



**Gold Coast
Health Plan**SM
A Public Entity

Pharmacy Newsletter

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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 the Plan's formulary, new drug approvals, and safety labeling changes.

GCHP's goal is to provide all medically-necessary pharmaceuticals in the most economical way possible. The Plan'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).

GCHP wants to ensure that all drugs are available to its 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 the Plan's 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,

A handwritten signature in black ink, appearing to read 'Anne Freese', written in a cursive style.

Anne Freese, Pharm.D.
Director of Pharmacy

Formulary Changes

The following changes to GCHP's formulary are effective as of July 1:

Additions

Drug	Formulary Status / Change
BALVERSA (erdafitinib)	Added with PA.
CABLIVI (caplacizumab-yhdp)	Added with PA.
MAYZENT (siponimod)	Added with PA.
MAVENCLAD (cladribine)	Added with PA.
EVENITY (romosozumab-aqqg)	Added with PA.

Removals

Drug	Formulary Status / Change
Renagel (sevelamer) Tablets, 400 mg, 800 mg	Generic now available. Brand name removed from formulary.
Faslodex (fulvestrant) Injection, 250 mg/5 mL (50 mg/mL)	Generic now available. Brand name removed from formulary.
Mestinon (pyridostigmine bromide) Syrup, 60 mg/5 mL	Generic now available. Brand name removed from formulary.
Letairis (ambrisentan) Tablets, 5 mg, 10 mg	Generic now available. Brand name removed from formulary.



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
SPRAVATO	ESKETAMINE	SPRAY; NASAL	Indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.
TRAZIMERA	TRASTUZUMAB-QYYP	INJECTABLE; INJECTION	HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
ROCKLATAN	NETARSUDIL; LATANOPROST	SOLUTION / DROPS; OPHTHALMIC	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
TETRACAINE HYDROCHLORIDE	TETRACAINE HYDROCHLORIDE	SOLUTION; OPHTHALMIC	Procedures requiring a rapid and short-acting topical ocular anesthetic.
EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	TABLET; ORAL	HIV-1 infection in adults and pediatric patients weighing at least 35 kg.
ZYKADIA	CERITINIB	TABLET; ORAL	NSCLC in adults whose tumors are ALK positive as detected by FDA-approved test.
ZULRESSO	BREXANOLONE	INJECTABLE; INJECTION	Postpartum depression (PPD) in adults.
SUNOSI	SOLRIAMFETOL	TABLET; ORAL	Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or OSA.
DOLUTEGRAVIR; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	UNKNOWN	AIDS relief.
MAYZENT	SIPONIMOD	TABLET; ORAL	Relapsing forms of multiple sclerosis (MS).
JATENZO	TESTOSTERONE UNDECANOATE	CAPSULE; ORAL	Testosterone replacement therapy in adult males.
MAVENCLAD	CLADRIBINE	TABLET; ORAL	Relapsing forms of multiple sclerosis (MS) and active secondary progressive disease in adults.
AVACLYR	ACYCLOVIR	OINTMENT; OPHTHALMIC	Acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV-1 and HSV-2) virus.
DUAKLIR PRESSAIR	ACLIDINIUM BROMIDE; FORMOTEROL FUMARATE DIHYDRATE	POWDER, METERED; INHALATION	Maintenance treatment for COPD.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
WELCHOL	COLESEVELAM HYDROCHLORIDE (Chewable Bar)	BAR, CHEWABLE; ORAL	Indicated as an adjunct to diet and exercise to reduce elevated low-density LDL-C in adults with hyperlipidemia, reduce LDL-C in boys and postmenarchal girls, ages 10 to 17 with HeFH, improve glycemic control in adults with type 2 DM.
EVENITY	ROMOSOZUMAB-AQQG	INJECTABLE; INJECTION	Osteoporosis in postmenopausal women at high risk for fracture, history of osteoporotic fracture, or multiple risk factors for fracture or patients who have t/f or are intolerant to osteoporosis therapy.
LEVOTHYROXINE SODIUM	LEVOTHYROXINE SODIUM (IV Injection)	INJECTABLE; INJECTION	Myxedema coma in adult patients.
BALVERSA	ERDAFITINIB	TABLET; ORAL	Locally advanced or metastatic urothelial carcinoma.
TRANEXAMIC ACID IN SODIUM CHLORIDE INJECTION	TRANEXAMIC ACID IN SODIUM CHLORIDE INJECTION	INJECTABLE; INJECTION	Short-term use for hemophilia to reduce or prevent hemorrhage following tooth extraction.
BUDESONIDE	BUDESONIDE (6mg, 9mg)	CAPSULE, EXTENDED RELEASE; ORAL	
CORLANOR	IVABRADINE (oral solution)	SOLUTION; ORAL	To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction and for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months of age and older.



