Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

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Table of Contents

SECTION 1: A Message from the Gold Coast Health Plan (GCHP) Pharmacy Director 3
SECTION 2: Medi-Cal Rx Update 4
SECTION 3: Formulary Changes 5
SECTION 4: Alerts from the U.S. Food and Drug Administration (FDA): FDA New Drug Approvals, Drug Safety Labeling Changes, Drug Shortages, FDA Drug Safety Communications 5

PN Q1 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.

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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

The timeline for Gold Coast Health Plan's (GCHP) pharmacy program transition has been extended to April 1, 2021. The new program by the state Department of Health Care Services (DHCS), known as Medi-Cal Rx, will carve-out all prescription benefits from managed care plans like GCHP. Upon implementation, all pharmacy claims will be submitted directly to the state via its pharmacy benefit manager, Magellan Medicaid Administration, Inc. DHCS announced the new implementation date last month, citing "the ongoing uncertainties caused by the COVID-19 public health emergency" for its decision to extend the timeline. GCHP will continue to offer pharmacy benefits through its pharmacy benefit manager, OptumRx, until the transition occurs.

GCHP encourages providers and their staff to continue preparing for the transition by becoming acquainted with the Medi-Cal Rx provider portal and completing any necessary training to learn how to help members access their pharmacy benefits.

Members will receive information about the transition in the mail. GCHP will reach out to providers as DHCS releases updated timelines for the implementation.

The Medi-Cal Rx provider portal can be accessed here.

GCHP will continue to update information on the GCHP website pharmacy page as it becomes available. Medi-Cal Rx-specific information can be found here.

GCHP has created a document with information on submitting pharmacy prior authorization requests and appeals upon the change to Medi-Cal Rx, which can be viewed here.

Formulary Changes

Due to the pending transition to Medi-Cal Rx, no recent changes to the formulary have been made.

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
ONUREG	AZACITIDINE	Oral Tablet	Indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.
QDOLO	TRAMADOL HYDROCHLORIDE	Oral Solution	Pain management
DETECTNET	COPPER DOTATATE CU-64	Intravenous Solution	Indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult patients.
GAVRETO	PRALSETINIB	Oral Capsule	Indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive nonsmall cell lung cancer (NSCLC) as detected by an FDA approved test.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
Xeljanz	Octreotide acetate	Oral Solution	Rheumatoid Arthritis: XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. • Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Psoriatic Arthritis: XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs). • Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Ulcerative Colitis: XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or who are intolerant to TNF blockers. • Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Polyarticular Course Juvenile Idiopathic Arthritis: XELJANZ/XELJANZ Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older. • Limitations of Use: Use of XELJANZ/ XELJANZ Oral Solution in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
ALKINDI SPRINKLE	HYDROCORTISONE	Oral Granule	Indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
INMAZEB	ATOLTIVIMAB; ODESIVIMAB; MAFTIVIMAB	Injectable Solution	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. Limitations of Use • The efficacy of INMAZEB has not been established for other species of the Ebolavirus and Marburgvirus genera. • Zaire ebolavirus can change over time, and factors such as emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating Zaire ebolavirus strains when deciding whether to use INMAZEB.
VEKLURY	REMDESIVIR	Intravenous Powder and Intravenous Solution	Indicated in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization.
SESQUIENT	FOSPHENYTOIN SODIUM	Intravenous Solution	Indicated for: • Treatment of generalized tonic-clonic status epilepticus in adult patients. • Prevention and treatment of seizures occurring during neurosurgery in adult patients. • Short-term substitution for oral phenytoin in patients 2 years of age and older. SESQUIENT should be used only when oral phenytoin administration is not possible.
SUTAB (COPACKAGED)	MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM SULFATE	Oral Tablet	Cleansing of the colon in preparation for colonoscopy in adults.
ZOKINVY	LONAFARNIB	Oral Capsule	• To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome • For treatment of processing-deficient Progeroid Laminopathies with either: ‣ Heterozygous LMNA mutation with progerin-like protein accumulation ‣ Homozygous or compound heterozygous ZMPSTE24 mutations
OXLUMO	LUMASIRAN	Subcutaneous Solution	Primary hyperoxaluria type 1

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
XOFLUZA	BALOXAVIR MARBOXIL	Oral Tablet and Oral Suspension	Indicated for: • Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are: ‣ Otherwise healthy, or at high risk of developing influenza-related complications. ‣ Post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza.
IMCIVREE	SETMELANOTIDE	Subcutaneous Solution	Chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin / kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).
DANYELZA	NAXITAMAB-GQGK	Intravenous Solution	In combination with granulocyte-macrophage colony-stimulating factor (GMCSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.
THYQUIDITY	LEVOTHYROXINE SODIUM	Oral Solution	
GALLIUM Ga 68 PSMA-11	PSMA-11 Ga 68	Injectable; Injection	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.
HETLIOZ	TASIMELTEON	Oral Capsule	HETLIOZ capsules are indicated for the treatment of: • Non-24-Hour Sleep-Wake Disorder (Non-24) in adults. • Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.
HETLIOZ LQ	TASIMELTEON	Oral Suspension	HETLIOZ LQ oral suspension is indicated for the treatment of: • Nighttime sleep disturbances in SMS in pediatric patients 3 years of age to 15 years of age.

