Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

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www.goldcoasthealthplan.org

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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 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

On Jan. 1, 2022, the state Department of Health Care Services (DHCS) carved out all prescription benefits from Managed Care Plans (MCP) under a new program called Medi-Cal Rx. All pharmacy claims are now submitted directly to DHCS via its pharmacy benefit administrator (PBA), 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), information regarding the transition policy and a high-level overview of the training and communication schedule. The website also serves as a member and provider portal and is instrumental in the prior authorization process. Make sure to bookmark this website and sign up for the Medi-Cal Rx Subscription Services (MCRxSS).

See below for additional information regarding the current status of the Medi-Cal Rx transition and how to help members:

Medi-Cal Rx Prescriber Office Hours
- Monday through Friday from 12 p.m. to 1 p.m., except holidays
- Zoom Link: Click here
- Provider assistance email: medicalrxeducationoutreach@magellanhealth.com

GCHP Pharmacy Department Contact Information
- Email: Pharmacy@goldchp.org
- Phone: 1-805-437-5738

Medi-Cal Rx Prior Authorization (PA) Backlog and Call Center Hold Times
- Medi-Cal Rx experienced long hold times and a PA backlog during January and February. This has been resolved.

PA Forms
- Medi-Cal Rx will only accept certain PA forms as noted on the Medi-Cal Rx website. These forms include:
  - Medi-Cal Rx Prior Authorization Request Form (DHCS 6560)
  - Treatment Authorization Request (TAR) Form 50-1
  - Treatment Authorization Request (TAR) Form 50-2
  - Prescription Drug Prior Authorization Request Form 61-211

Code 1 Restrictions
- Medi-Cal Rx requires that a pharmacy verify the diagnosis for the use of some drugs before it can be dispensed. This is similar to a prior authorization, but does not require that a form be sent to Medi-Cal Rx for approval. The pharmacy must verify the diagnosis and place the diagnosis and ICD-10 code in their system. All code 1 restrictions are noted on the Medi-Cal Rx Contract Drug List. To aid in this process and limit unnecessary calls, GCHP recommends that providers include the diagnosis for the use of medications in the following types of drugs (please note, this is not an exhaustive list):
  - Antineoplastics
  - ALS Agents
  - HIV Agents
  - Dementia / Alzheimer's Agents
  - ADD / ADHD Agents
  - GnRH Agents
  - Immunomodulators
  - Growth Hormone