FDA Safety Labeling Changes

This section includes all 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
AIMOVIG (<i>erenumab-aooe</i>)	Contraindications	Contraindications AIMOVIG is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Reactions have included anaphylaxis and andioedema.
ANDROGEL (<i>testosterone</i>)	Contraindications	ANDROGEL is contraindicated in women who are pregnant. ANDROGEL 1% and 1.62% can cause virilization of the female fetus when administered to a pregnant woman. Pregnant women need to be aware of the potential for transfer of testosterone from men treated with ANDROGEL 1% and 1.62%. If a pregnant woman is exposed to ANDROGEL 1% and 1.62%, she should be apprised of the potential hazard to the fetus.
BIDIL (<i>hydralazine hydrochloride; isosorbide dinitrate</i>)	Contraindications	Contraindications The use of BIDIL is contraindicated in patients who are allergic to nitrates. Do not use BIDIL in patients who are taking PDE-5 inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil. Concomitant use can cause severe hypotension, syncope, or myocardial ischemia. Do not use BiDil in patients who are taking the soluble guanylate cyclase (sGC) stimulator riociguat. Concomitant use can cause hypotension.
CISPLATIN (<i>cisplatin</i>)	Boxed Warning	CISPLATIN for injection is contraindicated in patients with severe hypersensitivity to cisplatin.
DEPACON (<i>valproate sodium</i>)		WARNING: LIFE THREATENING ADVERSE REACTIONS Fetal Risk Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores and neurodevelopmental disorders following in utero exposure. Valproate is therefore contraindicated for prophylaxis of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception. Valproate should not be used to treat women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant unless other medications have failed to provide adequate symptom control or are otherwise.
DEPAKENE (<i>valproic acid</i>)		For use in prophylaxis of migraine headaches: Depakene is contraindicated in women who are pregnant and in women of childbearing potential who are not using effective contraception.

Drug	Type of Change	Change
DEPAKOTE (divaloprex sodium); DEPAKOTE ER (divaloprex sodium)	Boxed Warning and Contraindications	<p>Boxed Warning</p> <p>WARNING: LIFE THREATENING ADVERSE REACTIONS</p> <p>Fetal Risk</p> <p>Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores and neurodevelopmental disorders following in utero exposure.</p> <p>Valproate is therefore contraindicated for prophylaxis of migraine headaches in pregnant women and in women of childbearing potential who are not using effective contraception. Valproate should not be used to treat women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant unless other medications have failed to provide adequate symptom control or are otherwise.</p> <p>Contraindications</p> <ul style="list-style-type: none"> • Depakote is contraindicated in patients with known urea cycle disorders. • For use in prophylaxis of migraine headaches: Depakote is contraindicated in women who are pregnant and in women of childbearing potential who are not using effective contraception.
E-Z-HD (barium sulfate)	Contraindications	<p>Contraindications</p> <p>High risk of aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation.</p>
FOCALIN (dexmethylphenidate hydrochloride); FOCALIN XR (dexmethylphenidate hydrochloride)	Boxed Warning	<p>WARNING: ABUSE AND DEPENDENCE</p> <p>CNS stimulants, including Focalin, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.</p>
GILENYA (fingolimod)	Contraindications	<p>Contraindications</p> <p>Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs.</p>
HALDOL (haloperidol lactate); HALDOL (haloperidol decanoate)	Contraindications	<p>HALDOL (haloperidol) is contraindicated in patients with:</p> <ul style="list-style-type: none"> • Severe toxic central nervous system depression or comatose states from any cause. • Hypersensitivity to this drug – Hypersensitivity reactions have included anaphylactic reaction and angioedema (see WARNINGS, Hypersensitivity Reactions and ADVERSE REACTIONS). • Parkinson's disease (see WARNINGS, Neurological Adverse Reactions in Patients with Parkinson's Disease or Dementia with Lewy Bodies). • Dementia with Lewy bodies (see WARNINGS, Neurological Adverse Reactions in Patients with Parkinson's Disease or Dementia with Lewy Bodies).

