Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q2 2021

MARCH 2021

www.goldcoasthealthplan.org

Table of Contents

PN Q2 2021

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.

Pharmacy Director:
Anne Freese, Pharm. D.

Chief Medical Officer:
Nancy R. Wharfield, MD

Editor-in-Chief:
Susana Enriquez-Euyoque

Copy Editor:
Calley Cederlof

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 On Hold

Gold Coast Health Plan (GCHP) was notified by the state Department of Health Care Services (DHCS) that the implementation of Medi-Cal Rx is on hold until further notice. In a communication to stakeholders, DHCS cited the need to look into a possible conflict after it was announced that the company the state had chosen to manage the pharmacy benefit was being acquired by a health plan that serves Medi-Cal members. You can read the update from DHCS here.

GCHP will be ready to implement this program when the time comes. In the meantime, we will continue to work with our pharmacy benefit manager, OptumRx, and our network of pharmacies to provide our members with the medications they need.

We will provide additional information about Medi-Cal Rx as it becomes available. If you have any questions, feel free to email Anne Freese, director of Pharmacy, at afreese@goldchp.org.

Formulary Changes

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

Additions

Drug	Formulary Status / Change
ENSPRYNG (satralizumab)	Added to formulary with PA.
EVRYSDI (risdiplam)	Added to formulary with PA.
LAMPIT (nifurtimox)	Added to formulary with PA.
ZOKINVY (lonafarnib)	Added to formulary with PA.
BAFIERTAM (monomethyl fumarate)	Added to formulary with PA.
PHEXXI (lactic acid; citric acid; potassium bitartrate)	Added to formulary with quantity limit one box / month.
GAVRETO (pralsetinib)	Added to formulary with PA.
ONUREG (azacitidine)	Added to formulary with PA.
ORGOVYX (relugolix)	Added to formulary with PA.
NYVEPRIA (pegfilgrastim-apgf)	Added to formulary.

Removals

Drug	Formulary Status / Change
Azopt (Brinzolamide) Ophthalmic Suspension USP, 1%	Brand removed from formulary due to generic availability.
Jublia (Efinaconazole) Topical Solution, 10%	Brand removed from formulary due to generic availability.
Glucagon for Injection USP, 1 mg/vial packaged in an emergency kit	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
RIABNI	*Rituximab-arrx*	Injectable	Indicated for the treatment of: • Adult patients with non-Hodgkin's Lymphoma (NHL). ‣ Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. ‣ Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. ‣ Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. ‣ Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens. • Adult patients with Chronic Lymphocytic Leukemia (CLL). ‣ Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids.
CABENUVA	*Cabotegravir; rilpivirine*	Injectable	CANENUVA, is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
GAVRETO	*Pralsetinib*	Oral capsule	GAVRETO is indicated for treatment of: • Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer as detected by an FDA approved test (NSCLC). • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
ORGOVYX	*Relugolix*	Oral tablet	ORGOVYX is indicated for the treatment of adult patients with advanced prostate cancer.
GEMTESA	*Vibegron*	Oral tablet	Indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.
KLISYRI	*Tirbanibulin*	Topical ointment	KLISYRI is indicated for the topical treatment of actinic keratosis of the face or scalp.
VERQUVO	*Vericiguat*	Oral tablet	Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
GALLIUM Ga 68 PSMA-11	*Psma-11 ga 68*	Injectable	Positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: • With suspected metastasis who are candidates for initial definitive therapy. • With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.
ACETAMINOPHEN	*Acetaminophen*	Injectable	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.
DOLUTEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE	*Dolutegravir; emtricitabine; tenofovir alafenamide*	Oral Tablet	HIV-1 infection in adults and pediatric patients weighing at least 40 kg.
EBANGA	*Ansuvimab-zykl*	IV infusion	Indicated for the treatment of infection caused by Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus infection.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
HETLIOZ LQ	*Tasimelteon*	Oral suspension	HETLIOZ LQ oral suspension is indicated for the treatment of: • Nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.
LUPKYNIS	*Voclosporin*	Oral capsule	Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).
MARGENZA	*Margetuximab-cmkb*	Injectable	Indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
NOREPINEPHRINE BITARTRATE; DEXTROSE	*Norepinephrine bitartrate; dextrose*	Injectable	Indicated for restoration of blood pressure in adult patients with acute hypotensive states.
ORLADEYO	*Berotralstat hydrochloride*	Oral capsule	ORLADEYO is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.
VOCABRIA	*Cabotegravir*	Oral tablet	In combination with Edurant (rilpivirine) 25 mg tablet for the short-term treatment of HIV1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpirivine, for use as an: • Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva (cabotegravir extended release injectable suspension; rilpivirine) extended release injectable suspension. • Oral therapy for patients who will miss planned injection dosing with Cabenuva (cabotegravir extended release injectable suspension; rilpivirine extended release injectable suspension).