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
TARPEYO	*Budesonide*	Oral capsule, delayed release	Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (igan) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.
DARTISLA ODT	*Glycopyrrolate*	Orally disintegrating tablet	Indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.
LANREOTIDE	*Lanreotide*	Injectable	Indicated for: • The long-term treatment of acromegalic patients who have had an inadequate response to, or cannot be treated with, surgery and/or radiotherapy. • The treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
OXBRYTA	*Voxelotor*	Oral tablet and oral suspension	Indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older.
VYVGART	*Efgartigimod alfa*	Injectable	Indicated for the treatment of generalized myasthenia gravis (gmg) in adult patients who are anti-acetylcholine receptor (achr) antibody positive.
TEZSPIRE	*Tezepelumabekko*	Subcutaneous solution	Indicated for the add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma.
APRETUDE	*Cabotegravir*	Intramuscular suspension, extended release	Indicated in at-risk adults and adolescents weighing at least 35 kg for prep to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 prep.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
XARELTO	*Rivaroxaban*	Oral suspension	Indicated: • To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation. • For treatment of deep vein thrombosis (DVT). • For treatment of pulmonary embolism (PE). • For reduction in the risk of recurrence of DVT or PE. • For the prophylaxis of DVT, which may lead to pe in patients undergoing knee or hip replacement surgery. • For prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients. • To reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD). • To reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD. • For treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years of age. • For thromboprophylaxis in pediatric patients 2 years of age and older with congenital heart disease after the Fontan procedure.
LEQVIO	*Inclisiran*	Injectable	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
ADBRY	*Tralokinumab*	Injectable	Indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
RECORLEV	*Levoketoconazole*	Oral tablet	For the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.
XACIATO	*Clindamycin phosphate*	Vaginal gel	Indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older.
ENTADFI	*Finasteride; tadalafil*	Oral capsule	Indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.
REZVOGLAR	*Insulin glargine-aglr*	Injectable	Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
YUSIMRY	*Adalimumab-aqvh*	Injectable	Indicated for: • Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. • Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. • Psoriatic Arthritis (PSA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PSA. • Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS. • Crohn's Disease (CD): Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. • Ulcerative Colitis (UC): Treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers. • Plaque Psoriasis (Ps): Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
CABAZITAXEL	*Cabazitaxel*	Intravenous solution	For intravenous use in combination with prednisone for treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.
QUVIVIQ	*Daridorexant hydrochloride*	Oral tablet	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*	Metered nasal spray	Indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older.
KIMMTRAK	*Tebentafusp-tebn*	Injectable	Indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
VABYSMO	*Faricimab-svoa*	Injectable; for intravitreal use	Indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (namd). • Diabetic Macular Edema (DME).
CITALOPRAM HYDROBROMIDE	*Citalopram hydrobromide*	Oral capsule	For treatment of Major Depressive Disorder (MDD) in adults.
RUZURGI	*Amifampridine*	Oral tablet	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*	Oral suspension	Indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
ENJAYMO	*Sutimlimab-jome*	Injectable	Indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).
PYRUKYND	*Mitapivat sulfate*	Oral tablet	Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.
NEPHROSCAN	*Technetium tc-99m succimer kit*	Intravenous powder	Indicated for use as an aid in the scintigraphic evaluation of renal parenchymal disorders in adults and pediatric patients including term neonates.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
NORLIQVA	*Amlodipine*	Oral solution	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%.
RELEUKO	*Filgrastim-ayow*	Injectable	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*	Oral capsule	Indicated 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.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
NALOXONE HYDROCHLORIDE	*Naloxone hydrochloride*	Injectable	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*	Extended-release granule	Indicated for the treatment of chronic angina.

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
BENZNIDAZOLE *(benznidazole)* *FEXINIDAZOLE* FLAGYL *(metronidazole);* FLAGYL ER *(metronidazole)* HELIDAC *(bismuth subsalicylate; metronidazole; tetracycline hydrochloride)* PYLERA *(bismuth subcitrate potassium; metronidazole; tetracycline)* TINDAMAX *(tinidazole)*	Contraindications	Contraindicated in patients with Cockayne syndrome. Severe irreversible hepatotoxicity / acute liver failure with fatal outcomes have been reported after initiation of metronidazole, which is structurally related to benznidazole, fexinidazole and tinidazole in patients with Cockayne syndrome.
UROCIT-K *(potassium citrate)*	Contraindications	Contraindicated in: • Patients in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract, such as those suffering from delayed gastric emptying, esophageal compression, intestinal obstruction or stricture, or those taking anticholinergic medication. • Patients with peptic ulcer disease because of its ulcerogenic potential. • Patients with active urinary tract infection (with either urea-splitting or other organisms, in association with either calcium or struvite stones). The ability of urocit-k to increase urinary citrate may be attenuated by bacterial enzymatic degradation of citrate. Moreover, the rise in urinary ph resulting from urocit-k therapy might promote further bacterial growth.