Drug	Type of Change	Change
LEXIVA (<i>fosamprenavir clacium</i>)	Contraindications	<p>LEXIVA is contraindicated when coadministered with drugs that are highly dependent on cytochrome P450 (CYP)3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events. These drugs and other contraindicated drugs (which may lead to reduced efficacy of LEXIVA and possible resistance) are listed below. The list of contraindicated drugs applies to the use of LEXIVA with or without ritonavir, unless otherwise indicated. If LEXIVA is coadministered with ritonavir, reference should be made to the full prescribing information for ritonavir for additional contraindications.</p> <p>LEXIVA is contraindicated when coadministered with the following drugs:</p> <ul style="list-style-type: none"> • Drugs highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events (eg, alfuzosin, rifampin, ergot derivatives [eg, dihydroergotamine, ergonovine, ergotamine, methylergonovine], cisapride, St. John's wort, lomitapide, lovastatin, simvastatin, pimozide, delavirdine, sildenafil [when used for treatment of pulmonary arterial hypertension], midazolam, triazolam); use of flecainide, lurasidone, or propafenone with concomitant ritonavir therapy. • Furthermore, the drug Lomitapide is added to the list of Lipid modifying agents.
METOZOLV ODT (<i>metoclopramide hydrochloride</i>)	Contraindications	<p>METOZOLV ODT is contraindicated:</p> <ul style="list-style-type: none"> • In patients with a history of tardive dyskinesia (TD) or a dystonic reaction to metoclopramide. • When stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation). • In patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Reglan may cause a hypertensive / pheochromocytoma crisis, probably due to release of catecholamines from the tumor. • In patients with epilepsy, Reglan may increase the frequency and severity of seizures. • In patients with hypersensitivity to metoclopramide. Reactions have included laryngeal and glossal angioedema and bronchospasm.
ONCASPAR (<i>pegaspargase</i>)	Contraindications	<p>ONCASPAR is contraindicated in patients with a:</p> <ul style="list-style-type: none"> • History of serious hypersensitivity reactions, including anaphylaxis, to ONCASPAR or to any of the excipients. • History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis, including pancreatitis related to prior L-asparaginase therapy.

Drug	Type of Change	Change
OSPHENA (ospemifene)	Boxed Warning	<p>WARNING: ENDOMETRIAL CANCER AND CARDIOVASCULAR DISORDERS</p> <p>OSPHENA is an estrogen agonist / antagonist with tissue selective effects. In the endometrium, OSPHENA has estrogen agonistic effects. There is a potential increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adequate diagnostic measures, including directed and random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.</p> <p>Cardiovascular Disorders</p> <p>In the clinical trials for OSPHENA (duration of treatment up to 15 months), the incidence rates of thromboembolic and hemorrhagic stroke were 1.13 and 3.39 per thousand women years, respectively in the OSPHENA 60 mg treatment group and 3.15 and 0 with placebo. The incidence of DVT was 2.26 per thousand women years (two reported cases) in the OSPHENA 60 mg treatment group and 3.15 per thousand women years (one reported case) with placebo. OSPHENA should be prescribed for the shortest duration consistent with treatment goals and risks for the individual woman.</p> <p>There is a reported increased risk of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) who received daily oral conjugated estrogens (CE) [0.625 mg]-alone therapy over 7.1 years as part of the Women's Health Initiative (WHI).</p>
PARSABIV (etelcalcetide)	Contraindications	<p>Hypersensitivity</p> <p>PARSABIV is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred with PARSABIV.</p>
PEGINTRON (peginterferon alfa-2b)	Contraindications	<p>PEGINTRON is contraindicated in patients with:</p> <ul style="list-style-type: none"> • Known hypersensitivity reactions, such as urticaria, angioedema, bronchoconstriction, anaphylaxis, Stevens-Johnson syndrome, and toxic epidermal necrolysis to interferon alpha or any other component of the product. • Autoimmune hepatitis. • Hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic CHC patients before or during treatment.