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
PEXEVA *(paroxetine mesylate)*	Boxed Warning And Contraindications	**Boxed Warning** **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS** Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all anti-depressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. PEXEVA is not approved for use in pediatric patients. PEXEVA is contraindicated in patients: • Taking, or within 14 days of stopping, MAOIs (including the MAOIs linezolid and intravenous methylene blue) because of an increased risk of serotonin syndrome. • Taking thioridazine because of risk of QT prolongation. • Taking pimozide because of risk of QT prolongation. • With known hypersensitivity (e.g., anaphylaxis, angioedema, Stevens-Johnson syndrome) to paroxetine or to any of the inactive ingredients in PEXEVA.

Drug	Type of Change	Change
DOCETAXEL	Boxed Warning	**WARNING: TOXIC DEATHS, HEPATOTOXICITY, NEUTROPENIA, HYPERSENSITIVITY REACTIONS, and FLUID RETENTION** Treatment-related mortality associated with DOCETAXEL is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive docetaxel as a single agent at a dose of 100 mg/m2. Avoid the use of DOCETAXEL injection in patients with bilirubin > upper limit of normal (ULN), or to patients with AST and/or ALT >1.5 x ULN concomitant with alkaline phosphatase >2.5 x ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of severe neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 x ULN also had a higher rate of febrile neutropenia. Measure bilirubin, AST or ALT, and alkaline phosphatase prior to each cycle of DOCETAXEL injection. Do not administer DOCETAXEL injection to patients with neutrophil counts of <1500 cells/mm3. Monitor blood counts frequently as neutropenia may be severe and result in infection. Do not administer DOCETAXEL injection to patients who have a history of severe hypersensitivity reactions to DOCETAXEL injection or to other drugs formulated with polysorbate 80. Severe hypersensitivity reactions have been reported in patients despite dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the DOCETAXEL injection infusion and administration of appropriate therapy.
TRINTELLIX *(vortioxetine hydrobromide)*	Boxed Warning	**WARNING: SUICIDAL THOUGHTS AND BEHAVIORS** Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors. TRINTELLIX is not approved for use in pediatric patients.
VFEND *(voriconazole)*	Contraindications	Coadministration of VFEND with naloxegol is contraindicated because VFEND may increase plasma concentrations of naloxegol which may precipitate opioid withdrawal symptoms. Coadministration of VFEND with tolvaptan is contraindicated because VFEND may increase tolvaptan plasma concentrations and increase risk of adverse reactions.

