Gold Coast Health Plan℠
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Pharmacy Newsletter

Q4 2021

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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

Starting Jan. 1, 2022, the state Department of Health Care Services (DHCS) will carve out all prescription benefits from managed care plans (MCP) under a new program called Medi-Cal Rx. Upon implementation, all pharmacy claims will be submitted directly to the state via its pharmacy benefit manager (PBM), Magellan Medicaid Administration, Inc.

The Medi-Cal Rx website contains the most accurate, up-to-date information regarding Medi-Cal Rx. The website includes a program overview and background information, frequently asked questions (FAQs), preliminary information regarding the transition policy, and a high-level overview of the training and communication schedule. In the future, the website will serve as a member and provider portal and will be instrumental in the prior authorization process. Please make sure to bookmark this website today and sign up for the Medi-Cal Rx Subscription Services (MCRxSS).

Formulary Changes

The following changes to the GCHP formulary are effective Oct. 1:

Additions

Drug	Formulary Status / Change
TRUSELTIQ *(infigratinib phosphate)*	Added to formulary with prior authorization.
LUMAKRAS *(sotorasib)*	Added to formulary with prior authorization.
COMBIVENT RESPIMAT *(ipratropium bromide and albuterol)*	Added to formulary.
SEMGLEE *(insulin glargine-yfgn)*	Added to formulary.

Removals

Drug	Formulary Status / Change
Brovana *(Arformoterol Tartrate)* Inhalation Solution, 15 mcg/2 mL Unit-Dose Vials	Brand removed from formulary due to generic availability.
Perforomist *(Formoterol Fumarate)* Inhalation Solution, 20 mcg/2 mL Single-Dose Vial	Brand removed from formulary due to generic availability.
Revlimid *(Lenalidomide)* Capsules, 5 mg, 10 mg, 15 mg and 25 mg	Brand removed from formulary due to generic availability.
Xtandi *(Enzalutamide)* Capsules, 40 mg	Brand removed from formulary due to generic availability.
Opsumit *(Macitentan)* Tablets, 10 mg	Brand removed from formulary due to generic availability.

FDA Alerts

FDA New Drug Approvals

This information 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
BREXAFEMME	*Ibrexafungerp citrate*	Oral tablet	Triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis.
KERENDIA	*Finerenone*	Oral tablet	A non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained egfr decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).
TEMBEXA	*Brincidofovir*	Oral suspension and oral tablet	Orthopoxvirus nucleotide analog DNA polymerase inhibitor indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates.
EPCLUSA	*Sofosbuvir; velpatasvir*	Oral pellets	Fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: • Without cirrhosis or with compensated cirrhosis. • With decompensated cirrhosis for use in combination with ribavirin.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
MAVYRET	*Glecaprevir; pibrentasvir*	Oral pellets	Fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). • MAVYRET is indicated for the treatment of adult and pediatric patients 3 years of age and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
SOAANZ	*Torsemide*	Oral tablet	A loop diuretic indicated in adults for the treatment of edema associated with heart failure or renal disease.
REZIPRES	*Ephedrine hydrochloride*	IV solution	Alpha- and beta-adrenergic agonist and a norepinephrine releasing agent indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
PRADAXA	*Dabigatran etexilate mesylate*	Oral pellets	A direct thrombin inhibitor indicated: • For the treatment of venous thromboembolic events (VTE) in pediatric patients 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least five days. • To reduce the risk of recurrence of VTE in pediatric patients 3 months to less than 12 years of age who have been previously treated.
VERKAZIA	*Cyclosporine*	Ophthalmic emulsion	Calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis in children and adults.
DOLUTEGRAVIR, LAMIVUDINE, and TENOFOVIR DISSOPROXIL FUMARATE	*Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate*	Oral tablet	Antiretroviral indicated for HIV infection.
FEXINIDAZOLE	*Fexinidazole*	Oral tablet	A nitroimidazole antimicrobial indicated for the treatment of both first-stage (hemolymphatic) and second-stage (meningoencephalitic) human African trypanosomiasis (HAT) due to Trypanosoma brucei gambiense in patients 6 years of age and older and weighing at least 20 kg.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
REZUROCK	*Belumosudil*	Oral tablet	Kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years of age and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.
BYLVAY	*Odevixibat*	Oral capsule	Ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
TWYNEO	*Tretinoin; benzoyl peroxide*	Topical cream	Combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.
UPTRAVI	*Selexipag*	IV powder	Prostacyclin receptor agonist pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.
SAPHNELO	*Anifrolumab-fnia*	Injectable	Type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.
NEXVIAZYME	*Avalglucosidase alfa-ngpt*	Injectable	Hydrolytic lysosomal glycogen-specific enzyme treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).
WELIREG	*Belzutifan*	Oral tablet	Hypoxia-inducible factor inhibitor indicated for von Hippel-Lindau (VHL) disease requiring therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pnet), not requiring immediate surgery.
JEMPERLI	*Dostarlimab-gxly*	Injectable	Programmed death receptor-1 indicated for the treatment of adult patients with mismatch repair deficient (dmmr) recurrent or advanced: • Endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen, or • Solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
KORSUVA	*Difelikefalin acetate*	IV solution	Kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-ap) in adults undergoing hemodialysis (HD).
SKYTROFA	*Lonapegsomatropin-tcgd*	Injectable	Human growth hormone indicated for treatment of pediatric patients 1 year of age and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

