Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

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Table of Contents

PN Q3 2022

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 related to the use of medications for GCHP members.

Our goal is to equip providers with the information necessary to safely prescribe medications and to ensure members have access to all necessary pharmaceutical services through Medi-Cal Rx. We are available to help any member or provider as needed.

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

Medi-Cal Rx will soon start reinstating its prior authorizations and other claim edits that were suspended in February. This reinstatement will begin in late summer. The state Department of Health Care Services (DHCS) has stated it will give, at minimum, a 30-day notice of the start of the reinstatement. It is expected that the reinstatement will occur over several phases over fall and winter 2022. Please look for additional information as it is released to ensure that you are up to date on the changes.

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. In the future, the website will serve as a member and provider portal, and will be instrumental in the prior authorization process. Please make sure to bookmark this website today and sign up for the Medi-Cal Rx Subscription Services (MCRxSS).

FDA Alerts

FDA New Drug Approvals

This 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
QUVIVIQ	*daridorexant hydrochloride*	Tablet; Oral	QUVIVIQ is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
RYALTRIS	*olopatadine hydrochloride and mometasone furoate monohydrate*	Spray, Metered; Nasal	Indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older.
DAPZURA RT	*daptomycin*	Powder; Intravenous	Complicated skin and skin structure infections (CSSSI) in adult and pediatric patients (1 to 17 years of age). • Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis. • Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).
KIMMTRAK	*tebentafusp-tebn*	Injectable; Injection	Indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
VABYSMO	*faricimab-svoa*	Injectable; Intravitreal	Indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (NAMD). • Diabetic Macular Edema (DME).
CITALOPRAM HYDROBROMIDE	*citalopram hydrobromide*	Capsule; Oral	For treatment of Major Depressive Disorder (MDD) in adults.
RUZURGI	*amifampridine*	Tablet; Oral	For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adult patients (patients 17 years of age or older) and in pediatric patients (patients 6 to less than 17 years of age).
FLEQSUVY	*baclofen*	Suspension; Oral	Indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. • FLEQSUVY may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ENJAYMO	*sutimlimab-jome*	Injectable; Injection	Indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).
PYRUKYND	*mitapivat sulfate*	Injectable; Injection	Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.
NEPHROSCAN	*technetium tc-99m succimer kit*	Tablet; Oral	Indicated for use as an aid in the scintigraphic evaluation of renal parenchymal disorders in adults and pediatric patients including term neonates.
NORLIQVA	*amlodipine*	Powder; Intravenous	For the treatment of: • Hypertension » Norliqva is indicated for the treatment of hypertension in adults and children 6 years of age and older to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Coronary artery disease » Chronic stable angina. » Vasospastic angina (prinzmetal's or variant angina). » Angiographically documented coronary artery disease in patients without heart failure or an ejection fraction <40%.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
RELEUKO	*filgrastim-ayow*	Injectable; Injection	Indicated to: • Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. • Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML). • Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). • Reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
VONJO	*pacritinib*	Capsule; Oral	For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L.
NALOXONE HYDROCHLORIDE	*naloxone hydrochloride*	Injectable; Injection	Indicated for use by military personnel and chemical incident responders for: • Emergency treatment of patients 12 years of age and older where use of high-potency opioids such as fentanyl analogues as a chemical weapon is suspected. • Temporary prophylaxis of respiratory and/or central nervous system depression in military personnel and chemical incident responders entering an area contaminated with high-potency opioids such as fentanyl analogues.
ASPRUZYO SPRINKLE	*ranolazine*	Granule; Extended Release	Indicated for the treatment of chronic angina.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ADLARITY	*donepezil hydrochloride*	System; Transdermal	Indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.
ATROPINE SULFATE	*atropine sulfate*	Solution; Ophthalmic	Indicated for: • Mydriasis. • Cycloplegia. • Penalization of the healthy eye in the treatment of amblyopia.
NASONEX 24HR ALLERGY	*mometasone furoate*	Spray, Metered; Nasal	Allergy symptom reliver.
ZTALMY	*ganaxolone*	Suspension; Oral	Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.
OPDUALAG	*nivolumab; relatlimab-rmbw*	Solution; Intravenous	Indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.
HYFTOR	*sirolimus*	Gel; Topical	Indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older
XELSTRYM	*dextroamphetamine*	System; Transdermal	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older.
PLUVICTO	*lutetium lu-177 vipivotide tetraxetan*	Solution; Intravenous	Indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (MCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.
TLANDO	*testosterone undecanoate*	Capsule; Oral	Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
TRIUMEQ PD	*abacavir sulfate; dolutegravir sodium; lamivudine*	Tablet, For Suspension; Oral	Indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
VIJOICE	*Ipelisib*	Tablet; Oral	Indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
IGALMI	*dexmedetomidine*	Film; Sublingual	Indicated in adults for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.
ALYMSYS	*bevacizumab-maly*	IV Infusion	Indicated for the treatment of: • Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. • Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidineoxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.