Drug	Type of Change	Change
RIFADIN (<i>rifampin</i>)	Contraindications	Rifampin is contraindicated in patients receiving praziquantel since therapeutically effective blood levels of praziquantel may not be achieved. In patients receiving rifampin who need immediate treatment with praziquantel alternative agents should be considered. However, if treatment with praziquantel is necessary, rifampin should be discontinued four weeks before administration of praziquantel. Treatment with rifampin can then be restarted one day after completion of praziquantel treatment.
RIFATER (<i>isoniazid</i> ; <i>pyrazinamide</i> ; <i>rifampin</i>)	Contraindications	Rifampin is contraindicated in patients receiving praziquantel since therapeutically effective blood levels of praziquantel may not be achieved. In patients receiving rifampin who need immediate treatment with praziquantel alternative agents should be considered. However, if treatment with praziquantel is necessary, rifampin should be discontinued four weeks before administration of praziquantel. Treatment with rifampin can then be restarted one day after completion of praziquantel treatment. Isoniazid Other contraindications include patients with severe hepatic damage; severe adverse reactions to isoniazid, such as drug fever, chills, and arthritis; patients with acute liver disease of any etiology; and patients with acute gout.
RITALIN (<i>methylphenidate hydrochloride</i>), RITALIN LA (<i>methylphenidate hydrochloride</i>), RITALIN-SR (<i>methylphenidate hydrochloride</i>)	Boxed Warning And Contraindications	WARNING: ABUSE AND DEPENDENCE CNS stimulants, including Ritalin and Ritalin-SR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy. Contraindications • Hypersensitivity to methylphenidate or other components of Ritalin or Ritalin-SR. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate.
RITUXAN (<i>rituximab</i>)	Boxed Warning	WARNING: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY Infusion-Related Reactions RITUXAN administration can result in serious, including fatal, infusion-related reactions. Deaths within 24 hours of RITUXAN infusion have occurred. Approximately 80% of fatal infusion reactions occurred in association with the first infusion. Monitor patients closely. Discontinue RITUXAN infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions.

Drug	Type of Change	Change
SYMTUZA (<i>cobicistat; darunavir ethanolate; emtricitabine; tenofovir alafenamide fumarate</i>)	Contraindications	<ul style="list-style-type: none"> Hepatitis C direct acting antiviral: elbasvir / grazoprevir. Lipid modifying agents: lomitapide, lovastatin, simvastatin.
TRACLEER (<i>bosentan</i>)	Boxed Warning	Because of the risks of hepatotoxicity and birth defects, Tracleer is available only through a restricted program called the Bosentan REMS Program. Under the Bosentan REMS, prescribers, patients, and pharmacies must enroll in the program.
TRANSDERM SCOP (<i>scopolamine</i>)	Contraindications	Addition of the following to the second bullet concerning belladonna alkaloids: Reactions have included rash generalized and erythema.
TREMFYA (<i>gueslkumab</i>)	Contraindications	TREMFYA is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.
VASOSTRICT (<i>vasopressin</i>)	Contraindications	Vasostriect® 10 mL multiple dose vial is contraindicated in patients with known allergy or hypersensitivity to 8-L-arginine vasopressin or chlorobutanol. The 1 mL single dose vial does not contain chlorobutanol and is therefore contraindicated only in patients with a known allergy or hypersensitivity to 8-L-arginine vasopressin.
XEOMIN (<i>incobotulinumtoxinA</i>)	Contraindications	Known hypersensitivity to any botulinum toxin product or to any of the components in the formulation.