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
GLYXAMBI *(EMPAGLIFLOZIN; LINAGLIPTIN)*	Contraindications	GLYXAMBI is contraindicated in: • Patients on dialysis. • Hypersensitivity to empagliflozin, linagliptin, or any of the excipients in GLYXAMBI, reactions such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity have occurred.
HICON *(sodium iodide i-131)*	Contraindications	HICON is contraindicated in: • Patients with vomiting and diarrhea. • Patients with thyroid malignancies shown to have no iodide uptake, which include the majority of medullary or anaplastic carcinomas. • Patients receiving concurrent anti-thyroid therapy. • Pregnancy. • Lactation.
SYNJARDY *(empagliflozin; metformin hydrochloride)*	Contraindications	SYNJARDY is contraindicated in patients with: • Severe renal impairment (eGFR less than 30 mL/min/1.73 m2), end stage renal disease, or dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. • Hypersensitivity to empagliflozin, metformin or any of the excipients in SYNJARDY, reactions such as angioedema have occurred.
SYNJARDY XR *(empagliflozin;metformin hydrochloride)*	Contraindications	SYNJARDY XR is contraindicated in patients with: • Severe renal impairment (eGFR less than 30 mL/min/1.73 m2), end stage renal disease, or dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. • Hypersensitivity to empagliflozin, metformin or any of the excipients in SYNJARDY XR, reactions such as angioedema have occurred.
ZELAPAR *(selegiline hydrochloride)*	Contraindications	ZELAPAR is contraindicated in patients with: • Concomitant use of opioid drugs (e.g., meperidine, tramadol, or methadone). Serotonin syndrome, a potentially serious condition, which can result in death, has been reported with concomitant use of meperidine (e.g., Demerol and other trade names). At least 14 days should elapse between discontinuation of ZELAPAR and initiation of treatment with these medications. • Concomitant use of other drugs in the monoamine oxidase inhibitor (MAOI) class or other drugs that are potent inhibitors of monoamine oxidase, including linezolid, because of an increased risk for hypertensive crisis. At least 14 days should elapse between discontinuation of ZELAPAR and initiation of treatment with any MAO inhibitor. • Concomitant use of St. John's wort or cyclobenzaprine (a tricyclic muscle relaxant). • Concomitant use of dextromethorphan, because of reported episodes of psychosis or bizarre behavior.

