Gold Coast Health Plan℠
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Pharmacy Newsletter

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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

Gold Coast Health Plan (GCHP) has not received an update on the Medi-Cal Rx implementation date. GCHP expects to receive additional information from the state Department of Health Care Services (DHCS) in the near future and will share additional information as it becomes available.

To ensure that you receive the most up-to-date information:

1. Visit the Medi-Cal Rx website.
2. Sign up for news and updates related to Medi-Cal Rx via the Medi-Cal Rx Subscription Services (MCRxSS).
3. Register for and access the Medi-Cal Rx secure provider portal.
4. Complete any necessary training and education modules to know how to help members access their pharmacy benefits, including how to submit prior authorizations or appeals.
5. Educate staff on new phones numbers, the web portal, etc.

Formulary Changes

The following changes to the GCHP formulary are effective July 1:

Additions

Drug	Formulary Status / Change
REDITREX *(methotrexate)*	Added to formulary with PA.
INQOVI *(decitabine-cedazuridine)*	Added to formulary with PA.
UKONIQ *(umbralisib tosylate)*	Added to formulary with PA.
TEPMETKO *(tepotinib hcl)*	Added to formulary with PA.
XTANDI *(enzalutamide)*	Added to formulary with PA.
FOTIVDA *(tivozanib hcl)*	Added to formulary with PA.
GEMTESA *(vibegron)*	Added to formulary with step therapy.
VERQUVO *(vericiguat)*	Added to formulary with PA.
IMCIVREE *(setmelanotide acetate)*	Added to formulary with PA.
ORLADEYO *(berotralstat hcl)*	Added to formulary with PA..

Removals

Drug	Formulary Status / Change
OTREXUP *(methotrexate)*	Removed from formulary due to REDITREX addition.
LINZESS *(linaclotide)* Capsules, 145 mcg and 290 mcg	Brand removed from formulary due to generic availability.
LOTEMAX *(loteprednol)* Etabonate Ophthalmic Gel, 0.5%	Brand removed from formulary due to generic availability.
OTEZLA *(apremilast)* Tablets, 10 mg, 20 mg and 30 mg	Brand removed from formulary due to generic availability.
NORTHERA *(droxidopa)* Capsules, 100 mg, 200 mg, 300 mg	Brand removed from formulary due to generic availability.
IMBRUVICA *(ibrutinib)* Capsules, 70 mg and 140 mg	Brand removed from formulary due to generic availability.

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
LUPKYNIS	VOCLOSPORIN	Oral capsule	Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).
POSIMIR	BUPIVACAINE	Extended release infiltration solution	Indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.
ACETAMINOPHEN	ACETAMINOPHEN	Intravenous solution	Indicated for the: • Management of mild to moderate pain in adult and pediatric patients 2 years of age and older. • Management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years of age and older. • Reduction of fever in adult and pediatric patients.
PEMETREXED	PEMETREXED	Injectable	Indicated for the treatment of pleural mesothelioma and non-small cell lung cancer (NSCLC).
AZSTARYS	SERDEXMETHYLPHENIDATE CHLORIDE; DEXMETHYLPHENIDATE HYDROCHLORIDE	Oral capsule	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.
KIMYRSA	ORITAVANCIN DIPHOSPHATE	Powder for intravenous injection	Indicated for the treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms.
DOLUTEGRAVIR SODIUM	DOLUTEGRAVIR SODIUM	Oral tablet and oral suspension	HIV-1 infection in adults and pediatric patients weighing at least 40 kg.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
PONVORY	PONESIMOD	Oral tablet	Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.
MIDAZOLAM IN SODIUM CHLORIDE	MIDAZOLAM	Intravenous solution	Indicated for continuous intravenous infusion for sedation of intubated and mechanically ventilated adult, pediatric, and neonatal patients as a component of anesthesia or during treatment in a critical care setting.
MYRBETRIQ	MIRABEGRON	Oral suspension	Indicated for the treatment of: • Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. • Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years of age and older and weighing 35 kg or more. • MYRBETRIQ granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients 3 years of age and older.
QELBREE	VILOXAZINE HYDROCHLORIDE	Extended-release oral capsule	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
BORTEZOMIB	BORTEZOMIB	Powder for intravenous or subcutaneous injection	Label not available
KLOXXADO	NALOXONE HYDROCHLORIDE	Nasal spray	Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.