Drug	Type of Change	Change
XIGDUO XR (dapagliflozin propanediol; metformin hydrochloride)	Boxed Warning And Contraindications	<p>WARNING: LACTIC ACIDOSIS</p> <p>Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate / pyruvate ratio; and metformin plasma levels generally >5 mcg/mL.</p> <p>Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), 65 years of age or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment.</p> <p>Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the full prescribing information.</p> <p>If metformin-associated lactic acidosis is suspected, immediately discontinue XIGDUO XR and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.</p> <p>Contraindications</p> <p>XIGDUO XR is contraindicated in patients with severe renal impairment (eGFR below 30 mL/min/1.73 m²), end stage renal disease or patients on dialysis.</p>
XULTOPHY 100/3.6 (insulin degludec; liraglutide)	Contraindications	In patients with hypersensitivity to XULTOPHY 100/3.6, either insulin degludec or liraglutide, or any of its excipients. Serious hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with liraglutide, one of the components of XULTOPHY 100/3.6.
ZELNORM (tegaserod maleate)	Contraindications	<p>ZELNORM is contraindicated in patients with:</p> <ul style="list-style-type: none"> • A history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina. • A history of ischemic colitis or other forms of intestinal ischemia. • Severe renal impairment (eGFR < 15 mL/min/1.73 m²) or end-stage renal disease. • Moderate and severe hepatic impairment (Child-Pugh B or C). • Hypersensitivity to tegaserod.

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
Furosemide Tablets; 20 mg, 40 mg and 80 mg	Hikma Major Mylan Sandoz Teva	<ul style="list-style-type: none"> Major discontinued furosemide tablets in early-2018. Mylan refuses to provide availability information. Hikma states the shortage is due to manufacturing delays. Sandoz discontinued furosemide tablets in late-August 2017. Teva discontinued furosemide tablets in June 2018.
Shingrix	GlaxoSmithKline	<ul style="list-style-type: none"> GlaxoSmithKline has Shingrix on shortage due to high demand for the product. GlaxoSmithKline has Shingrix on intermittent back order and the company is shipping orders according to order date and supply available.
Ciprofloxacin oral powder for suspension; 250 mg/5 ml and 500 mg/5 ml	Lupin	<ul style="list-style-type: none"> Lupin did not provide a reason for the shortage. Bayer has Cipro oral suspension available.
Clotrimazole Lozenges (Clotrimazole Troches); 10 mg	Hikma Perrigo	<ul style="list-style-type: none"> Hikma did not provide a reason for the shortage. Perrigo has clotrimazole lozenges on shortage due to increased demand. <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> Hikma has clotrimazole 10 mg lozenges in 70- and 140-count bottles on allocation. The 10 mg lozenges in 70-count unit-dose packs are on allocation. Perrigo has clotrimazole 10 mg lozenges in 70-count bottles on allocation. The 10 mg lozenges in 140-count bottles are on back order and the company estimates a release date of late-July 2019. The 10 mg lozenges in 70-count unit-dose packs are on back order and the company estimates a release date of late-July 2019.