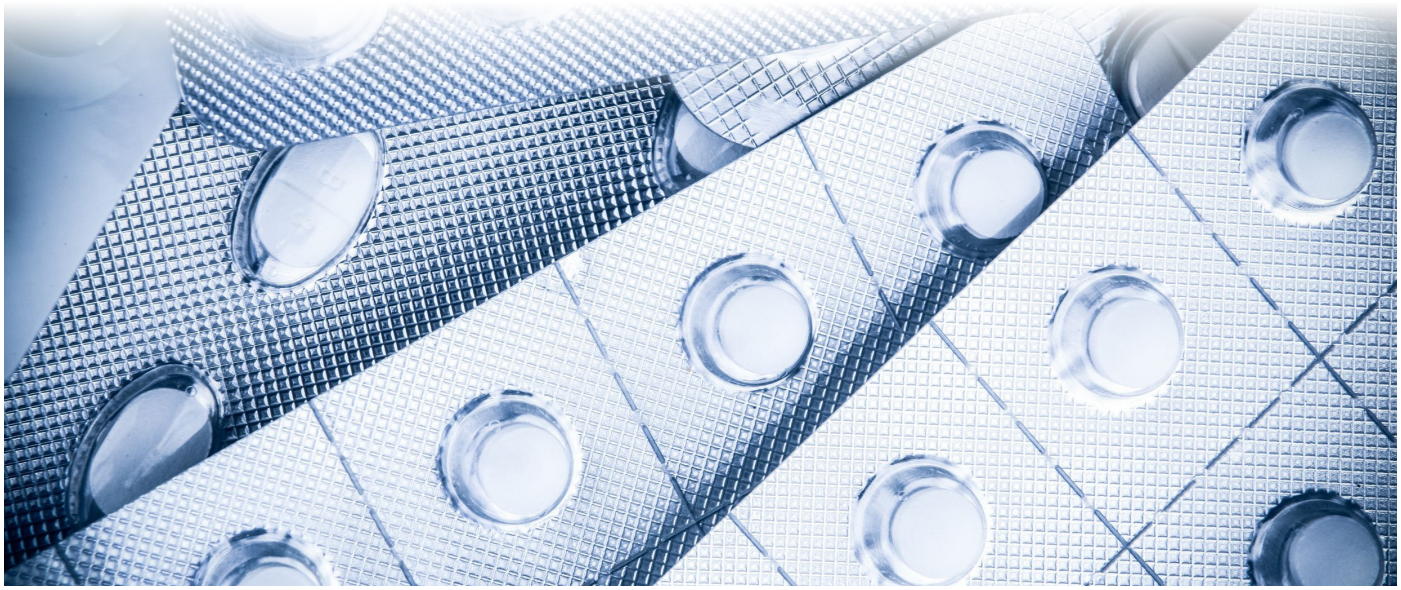
Drug	Type of Change	Change
BYETTA *(exenatide synthetic)*	Contraindications	BYETTA is contraindicated in patients with: • A prior severe hypersensitivity reaction to exenatide or to any of the excipients in BYETTA. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with BYETTA.
INFLECTRA *(infliximab-dyyb)*	Contraindications	The use of INFLECTRA at doses > 5 mg/kg is contraindicated in patients with moderate or severe heart failure. INFLECTRA is contraindicated in patients with a previous severe hypersensitivity reaction to infliximab products or any of the inactive ingredients of INFLECTRA or any murine proteins (severe hypersensitivity reactions have included anaphylaxis, hypotension, and serum sickness).
TOVIAZ *(fesoterodine fumarate)*	Contraindications	TOVIAZ is contraindicated in patients with any of the following: • Known or suspected hypersensitivity to TOVIAZ or any of its ingredients, or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. Reactions have included angioedema, urinary retention, gastric retention and uncontrolled narrow-angle glaucoma.
PRADAXA *(dabigatran etexilate mesylate)*	Contraindications	Contraindicated in patients with a history of a serious hypersensitivity reaction to dabigatran, dabigatran etexilate, or to one of the excipients of the product (e.g., anaphylactic reaction or anaphylactic shock).