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
CEFEPIME AND DEXTROSE IN DUPLEX CONTAINER *(cefepime hydrochloride)*	Contraindications	**Hypersensitivity to CEFEPIME or the Cephalosporin Class of Antibacterials, Penicillins, or Other Beta-lactam Antibacterials** *Subsection title revised; Additions and/or revisions underlined:* CEFEPIME for Injection and Dextrose Injection is contraindicated in patients who have shown immediate hypersensitivity reactions to CEFEPIME or the cephalosporin class of antibacterial drugs, penicillins or other beta-lactam antibacterials.
EPIDUO FORTE *(adapalene;benzoyl peroxide)*	Contraindications	EPIDUO FORTE is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in EPIDUO FORTE.
OMNIPRED *(prednisolone acetate)*	Contraindications	OMNIPRED® (prednisolone acetate ophthalmic suspension) is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. OMNIPRED® (prednisolone acetate ophthalmic suspension) is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.
PREZCOBIX *(cobicistat; darunavir ethanolate)*	Contraindications	Darunavir and cobicistat are both inhibitors of the cytochrome P450 3A (CYP3A) isoform. PREZCOBIX should not be co-administered with medicinal products that are highly dependent on CYP3A for clearance and for which increased plasma concentrations are associated with serious and/or life threatening events (narrow therapeutic index). Darunavir and cobicistat are both substrates of the cytochrome P450 3A (CYP3A) isoform. Co-administration of PREZCOBIX with CYP3A inducers may lead to lower exposures of darunavir and cobicistat and potential loss of efficacy of darunavir and possible resistance.

Drug	Type of Change	Change
SOLARAZE *(diclofenac sodium)*	Boxed Warning / Contraindications	**WARNING: RISK OF SERIOUS CARDIOVASCULAR EVENTS AND GASTROINTESTINAL EVENTS** ***See full prescribing information for complete boxed warning.*** • **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.** • **SOLARAZE is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.** • **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.** SOLARAZE is contraindicated in the following patients: • With known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product. • With a history of asthma, urticaria, or other allergic type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. • Application on damaged skin resulting from any etiology, including exudative dermatitis, eczema, infected lesions, burns or wounds. • In the setting of coronary bypass graft (CABG) surgery.

Drug	Type of Change	Change
TRIPHASIL-21 *(ethinyl estradiol; levonorgestrel)* TRIPHASIL-28 *(ethinyl estradiol; levonorgestrel)* TWIRLA *(ethinyl estradiol; levonorgestrel)* TYBLUME *(ethinyl estradiol; levonorgestrel)* YASMIN *(drospirenone; ethinyl estradiol)* YAZ *(drospirenone; ethinyl estradiol)*	Contraindications	Contraindicated in females who are known to have or develop the following conditions: • Current diagnosis or history of breast cancer, which may be hormone sensitive.

Drug Shortages

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

Drug Product	Affected Manufacturers	Summary
Nizatidine capsule 150mg and 300 mg	Glenmark Mylan Teva	• Glenmark discontinued nizatidine capsules • Mylan discontinued nizatidine capsules. • Teva did not provide a reason for the shortage. **Estimated Resupply Date** • Teva has nizatidine capsules temporarily unavailable and the company cannot estimate a release date.
Doxercalciferol oral capsule	Winthrop	• Teva has nizatidine capsules temporarily unavailable and the company cannot estimate a release date. **Estimated Resupply Date** • Winthrop has 0.5 mcg and 2.5 mcg capsules on intermittent back order and the company is releasing supplies as they become available. The 1 mcg capsules are available with short expiration dating (< 12 months).
Bacitracin ophthalmic ointment	Padagis	• Padagis has temporarily discontinued bacitracin ophthalmic ointment. **Estimated Resupply Date** • Padagis has temporarily discontinued bacitracin 3.5 gram tubes and the company cannot estimate when product will return to market.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the Medi-Cal Rx prescription benefit. Click here to access this information on the FDA's website.

Drug	Communications Summary
Iodine-containing contrast media	The U.S. Food and Drug Administration (FDA) recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging children with underlying conditions and newborns at higher risk. Based on a recent review of published studies, the FDA is recommending that newborns and children through 3 years old have follow-up thyroid monitoring within three weeks after receiving injections of contrast media containing iodine, also called "contrast dye," for X-rays and other medical imaging procedures. Their review showed that underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon. However, the conditions should be identified and treated early when needed to prevent potential future complications. Newborns, particularly those born premature, and children in their first three years with underlying conditions, such as heart issues, may be at a higher risk for problems of the thyroid, a gland in the neck that releases hormones that help control many of the body's functions.

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For additional information, contact the
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