Drug Product	Affected Manufacturers	Summary
Diclofenac potassium oral tablet; 50 mg	Mylan Teva Sandoz	<ul style="list-style-type: none"> • Mylan did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. • Sandoz discontinued diclofenac potassium tablets. <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Mylan has diclofenac potassium 50 mg tablets on back order and the company estimates a release date of early- to mid-July 2019. • Teva has diclofenac potassium 50 mg tablets in 100 count and 500 count on back order and the company estimates a release date of early-June 2019.
Albuterol Sulfate extended release tablet; 4 mg and 8 mg	MYLAN	<p>Mylan did not provide a reason for the shortage. They are the sole suppliers of albuterol sulfate extended-release tablets.</p> <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Mylan has albuterol sulfate 4 mg and 8 mg extended-release tablets on back order and the company estimates a release date of early- to mid-July 2019 for the 4 mg tablets and mid- to late-June 2019 for the 8 mg tablets.
Morphine immediate-release tablet; 15 mg and 30 mg	Hikma	<p>Hikma did not provide a reason for the shortage.</p> <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Hikma has all morphine immediate-release tablets on allocation.
Flurazepam capsule; 15 mg and 30 mg	Mylan	<p>Mylan did not provide a reason for the shortage. They are the sole suppliers of flurazepam.</p> <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Mylan has flurazepam 15 mg and 30 mg capsules on back order and the company estimates a release date of early- to mid-December 2019.
Fludrocortisone acetate tablet; 0.1 mg	Impax Teva	<ul style="list-style-type: none"> • Impax did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Impax has fludrocortisone acetate 0.1 mg tablets on intermittent back order and the company is releasing product regularly. • Teva has fludrocortisone acetate 0.1 mg tablets temporarily unavailable and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Bisoprolol Fumarate oral tablet; 5 mg and 10 mg	Mylan Unichem Pharmaceuticals	<ul style="list-style-type: none"> • Mylan reports that product is on shortage due to manufacturing delays. • Unichem Pharmaceuticals has product on shortage due to market demand. <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Mylan has bisoprolol 5 mg tablets in 30- and 100-count bottles and 10 mg tablets in 30- and 100-count bottles on back order and the company estimates a release date of mid-July 2019. • Unichem has bisoprolol 5 mg tablets in 30- and 100-count bottles and 10 mg tablets in 30- and 100-count bottles on allocation.
<ul style="list-style-type: none"> • Calan SR extended release tablet; 180 mg • Verapamil hydrochloride extended release tablet; 120 mg, 180 mg, 240 mg 	Pfizer Glenmark Mylan	<ul style="list-style-type: none"> • Glenmark did not provide a reason for the shortage. • Mylan did not provide a reason for the shortage. • Pfizer did not provide a reason for the shortage. <p>Estimated resupply dates:</p> <ul style="list-style-type: none"> • Glenmark has verapamil 180 mg extended-release tablets in 100 count and 500 count and 240 mg extended-release tablets in 100 count and 500 count on back order and the company estimates a release date of late-April 2019. • Mylan has verapamil 120 mg extended-release tablets in 100 count, 180 mg tablets extended-release tablets in 100 count and 500 count, and 250 mg extended-release tablets in 90 count, 100 count, and 500 count on back order and the company estimates a release date of mid-July 2019. The 120 mg extended-release tablets, 180 mg extended-release tablets, and 240 mg extended-release tablets in 100-count unit-dose packs are on back order and the company estimates a release date of late-July to early-August 2019. • Pfizer has Calan SR 180 mg extended-release tablets on back order and the company estimates a release date of July 2019.
Prochlorperazine maleate tablet; 5 mg and 10 mg	Cadista Mylan	<ul style="list-style-type: none"> • Cadista has prochlorperazine maleate tablets on shortage due to increased demand. • Mylan did not provide a reason for the shortage. <p>Estimated resupply rates:</p> <ul style="list-style-type: none"> • Cadista has prochlorperazine maleate 5 mg and 10 mg tablets on allocation. • Mylan has prochlorperazine maleate 5 mg and 10 mg tablets in 100-count bottles on back order and the company estimates a release date of late-August 2019. • Mylan Institutional has prochlorperazine maleate 10 mg tablets in 100-count unit-dose packs on back order and the company estimates a release date of mid-September 2019.

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
eszopiclone (Lunesta) zaleplon (Sonata) zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist)	The FDA is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep.
Opioid pain medications	The FDA has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.



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