Drug	Type of Change	Change
OLUMIANT *(baricitinib)*	Boxed Warning	**WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), AND THROMBOSIS** *See full prescribing information for complete boxed warning.* • Increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with OLUMIANT if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test. • Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients. • Malignancies have occurred in patients treated with OLUMIANT. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients. • Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients. • Thrombosis has occurred in patients treated with OLUMIANT. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.
DUTOPROL *(hydrochlorothiazide; metoprolol succinate)*	Boxed Warning	The box warning has been removed in its entirety.
NOXAFIL *(posaconazole)*, NOXAFIL POWDERMIX KIT *(posaconazole)*	Contraindications	• Coadministration of NOXAFIL with venetoclax at initiation and during the ramp-up phase is contraindicated in patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) due to the potential for increased risk of tumor lysis syndrome. • NOXAFIL POWDERMIX for delayed-release oral suspension is contraindicated in patients with known or suspected hereditary fructose intolerance (HFI).
TOPROL-XL *(metoprolol succinate)*	Boxed Warning	The box warning has been removed in its entirety.

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
Diazepam Oral Solution 5 mg/mL	Hikma Lannett	• Hikma did not provide a reason for the shortage. • Lannett discontinued diazepam oral solution in January 2022. **Estimated Resupply Dates** • Hikma has diazepam 5 mg/mL 30 mL bottles on allocation.
Dicloxacillin Sodium Capsules 500 mg	Sandoz Teva	• Sandoz discontinued dicloxacillin sodium capsules in January 2022. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Teva has dicloxacillin sodium 500 mg capsules on back order and the company estimated a release date of early-February 2022. • Dicloxacillin sodium oral capsule, Teva, 250 mg, 100-count bottle, NDC 00093-3123-01 is currently available.
Doxercalciferol (vitamin D2) 0.5 mcg, 1 mcg, 2.5 mcg	Winthrop	• Winthrop did not provide a reason for the shortage. **Estimated Resupply Dates** • 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 (December 2022).
Cefixime capsule 400 mg	Ascend Lupin	• Ascend has cefixime capsules on shortage due to a manufacturing issue. • Lupin has cefixime capsules on shortage due to increased demand. **Estimated Resupply Dates** • Ascend has cefixime capsules on back order and the company estimates a release date of April 2022. • Lupin has cefixime capsules available in limited supply.
Neomycin sulfate tablet 500 mg	Akorn Teva X-gen	• Akorn has neomycin sulfate tablets on shortage due to manufacturing delays. • Teva did not provide a reason for the shortage. • X-gen has neomycin sulfate tablets on shortage due to manufacturing delays. **Estimated Resupply Dates** • Akorn has neomycin sulfate tablets on back order and the company cannot estimate a release date. • Teva has neomycin sulfate tablets on back order and the company estimated a release date in early-March 2022. • X-gen has neomycin sulfate tablets on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Nizatidine capsule 150 mg, 300 mg	Glenmark Mylan Teva	• Glenmark discontinued nizatidine capsules. • Mylan discontinued nizatidine capsules. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Teva has nizatidine capsules temporarily unavailable and the company cannot estimate a release date.
Gentamicin Sulfate Ophthalmic Ointment 3%	Akorn	• Akorn did not provide a reason for the shortage. **Estimated Resupply Dates** • Akorn has short-dated Gentak 3.5 gram tubes available. The next estimated release date for tubes with better dating is 3rd quarter 2022.

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
Buprenorphine containing medications	The U.S. Food and Drug Administration (FDA) is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks. Regular adherence to buprenorphine to treat OUD reduces withdrawal symptoms and the desire to use opioids without causing the cycle of highs and lows associated with opioid misuse. The comprehensive approach of buprenorphine combined with counseling and other behavioral therapies is often one of the most effective ways to treat OUD. This approach, called medication-assisted treatment (MAT), is tailored to meet each patient's needs and can help sustain recovery and prevent or reduce opioid overdose. According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), MAT has been shown to be effective in improving patient survival, decreasing opioid use, and allowing patients to live a self-directed life, including the ability to gain and maintain employment.
Ukoniq *(umbralisib)*	The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. The FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, the FDA is alerting patients and health care professionals that they are re-evaluating this risk against the benefits of Ukoniq for its approved uses.

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