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
ACULAR LS *(ketorolac tromethamine)*	Contraindications	ACULAR LS ophthalmic solution is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.
BACTRIM PEDIATRIC *(sulfamethoxazole; trimethoprim)*	Contraindications	ACTRIM is contraindicated in the following situations: • Known hypersensitivity to trimethoprim or sulfonamides. • History of drug-induced immune thrombocytopenia with use of trimethoprim and/or sulfonamides. • Documented megaloblastic anemia due to folate deficiency. • Pediatric patients less than 2 months of age. • Marked hepatic damage. • Severe renal insufficiency when renal function status cannot be monitored. • Concomitant administration with dofetilide.
BOSULIF *(bosutinib monohydrate)*	Contraindications	BOSULIF is contraindicated in patients with a history of hypersensitivity to BOSULIF. Reactions have included anaphylaxis.
BUPIVACAINE HYDROCHLORIDE *(bupivacaine hydrochloride)*	Boxed Warning and Contraindications	**WARNING: RISK OF CARDIAC ARREST WITH USE OF BUPIVACAINE HYDROCHLORIDE INJECTION IN OBSTETRICAL ANESTHESIA** There have been reports of cardiac arrest with difficult resuscitation or death during use of BUPIVACAINE HYDROCHLORIDE injection for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of BUPIVACAINE HYDROCHLORIDE injection is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.
CASPOFUNGIN ACETATE *(caspofungin acetate)*	Contraindications	CASPOFUNGIN ACETATE for injection is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis) to any component of this product.
DEFINITY *(perflutren)*	Contraindications	Do not administer DEFINITY to patients with known or suspected hypersensitivity to perflutren lipid microsphere or its components, such as polyethylene glycol (PEG).

Drug	Type of Change	Change
FENTORA *(fentanyl citrate)*	Boxed Warning	Risk Evaluation and Mitigation Strategy (REMS) Because of the risk for accidental exposure, misuse, abuse, addiction, and overdose, FENTORA is available only through a restricted program required by the U.S. Food and Drug Administration (FDA), called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS, pharmacies, outpatients, and health care professionals who prescribe to outpatients must enroll in the program. Inpatient pharmacies must develop policies and procedures to verify opioid tolerance in inpatients who require FENTORA while hospitalized.
GLUCAGEN *(glucagon hydrochloride)*	Contraindications	GLUCAGEN is contraindicated in: • Pheochromocytoma because of the risk of substantial increase in blood pressure. • Insulinoma because of the risk of hypoglycemia. • Known hypersensitivity to glucagon or the excipients in GLUCAGEN. Allergic reactions have been reported with GLUCAGEN and include anaphylactic shock with breathing difficulties and hypotension. • Glucagonoma when used as a diagnostic aid because of risk of hypoglycemia.
H.P. ACTHAR GEL *(corticotropin)*	Contraindications	ACTHAR GEL is contraindicated: • For intravenous administration. • In infants under 2 years of age who have suspected congenital infections. • With concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of ACTHAR GEL. • In patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex.
IMPAVIDO *(miltefosine)*	Contraindications	IMPAVIDO is contraindicated in patients who are pregnant. Based on animal data, miltefosine may cause fetal harm.
LAZANDA *(fentanyl citrate)*	Boxed Warning	Risk Evaluation and Mitigation Strategy (REMS) Because of the risk for accidental exposure, misuse, abuse, addiction, and overdose, LAZANDA is available only through a restricted program required by the U.S. Food and Drug Administration (FDA), called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS, pharmacies, outpatients, and health care professionals who prescribe to outpatients must enroll in the program. Inpatient pharmacies must develop policies and procedures to verify opioid tolerance in inpatients who require LAZANDA while hospitalized.
LUMASON *(sulfur hexafluoride lipid-type a microspheres)*	Contraindications	LUMASON is contraindicated in patients with known or suspected: • Hypersensitivity to sulfur hexafluoride lipid microsphere or its components, such as polyethylene glycol (PEG).

Drug	Type of Change	Change
LUPRON DEPOT-PED KIT *(leuprolide acetate)*	Contraindications	Hypersensitivity to GnRH, GnRH agonists or any of the excipients in LUPRON DEPOT-PED. Anaphylactic reactions to synthetic GnRH or GnRH agonists have been reported.
METHOTREXATE LPF *(methotrexate sodium)*	Boxed Warning and Contraindications	**WARNING: EMBRYO-FETAL TOXICITY, HYPERSENSITIVITY REACTIONS, BENZYL ALCOHOL TOXICITY, AND OTHER SERIOUS ADVERSE REACTIONS** METHOTREXATE injection can cause embryo-fetal toxicity, including fetal death. For non-neoplastic diseases, METHOTREXATE injection is contraindicated in pregnancy. Advise females and males of reproductive potential to use effective contraception. METHOTREXATE injection is contraindicated in patients with a history of severe hypersensitivity reactions to METHOTREXATE, including anaphylaxis. Formulations with benzyl alcohol can cause severe central nervous toxicity or metabolic acidosis. Use only preservative-free METHOTREXATE injection for treatment of neonates or low-birth weight infants and for intrathecal use. Do not use benzyl alcohol-containing formulations for high-dose regimens unless immediate treatment is required and preservative-free formulations are not available. Other serious adverse reactions, including death, have been reported with METHOTREXATE. Closely monitor for infections and adverse reactions of the bone marrow, kidneys, liver, nervous system, gastrointestinal tract, lungs, and skin. Withhold or discontinue METHOTREXATE injection as appropriate. METHOTREXATE injection is contraindicated in: • Patients with history of severe hypersensitivity to METHOTREXATE. • Pregnancy in patients with non-neoplastic diseases.

