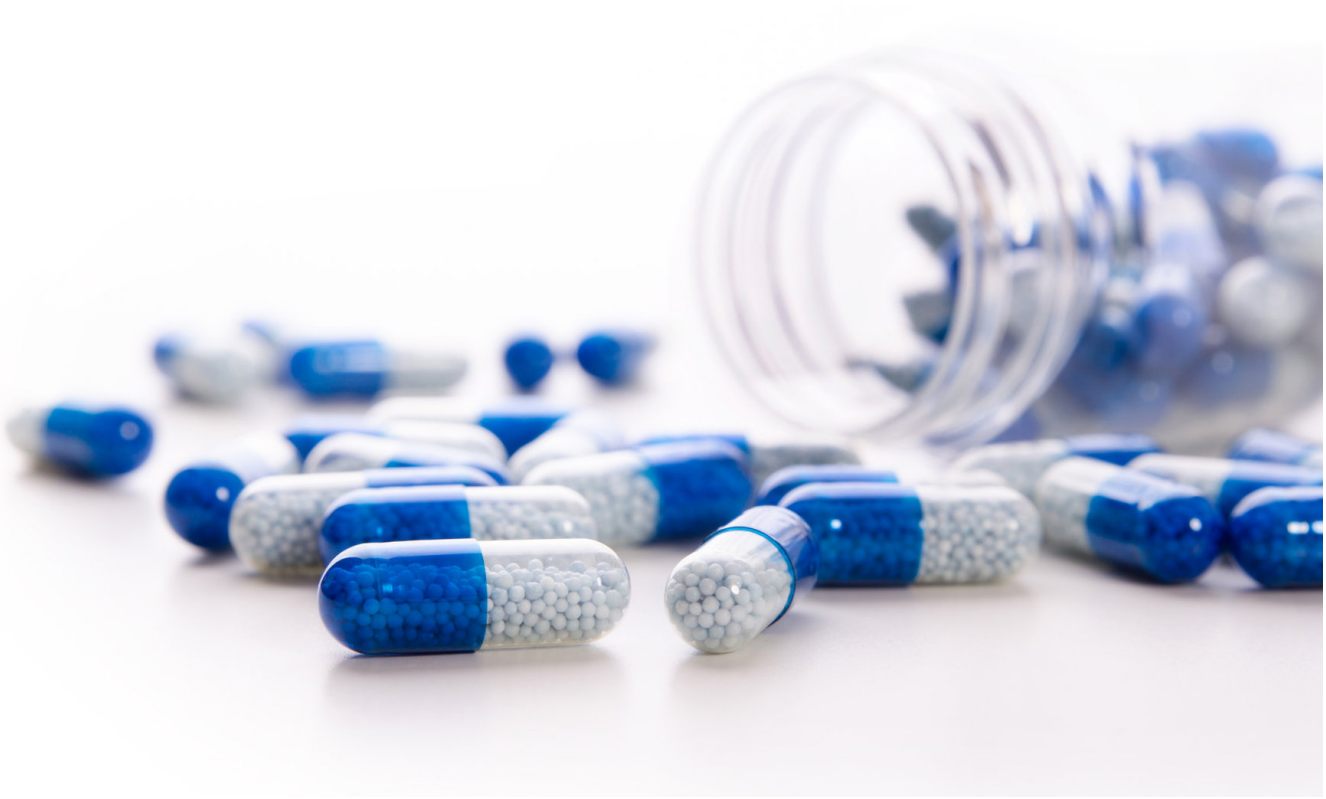
Sincerely,

Anne Freese, Pharm.D.
Director of Pharmacy

Medi-Cal Rx Update

Starting Jan. 1, 2022, the state Department of Health Care Services (DHCS) will carve out all prescription benefits from Managed Care Plans (MCP) under a new program called Medi-Cal Rx. Upon implementation, all pharmacy claims will be submitted directly to the state via its pharmacy benefit manager (PBM), Magellan Medicaid Administration, Inc.

The DHCS Medi-Cal Rx website contains the most accurate, up-to-date information regarding Medi-Cal Rx. The website includes an overview and background information, frequently asked questions (FAQs), preliminary information regarding the transition policy and a high-level overview of the training and communication schedule. It will also serve as a member and provider portal and will be instrumental in the prior authorization process. Please make sure to bookmark this website and sign up for the Medi-Cal Rx Subscription Services (MCRxSS).