Drug	Type of Change	Change
BIJUVA *(estradiol; progesterone)*	Boxed Warnings	**Breast Cancer** The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer. Only daily oral 0.625 mg CE and 2.5 mg MPA were studied in the estrogen plus progestin substudy of the WHI. Therefore, the relevance of the WHI findings regarding adverse cardiovascular events, dementia and breast cancer to lower CE plus other MPA doses, other routes of administration, or other estrogen plus progestogen products is not known. Without such data, it is not possible to definitively exclude these risks or determine the extent of these risks for other products. Discuss with your patient the benefits and risks of estrogen plus progestogen therapy, taking into account her individual risk profile. Prescribe estrogens with or without progestogens at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. **Cardiovascular Disorders and Probable Dementia** The WHI estrogen-alone substudy reported increased risks of stroke and DVT in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral CE (0.625 mg)-alone, relative to placebo. The WHIMS estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age and older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. Do not use estrogen-alone therapy for the prevention of cardiovascular disease or dementia. Only daily oral 0.625 mg CE was studied in the estrogen-alone substudy of the WHI. Therefore, the relevance of the WHI findings regarding adverse cardiovascular events and dementia to lower CE doses, other routes of administration, or other estrogen-alone products is not known. Without such data, it is not possible to definitively exclude these risks or determine the extent of these risks for other products. Discuss with your patient the benefits and risks of estrogen-alone therapy, taking into account her individual risk profile. Prescribe estrogens with or without progestogens at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Drug	Type of Change	Change
ESTROSTEP FE *(ethinyl estradiol; norethindrone acetate)*	Boxed Warning	Combined oral contraceptives should not be used in women who currently have the following: • A high risk of arterial or venous thrombotic diseases. Examples include women who are known to: ‣ Smoke, if over 35 years of age. ‣ Have cerebrovascular disease. ‣ Have coronary artery disease. ‣ Have current or history of deep vein thrombosis or pulmonary embolism. ‣ Have thrombogenic valvular or thrombogenic rhythm diseases of the heart. ‣ Have inherited or acquired hypercoagulopathies. ‣ Have uncontrolled hypertension or hypertension with vascular disease. ‣ Have headaches with focal neurological symptoms, migraine headaches with aura, or who are over 35 years of age with any migraine headaches. ‣ Have diabetes mellitus and are over 35 years of age, diabetes mellitus with hypertension or with vascular disease or end-organ damage, or diabetes mellitus of > 20 years duration. • Known or suspected carcinoma of the breast. • Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia. • Undiagnosed abnormal genital bleeding. • Cholestatic jaundice of pregnancy or jaundice with prior pill use. • Hepatic adenomas or carcinomas. • Known or suspected pregnancy. • Are receiving Hepatitis C drug combinations containing ombitasvir / paritaprevir / ritonavir, with or without dasabuvir, due to the potential for ALT elevations.
GVOKE HYPOPEN *(glucagon)*	Contraindications	GVOKE 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 GVOKE. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.
GVOKE PFS *(glucagon)* GLUCAGON *(glucagon hydrochloride)*	Contraindications	GLUCAGON 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 GVOKE. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.
MEPHYTON *(phytonadione)*	Contraindications	MEPHYTON is contraindicated in patients with a history of a hypersensitivity reaction to phytonadione or inactive ingredients.

Drug	Type of Change	Change
METHYLIN *(methylphenidate hydrochloride)*	Boxed Warning	METHYLIN is contraindicated in patients: • With known hypersensitivity to methylphenidate or other components of METHYLIN. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate. • Receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of treatment with an MAOI, because of the risk of hypertensive crises.
SOLIQUA 100/33 *(insulin glargine; lixisenatide)*	Contraindications	SOLIQUA is contraindicated in patients with serious hypersensitivity to insulin glargine, lixisenatide, or any of the excipients in SOLIQUA 100/33. Hypersensitivity reactions including anaphylaxis have occurred with both lixisenatide and insulin glargine.
ADLYXIN *(lixisenatide)*	Contraindications	ADLYXIN is contraindicated in patients with known severe hypersensitivity to lixisenatide or to any component of ADLYXIN. Hypersensitivity reactions including anaphylaxis have occurred with ADLYXIN.
OMNIPAQUE *(iohexol)*	Contraindications	• OMNIPAQUE is contraindicated for intrathecal use. • OMNIPAQUE oral solution 9 and 12 are contraindicated for parenteral administration. • OMNIPAQUE body cavity 240 and 300 for hysterosalpingography is contraindicated during pregnancy or suspected pregnancy, menstruation or when menstruation is imminent, within six months after termination of pregnancy, within 30 days after conization or curettage, when signs of infection are present in any portion of the genital tract including the external genitalia, and when reproductive tract neoplasia is known or suspected because of the risk of peritoneal spread of neoplasm.
ACTIVELLA *(estradiol; norethindrone acetate)*	Contraindications	ACTIVELLA is contraindicated in women with any of the following conditions: • Undiagnosed abnormal genital bleeding. • Breast cancer or history of breast cancer. • Estrogen-dependent neoplasia. • Active DVT, PE, or history of these conditions. • Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions. • Known anaphylactic reaction, angioedema, or hypersensitivity to ACTIVELLA. • Hepatic impairment or disease. • Protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.
MAXIPIME *(cefepime hydrochloride)*	Contraindications	MAXIPIME is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibacterial drugs, penicillins or other beta-lactam antibacterial drugs.