Drug	Type of Change	Change
NORDETTE-21 *(ethinyl estradiol; levonorgestrel)*	Contraindications	NORDETTE-21 is contraindicated in females who are known to have the following conditions: • A high risk of arterial or venous thrombotic diseases. Examples include women who are known to: ‣ Smoke, if over 35 years of age. ‣ Have current or a history of deep vein thrombosis or pulmonary embolism. ‣ Have cerebrovascular disease. ‣ Have coronary artery disease. ‣ Have thrombogenic valvular or thrombogenicrhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation). ‣ Have inherited or acquired hypercoagulopathies. ‣ Have uncontrolled hypertension or hypertension with vascular disease. ‣ Have diabetes mellitus and are over 35 years of age, diabetes mellitus with hypertension or vascular disease or other end-organ damage, or diabetes mellitus of >20 years duration. ‣ Have headaches with focal neurological symptoms, migraine headaches with aura, or over 35 years of age with any migraine headaches. • Current or history of breast cancer or other estrogen- or progestin-sensitive cancer. • Liver tumors, acute viral hepatitis, or severe (decompensated) cirrhosis. • Use of Hepatitis C drug combinations containing ombitasvir / paritaprevir / ritonavir, with or without dasabuvir, due to the potential for ALT elevations. • Undiagnosed abnormal uterine bleeding.
OCALIVA *(obeticholic acid)*	Contraindications	OCALIVA is contraindicated in patients with: • Decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event. • Compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). • Complete biliary obstruction.
ONSOLIS *(fentanyl citrate)*	Boxed Warning	Risk Evaluation and Mitigation Strategy (REMS) Because of the risk for accidental exposure, misuse, abuse, addiction, and overdose, ONSOLIS is available only through a restricted program required by the U.S. Food and Drug Administration (FDA), called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS, pharmacies, outpatients, and health care professionals who prescribe to outpatients must enroll in the program. Inpatient pharmacies must develop policies and procedures to verify opioid tolerance in inpatients who require ONSOLIS while hospitalized.

Drug	Type of Change	Change
OZEMPIC *(semaglutide)*	Contraindications	A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in OZEMPIC. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with OZEMPIC.
PENTASA *(mesalamine)*	Contraindications	PENTASA is contraindicated in patients with known or suspected hypersensitivity to salicylates, aminosalicylates, or any components of this medication.
PRALUENT *(alirocumab)*	Contraindications	PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to alirocumab or any of the excipients in PRALUENT. Hypersensitivity vasculitis, angioedema, and hypersensitivity reactions requiring hospitalization have occurred.
RYBELSUS *(semaglutide)*	Contraindications	RYBELSUS is contraindicated in patients with: • A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in RYBELSUS. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with RYBELSUS.
SAMSCA *(tolvaptan)*	Contraindications	SAMSCA is contraindicated in the following conditions: • Patients with autosomal dominant polycystic kidney disease (ADPKD) outside of FDA-approved REMS. • Unable to sense or respond to thirst. • Hypovolemic hyponatremia. • Taking strong CYP3A inhibitors. • Anuria. • Hypersensitivity (e.g., anaphylactic shock, rash generalized) to tolvaptan or any components of the product.
SUBSYS *(fentanyl)*	Boxed Warning	Risk Evaluation and Mitigation Strategy (REMS) Because of the risk for accidental exposure, misuse, abuse, addiction, and overdose, SUBSYS is available only through a restricted program required by the U. S. Food and Drug Administration (FDA), called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS, pharmacies, outpatients, and health care professionals who prescribe to outpatients must enroll in the program. Inpatient pharmacies must develop policies and procedures to verify opioid tolerance in inpatients who require SUBSYS while hospitalized.

Drug	Type of Change	Change
VFEND *(voriconazole)*	Contraindications	Coadministration of cisapride, pimozide, quinidine or ivabradine with VFEND is contraindicated because increased plasma concentrations of these drugs can lead to QT prolongation and rare occurrences of torsade de pointes. Coadministration of VFEND 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.
XANAX *(alprazolam)* XANAX XR *(alprazolam)*	Contraindications	XANAX is contraindicated in patients: • With known hypersensitivity to alprazolam or other benzodiazepines. Angioedema has been reported. • Taking strong cytochrome P450 3A (CYP3A) inhibitors (e.g., ketoconazole, itraconazole), except ritonavir.
XOLAIR *(omalizumab)*	Boxed Warning	**WARNING: ANAPHYLAXIS** Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond one year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a health care setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

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
Fluorometholone Ophthalmic Ointment	Allergan	• Allergan did not provide a reason for the shortage. They are the sole suppliers of fluorometholone ointment. • Allergan has FML ophthalmic ointment on long-term back order and the company cannot estimate a release date.
Maprotiline oral tablet	Mylan	• Mylan did not provide a reason for the shortage. • Mylan is the sole supplier of maprotiline tablets. • Mylan has maprotiline 25 mg, 50 mg, and 75 mg tablets on back order and the company cannot estimate a release date.

FDA Drug Safety Communications

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

Drug	Communications Summary
OCALIVA *(obeticholic acid)*	Due to risk of serious liver injury, the FDA restricts use of OCALIVA (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis.

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For additional information, contact Pharmacy Relations at 888.531.0998.
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