FDA Alerts

FDA New Drug Approvals

This information is a list of new drugs approved by the FDA. This is only a subset of all drugs that were approved and include all first-time approvals and any other significant drug approvals. Click here to access the FDA's website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
TAVNEOS	*Avacopan*	Oral capsule	Complement 5a receptor (C5AR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [granulomatosis with Polyangiitis (GPA) and microscopic polyangiitis (MPA)] in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.
TIVDAK	*Tisotumab vedotin-tftv*	Injectable	Tissue factor-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
LOREEV XR	*Lorazepam*	Oral capsule, extended release	Benzodiazepine for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets.
TRUDHESA	*Dihydroergotamine mesylate*	Nasal spray	Ergotamine derivative indicated for the acute treatment of migraines with or without aura in adults.
SERTRALINE HYDROCHLORIDE	*Sertraline hydrochloride*	Oral capsule	Selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of major depressive disorder (MDD) in adults, obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years of age and older.
EXKIVITY	*Mobocertinib succinate*	Oral capsule	Kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
OPZELURA	*Ruxolitinib phosphate*	Topical cream	Indicated for the short-term and non-continuous chronic treatment of mild-to-moderate atopic dermatitis in nonimmunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
QULIPTA	*Atogepant*	Oral tablet	Calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.
LIVMARLI	*Maralixibat chloride*	Oral solution	Ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with alagille syndrome (ALGS) 1 year of age and older.
TYRVAYA	*Varenicline tartrate*	Nasal solution	Cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease.
SITAGLIPTIN	*Sitagliptin*	Oral tablet	Anti-diabetic adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
BYOOVIZ	*Ranibizumab-nuna*	Injectable	Vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with: • Neovascular (wet) age-related macular degeneration (AMD). • Macular edema following retinal vein occlusion (RVO). • Myopic choroidal neovascularization (MCNV).
ZIMHI	*Naloxone hydrochloride*	Intramuscular, subcutaneous solution	Opioid antagonist indicated in adult and pediatric patients for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
SEGLENTIS	*Celecoxib; tramadol hydrochloride*	Oral tablet	Tramadol hydrochloride, an opioid agonist, and celecoxib, a nonsteroidal anti-inflammatory drug, for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
TASCENSO ODT	*Fingolimod lauryl sulfate*	Orally disintegrating tablet	
XIPERE	*Triamcinolone acetonide*	Injectable suspension	Corticosteroid indicated for the treatment of macular edema associated with uveitis.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SUSVIMO	*Ranobizumab*	Injectable	Vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a vegf inhibitor.
VUITY	*Pilocarpine hydrochloride*	Ophthalmic solution/drops	Cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults.
SCEMBLIX	*Asciminib hydrochloride*	Oral tablet	Kinase inhibitor indicated for the treatment of adult patients with: • Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIS). • Ph+ CML in CP with the t315i mutation.
DYANAVEL XR	*Amphetamine*	Extended release; oral tablet	Central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age and older.
EPRONTIA	*Topiramate*	Oral solution	Anticonvulsant and nerve pain medication indicated for: • Monotherapy epilepsy: initial monotherapy for the treatment of partial-onset or primary generalized tonic-colonic seizures in patients 2 years of age or older. • Adjunctive therapy epilepsy: adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-colonic seizures, and seizures associated with lennox-gastuat syndrome in patients 2 years of age or older. • Migraine: preventive treatment of migraines in patients 12 years of age and older.
DHIVY	*Carbidopa;levodopa*	Oral tablet	Combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.
BESREMI	*Ropeginterferon alfa-2b-njft*	Subcutaneous injectable	Interferon alfa-2b indicated for the treatment of adults with polycythemia vera.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
VOXZOGO	*Vosoritide*	Injectable	C-type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses.
FYARRO	*Sirolimus albumin-bound nanoparticles*	Intravenous powder	mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (pecoma).
LYVISPAH	*Baclofen*	Oral granule	Gamma-aminobutyric acid (gaba-ergic) agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
LIVTENCITY	*Maribavir*	Oral tablet	Antiviral for the treatment of adults and pediatric patients 12 years of age and older and weighing at least 35 kg with post-transplant cytomegalovirus (CMV) infection / disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.
CYTALUX	*Pafolacianine*	Injectable	Optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions.

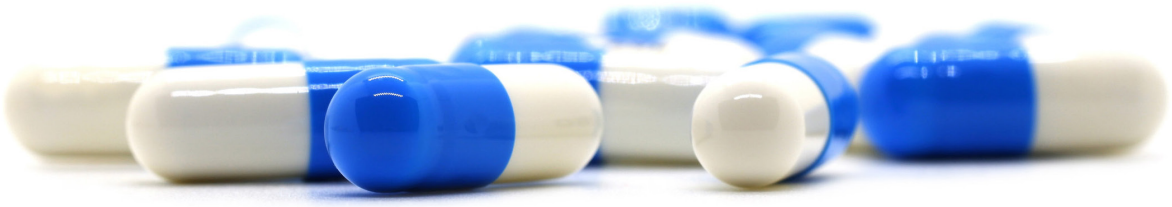
FDA Safety Labeling Changes

This section includes new safety labeling changes or updated boxed warnings or contraindications. Click here to access this information on the FDA's website.

Drug	Type of Change	Change
INVEGA TRINZA *(paliperidone palmitate)*	Boxed Warning	WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. INVEGA HAFYERA is not approved for use in patients with dementia-related psychosis.