Drug	Type of Change	Change
QUELICIN *(succinylcholine chloride)*	Contraindications	QUELICIN is contraindicated: • In patients with skeletal muscle myopathies. • In patients with known hypersensitivity to succinylcholine. Severe anaphylactic reactions to succinylcholine have been reported. • After the acute phase of injury following major burns, multiple traumas, extensive denervation of skeletal muscle, or upper motor neuron injury, which may result in severe hyperkalemia and cardiac arrest. • In patients with personal or familial history of malignant hyperthermia.
LYUMJEV *(insulin lispro-aabc)*	Contraindications	LYUMJEV is contraindicated: • During episodes of hypoglycemia. • In patients with hypersensitivity to insulin lispro-aabc or any of the excipients in LYUMJEV.
INNOPRAN XL *(propranolol hydrochloride)*	Boxed Warnings	Use in specific populations: • Pregnancy. • Lactation. • Females and males of reproductive potential infertility. • Males: Based on the published literature, beta-blockers, including propranolol, may cause erectile dysfunction. In rats, propranolol inhibits spermatogenesis.
LINZESS *(linaclotide)*	Boxed Warning and Contraindications	**WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE** LINZESS is contraindicated in patients less than 2 years of age; in nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration.
NEXIUM *(esomeprazole magnesium)*	Contraindications	Proton pump inhibitors (PPIs), including NEXIUM, are contraindicated in patients receiving rilpivirine containing products.



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
Hydrocortisone oral tablet 5 mg, 10 mg, 20 mg	Amneal Greenstone	• Amneal discontinued all hydrocortisone tablets presentations in the first half of 2020. • Greenstone did not provide a reason for the shortage. • Pfizer has Cortef tablets available. **Estimated Resupply Dates** • Greenstone has all hydrocortisone tablet presentations on allocation.
Dicloxacillin sodium oral capsule 250 mg, 500 mg	Sandoz Teva	• Sandoz did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Sandoz has dicloxacillin sodium capsules on back order and the company cannot estimate a release date. • Teva has dicloxacillin sodium capsules on back order and the company estimates a release date of early-November 2021.
Nefazodone hydrochloride oral tablet 50 mg, 100 mg, 150 mg, 200 mg, 250 mg	Teva	• Teva has nefazodone on shortage due to raw ingredient supply issues. They are the sole suppliers of nefazodone tablets. **Estimated Resupply Dates** • Teva has all presentations temporarily unavailable, 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
XELJANZ *(tofacitinib)* XELJANZ XR *(tofacitinib)* OLUMIANT *(baricitinib)* RINVOQ *(upadacitinib)*	Based on a completed U.S. Food and Drug Administration (FDA) review of a large, randomized safety clinical trial, we have concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicines XELJANZ and XELJANZ XR (tofacitinib). This trial compared XELJANZ with another type of medicine used to treat arthritis called tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis. The trial's final results also showed an increased risk of blood clots and death with the lower dose of XELJANZ. A prior DSC based upon earlier results from this trial reported an increased risk of blood clots and death only seen at the higher dose. The FDA is requiring new and updated warnings for two other arthritis medicines in the same drug class as XELJANZ, called Janus kinase (JAK) inhibitors, OLUMIANT (baricitinib) and RINVOQ (upadacitinib). OLUMIANT and RINVOQ have not been studied in trials similar to the large safety clinical trial with XELJANZ, so the risks have not been adequately evaluated. However, since they share mechanisms of action with XELJANZ, FDA considers that these medicines may have similar risks as seen in the XELJANZ safety trial.
Statins – entire class	The U.S. Food and Drug Administration (FDA) is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients. Despite the change, most patients should stop statins once they learn they are pregnant. The FDA has conducted a comprehensive review of all available data and is requesting that statin manufacturers make this change to the prescribing information as part of FDA's ongoing effort to update the pregnancy and breastfeeding information for all prescription medicines. Patients should not breastfeed when taking a statin because the medicine may pass into breast milk and pose a risk to the baby. Many can stop statins temporarily until breastfeeding ends. However, patients requiring ongoing statin treatment should not breastfeed and instead use infant formula or other alternatives.

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For additional information, contact Pharmacy Relations at 888.531.0998.
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