Drug	Type of Change	Change
ORILISSA *(elagolix sodium)*	Contraindications	ORILISSA is contraindicated in women: • Who are pregnant. Exposure to ORILISSA early in pregnancy may increase the risk of early pregnancy loss. • With known osteoporosis because of the risk of further bone loss. • With severe hepatic impairment. • Taking inhibitors of organic anion transporting polypeptide (OATP)1B1 (a hepatic uptake transporter) that are known or expected to significantly increase elagolix plasma concentrations. • With known hypersensitivity reaction to ORILISSA or any of its inactive components. Reactions have included anaphylaxis and angioedema.
SAXENDA *(liraglutide recombinant)*	Contraindications	SAXENDA is contraindicated in: • Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the excipients in SAXENDA.
ICLUSIG *(ponatinib hydrochloride)*	Boxed Warning	**WARNING: ARTERIAL OCCLUSIVE EVENTS, VENOUS THROMBOEMBOLIC EVENTS, HEART FAILURE, and HEPATOTOXICITY** Arterial occlusive events (AOEs), including fatalities, have occurred in ICLUSIG-treated patients. AOEs included fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors, including patients 50 years of age or younger, experienced these events. Monitor for evidence of AOEs. Interrupt or discontinue ICLUSIG based on severity. Consider benefit-risk to guide a decision to restart ICLUSIG. Venous thromboembolic events (VTEs) have occurred in ICLUSIG-treated patients. Monitor for evidence of VTEs. Interrupt or discontinue ICLUSIG based on severity. Heart failure, including fatalities, occurred in ICLUSIG-treated patients. Monitor for heart failure and manage patients as clinically indicated. Interrupt or discontinue ICLUSIG for new or worsening heart failure. Hepatotoxicity, liver failure and death have occurred in ICLUSIG-treated patients. Monitor liver function tests. Interrupt or discontinue ICLUSIG based on severity.

Drug	Type of Change	Change
BENZODIAZEPINES: *ALPRAZOLAM*, ATIVAN *(lorazepam)*, *CLOBAZAM, DIAZEPAM,* DORAL *(quazepam)*, KLONOPIN *(clonazepam)*, LIBRAX *(chlordiazepoxide hydrochloride; clidinium bromide), LORAZEPAM*, NAYZILAM *(midazolam),* ONFI *(clobazam)*, SEIZALAM *(midazolam hydrochloride)*, SYMPAZAN *(clobazam)*, VALTOCO *(diazepam)*, LIMBITROL *(amitriptyline hydrochloride; chlordiazepoxide)*, RESTORIL *(temazepam)*, DIASTAT *(diazepam)*, HALCION *(triazolam)*, VALIUM *(diazepam)*, TRANXENE *(clorazepate dipotassium)*, TRANXENE SD *(clorazepate dipotassium)*, CLOZARIL *(clozapine)*, XANAX *(alprazolam)*, XANAX XR *(alprazolam)*	Boxed Warning	**WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS** • Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation. • The use of benzodiazepines, including injectables, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing a benzodiazepine injection and throughout treatment, assess each patient's risk for abuse, misuse, and addiction. • The continued use of benzodiazepines for several days to weeks may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. If benzodiazepine injectables are used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of benzodiazepine injections may precipitate acute withdrawal reactions, which can be life-threatening. For patients using benzodiazepine injections more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue injection.

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
Famotidine tablets	• Alembic • Aurobindo • Major • Mylan • Teva • Bausch Health • Dr. Reddy's	• Alembic has famotidine tablets on allocation due to increased demand. • Aurobindo refuses to provide availability information. • Major did not provide a reason for the shortage. • Mylan discontinued famotidine tablets in all presentations in April 2019. • Teva has famotidine tablets on shortage due to increased demand. • Bausch Health did not provide a reason for the shortage. • Dr. Reddy's discontinued famotidine tablets in all presentations. **Estimated Resupply Dates** • Alembic has famotidine tablets on allocation. • Major has famotidine 20 mg tablets on back order and the company estimated a release date of mid-February 2021. • Teva has famotidine tablets on intermittent back order and the company is releasing product as it becomes available. • Bausch Health has Pepcid 20 mg tablets in 100-count on back order and the company estimates a release date of late-April 2021.

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
XELJANZ *(tofacitinib)*, XELJANZ XR *(tofacitinib)*	The FDA has alerted the public that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with the arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. The FDA required the safety trial, which also investigated other potential risks, including blood clots in the lungs and death. Those final results are not yet available.

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter Q2 2021

MARCH 2021

For additional information, contact Pharmacy Relations at 888.531.0998.
Gold Coast Health Plan
711 East Daily Drive, Suite 106, Camarillo, CA 93010
www.goldcoasthealthplan.org