Drug	Type of Change	Change
ERLEADA *(apalutamide)*	Contraindications	**Cerebrovascular and Ischemic Cardiovascular Events** Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA for Grade 3 and 4 events. In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic, cardiovascular events occurred in 4.4% of patients treated with ERLEADA and 1.5% of patients treated with placebo. Across the SPARTAN and TITAN studies, four patients (0.3%) treated with ERLEADA, and two patients (0.2%) treated with placebo died from an ischemic cardiovascular event. In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, three patients (0.2%) treated with ERLEADA, and two patients (0.2%) treated with placebo died from a cerebrovascular event. **Fractures** Fractures occurred in patients receiving ERLEADA. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents. In a randomized study (SPARTAN) of patients with non-metastatic castration-resistant prostate cancer, fractures occurred in 12% of patients treated with ERLEADA and in 7% of patients treated with placebo. Grade 3-4 fractures occurred in 2.7% of patients treated with ERLEADA and in 0.8% of patients treated with placebo. The median time to onset of fracture was 314 days (range: 20 to 953 days) for patients treated with ERLEADA. Routine bone density assessment and treatment of osteoporosis with bone-targeted agents were not performed in the SPARTAN study. In a randomized study (TITAN) of patients with metastatic castration-sensitive prostate cancer, fractures occurred in 9% of patients treated with ERLEADA and in 6% of patients treated with placebo. Grade 3-4 fractures were similar in both arms at 1.5%.
AVSOLA *(infliximab-axxq)*	Contraindications	The use of AVSOLA at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure AVSOLA is contraindicated in patients with a previous severe hypersensitivity reaction to infliximab products or any of the inactive ingredients of AVSOLA or any murine proteins (severe hypersensitivity reactions have included anaphylaxis, hypotension, and serum sickness).

Drug	Type of Change	Change
ADEMPAS *(riociguat)*	Contraindications	Adempas is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators
SEGLUROMET *(ertugliflozin; metformin hydrochloride)* STEGLATRO *(ertugliflozin)* STEGLUJAN *(ertugliflozin; sitagliptin phosphate)*	Contraindications	Ertugliflozin is contraindicated in patients with: • Hypersensitivity to etrugliflozin. Reactions such as angioedema or anaphylaxis have occurred. • Patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m2), end stage-renal disease (ESRD), or who are on dialysis.
FORANE *(isoflurane)*	Contraindications	Isoflurane is contraindicated in patients: • In whom general anesthesia is contraindicated. • With known sensitivity to FORANE or to other halogenated agents. • With known or suspected genetic susceptibility to malignant hyperthermia. • With a history of confirmed hepatitis due to a halogenated inhalational anesthetic or a history of unexplained moderate to severe hepatic dysfunction (e.g., jaundice associated with fever and/or eosinophilia) after anesthesia with isoflurane or other halogenated inhalational anesthetics.
PHOSPHOLINE IODIDE *(echothiophate iodide)*	Contraindications	• Active uveal inflammation. • Most cases of angle-closure glaucoma without iridectomy, due to the possibility of increasing angle block. • Hypersensitivity to the active or inactive ingredients.
CLIMARA PRO *(estradiol; levonorgestrel)*	Contraindications	ESTRADIOL is contraindicated in women with any of the following conditions: • Undiagnosed abnormal genital bleeding. • Breast cancer or history of breast cancer. • Estrogen-dependent neoplasia. • Active DVT, PE or a history of these conditions. • Active arterial thromboembolic disease (for example, stroke or MI), or a history of these conditions. • Known anaphylactic reaction, or angioedema, or hypersensitivity to CLIMARA PRO. • Hepatic impairment or disease, protein C, protein S, or antithrombin deficiency, or other thrombophilic disorders.



Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Priftin *(rifapentine)* oral tablet 150 mg	Sanofi-Aventis	Sanofi-Aventis did not provide a reason for the shortage. There is insufficient supply for usual ordering. **Estimated Resupply Dates** Sanofi-Aventis has Priftin on allocation.
Dicloxacillin sodium oral capsule 250 mg, 500 mg	Sandoz Teva	• Sandoz did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Sandoz has dicloxacillin sodium capsules on back order and the company cannot estimate a release date. • Teva has dicloxacillin sodium 250 mg capsules on back order and the company estimates a release date of mid-December 2021. The 500 mg capsules are on back order and the company estimates a release date in early-December 2021.
Nefazodone hydrochloride oral tablet 50 mg, 100 mg, 150 mg, 200 mg, 250 mg	Teva	Teva has nefazodone on shortage due to raw ingredient supply issues. They are the sole suppliers of nefazodone tablets. **Estimated Resupply Dates** Teva has all presentations temporarily unavailable, and the company estimates a release date of late-fourth quarter 2021 to first quarter 2022.
FML ophthalmic ointment	Allergan	Allergan did not provide a reason for the shortage. They are the sole suppliers of fluorometholone ointment. Fluorometholone ophthalmic suspension is not affected by this shortage. **Estimated Resupply Dates** Allergan has FML ophthalmic ointment on long-term back order and the company cannot estimate a release date.
Chantix *(Varenicline)* Oral tablets 0.5 mg, 1 mg, 0.5 mg / 1 mg	Pfizer	Pfizer has Chantix on shortage due to a manufacturing delay to evaluate the active ingredient of the product. Pfizer has recalled all presentations of Chantix. More information on the recall can be found here.

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For additional information, contact Pharmacy Relations at 888.531.0998.
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