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
TRELEGY ELLIPTA *(fluticasone furoate; umeclidinium bromide; vilanterol trifenatate)*	Contraindications	TRELEGY ELLIPTA is contraindicated in the following conditions: • Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required. • Severe hypersensitivity to milk proteins. • Demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients.
ADCIRCA *(tadalafil)*	Contraindications	ADCIRCA is contraindicated in patients who are using any form of organic nitrate, either regularly or intermittently. Do not use nitrates within 48 hours of the last dose of ADCIRCA. ADCIRCA potentiates the hypotensive effect of nitrates. This potentiation is thought to result from the combined effects of nitrates and ADCIRCA on the nitric oxide / cGMP pathway.
CEFOBID *(cefoperazone sodium)*	Contraindications	CEFOBID is contraindicated in patients with known hypersensitivity to any component of this product or to other drugs in the same class or in patients who have demonstrated severe hypersensitivity to beta-lactams.
ERAXIS *(anidulafungin)*	Contraindications	ERAXIS is contraindicated in: • Patients with known hypersensitivity to anidulafungin, any component of ERAXIS, or other echinocandins. • Patients with known or suspected Hereditary Fructose Intolerance (HFI).
NUCALA *(mepolizumab)*	Contraindications	NUCALA is contraindicated in patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.
LEMTRADA *(alemtuzumab)*	Boxed Warning and Contraindications	**Boxed warning:** **LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts before starting treatment and then at monthly intervals until 48 months after the last dose of LEMTRADA.** **Contraindications:** LEMTRADA is contraindicated in patients: • With known hypersensitivity or anaphylactic reactions to alemtuzumab or any of the excipients in LEMTRADA. • Who are infected with human immunodeficiency virus (HIV) because LEMTRADA causes prolonged reductions of CD4+ lymphocyte counts. • With active infections.

Drug	Type of Change	Change
NEXPLANON *(etonogestrel)*	Contraindications	There have been reports of migration of the implant within the arm from the insertion site, which may be related to deep insertion. There also have been post-marketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Some cases of implants found within the pulmonary artery were associated with chest pain and/or respiratory disorders (such as dyspnea, cough, or hemoptysis); others were asymptomatic. In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.
GIAZO *(balsalazide disodium)*	Boxed Warning	Renal impairment, including minimal change disease, acute and chronic interstitial nephritis and renal failure, has been reported in patients given products that release mesalamine in the gastrointestinal tract. Evaluate renal function prior to initiation of GIAZO and periodically while on therapy. Evaluate the risks and benefits of using GIAZO in patients with known renal impairment, a history of renal disease or taking nephrotoxic drugs.
DIPENTUM *(olsalazine sodium)*	Contraindications	DIPENTUM is contraindicated in patients with known or suspected hypersensitivity to salicylates, aminosalicylates or their metabolites, or to any of the excipients in DIPENTUM.
TRISENOX *(arsenic trioxide)*	Boxed Warning	**WARNING: DIFFERENTIATION SYNDROME, CARDIAC CONDUCTION ABNORMALITIES AND ENCEPHALOPATHY INCLUDING WERNICKE'S DIFFERENTIATION SYNDROME:** Patients with acute promyelocytic leukemia (APL) treated with TRISENOX have experienced differentiation syndrome, which may be life-threatening or fatal. Signs and symptoms may include unexplained fever, dyspnea, hypoxia, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, weight gain, peripheral edema, hypotension, renal insufficiency, hepatopathy, and multi-organ dysfunction, in the presence or absence of leukocytosis. If differentiation syndrome is suspected, immediately initiate high-dose corticosteroids and hemodynamic monitoring until resolution. Temporarily withhold TRISENOX. **Cardiac Conduction Abnormalities:** TRISENOX can cause QTc interval prolongation, complete atrioventricular block and torsade de pointes, which can be fatal. Before administering TRISENOX, assess the QTc interval, correct electrolyte abnormalities, and consider discontinuing drugs known to prolong QTc interval. Do not administer TRISENOX to patients with a ventricular arrhythmia or prolonged QTc interval. Withhold TRISENOX until resolution and resume at reduced dose for QTc prolongation.
ZYDELIG *(idelalisib)*	Contraindications	Zydelig is contraindicated in patients with a history of serious hypersensitivity reactions to idelalisib, including anaphylaxis, or patients with a history of toxic epidermal necrolysis with any drug.

Drug	Type of Change	Change
BAQSIMI *(glucagon)*	Contraindications	BAQSIMI is contraindicated in patients with: • Pheochromocytoma because of the risk of substantial increase in blood pressure. • Insulinoma because of the risk of hypoglycemia. • Known hypersensitivity to glucagon or to any of the excipients in BAQSIMI. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

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
Sertraline oral solution 20 mg/mL	Greenstone	Greenstone has sertraline hydrochloride 20 mg/mL oral solution on backorder due to manufacturing delays. Estimated Resupply Dates Greenstone has sertraline hydrochloride 20 mg/mL oral solution on allocation.

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
Nonsteroidal anti-inflammatory drugs (NSAIDs)	The FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid. NSAIDs may cause rare kidney problems in unborn babies. The FDA is warning that use of nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby and possible complications. NSAIDs are commonly used to relieve pain and reduce fevers. They include medicines such as aspirin, ibuprofen, naproxen, diclofenac, and celecoxib. After around 20 weeks of pregnancy, the unborn babies' kidneys produce most of the amniotic fluid, so kidney problems can lead to low levels of this fluid. Amniotic fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop.

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