Gold Coast Health Plan℠
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Pharmacy Newsletter

Q4 2022

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Table of Contents

PN Q4 2022

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 Clinical Programs Pharmacist Lily Yip, at lyip@goldchp.org or 1-805-437-5873.

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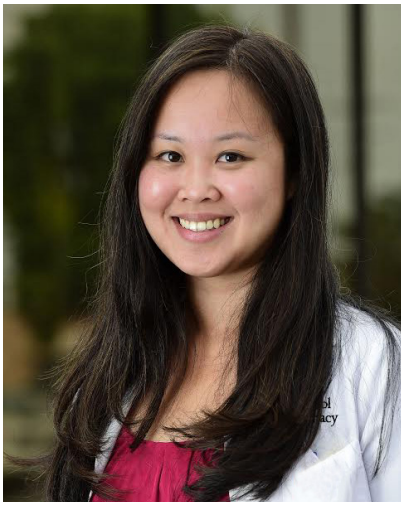
Meet Gold Coast Health Plan's (GCHP) new Clinical Programs Pharmacist



Lily Yip, Pharm.D., APh, CDCES, BCACP

Gold Coast Health Plan (GCHP) is excited to introduce our new Clinical Programs Pharmacist, Lily Yip, Pharm.D., APh, CDCES, BCACP. She has more than six years of experience working in an outpatient pharmacy and more than 10 years of experience creating and developing clinical pharmacy programs for multiple medical groups in the Los Angeles and Santa Barbara communities. She has experience with medication therapy management (MTM), chronic disease state management, population health management, and collaborating with medical leadership to develop strategies for an interdisciplinary team approach to patient care. Her experiences as a clinical pharmacist have given her the exposure of working closely with both the Medicaid and Medicare populations. She is also a Board Certified Ambulatory Care Pharmacist (BCACP), a Certified Diabetes Care and Education Specialist (CDCES), and a licensed Advanced Practice Pharmacist (APh) in California.

GCHP is pleased to welcome her to the team and looks forward to the development of new clinical programs aimed at providing the best level of care experience for our members.

Medi-Cal Rx Update

New Pharmacy Benefit: Blood Pressure Monitors

Effective June 1, 2022, Medi-Cal Rx began covering blood pressure monitors as a pharmacy benefit.

- Members are eligible to receive a new monitor if they have an ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis.
- One monitor is covered once every five years.
- Covered products are listed on the Medi-Cal Rx website, which is frequently updated.

Medical Supplies: Removal of Prior Authorization Requirement for Covered Blood Pressure Cuffs

Effective Nov. 1, 2022, covered blood pressure cuffs on the List of Covered Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs will no longer require a prior authorization (PA) for coverage. A Code 1 Indicator for diagnosis on the prescription is required.

These blood pressure cuffs work with covered personal home use blood pressure monitors for use during personal home blood pressure monitoring. Covered products continue to be restricted to the List of Covered Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs. Quantity and billing restrictions also apply. Refer to the List of Covered Medical Supplies Product Descriptions and Billing Information for billing and reimbursement information.

Updates to Continuous Glucose Monitoring Systems

Effective Oct. 1, 2022, both types of continuous glucose monitoring (CGM) systems will be medical supplies pharmacy-billed benefits through Medi-Cal Rx, subject to prior authorization (PA) and a contracted List of Covered Continuous Glucose Monitoring Systems. Please refer to the updated List of Covered Continuous Glucose Monitoring (CGM) Systems and the Medi-Cal Rx Provider Manual on the Medi-Cal Rx Web Portal for specific information.

For Fee-for-Service Medi-Cal beneficiaries: Beginning Oct. 1, 2022, claims previously paid as a medical benefit billed on a Centers for Medicare & Medicaid Services (CMS) 1500 form via a Healthcare Common Procedure Coding System (HCPCS) must be submitted as a pharmacy claim to Medi-Cal Rx. These HCPCS codes will deny for medical claims submitted with a date of service after Dec. 1, 2022.

Note: Corresponding insulin pumps for some CGM devices will continue to remain a Durable Medical Equipment (DME) billable as a medical benefit billed on a CMS 1500 form via a HCPCS code. Please refer to the DME section of the Provider Manual on the Medi-Cal website for coverage and billing information of DME insulin pumps and accessories.

Diabetic Supplies Updates

Effective Nov. 20, 2022, LifeScan test strips, lancets, self-monitoring blood glucose meters and their accessories will no longer be Medi-Cal Rx-covered pharmacy benefits.

Products deleted from the list will no longer be reimbursable, even with an approved prior authorization (PA), on or after Nov. 20, 2022, and continuing care does not apply. The Maximum Acquisition Cost (MAC) for these products will no longer be guaranteed.

Medi-Cal Rx beneficiaries with coverage through California Children's Services (CCS), Genetically Handicapped Persons Program (GHPP), or Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) may continue to receive these test strips and lancets with an approved PA demonstrating medical necessity and that no other contracted product could provide the required benefit.

The List of Covered Diabetic Test Strips and Lancets and List of Covered Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices have been updated on the Medi-Cal Rx Web Portal.

Phasing Out of the Transition Policy for Medi-Cal Rx

Medi-Cal Rx recently began reinstating its prior authorization requirements and other claim edits that were suspended in February. Phase I of the reinstatement included three waves and has been implemented as follows:

- Phase I, Wave I, which reinstated Drug Utilization Review (DUR) rejections (soft rejections that are overridden in the pharmacy) went into effect in mid-July with no reported disruptions.
- Phase I, Wave II went into effect in August. This wave was related to the promotion of CoverMyMeds and encouraging more providers to use this as an option to submit prior authorization (PA) requests electronically.
- Phase I, Wave III went into effect on September 16. Wave III relates to reinstatement of PA requirements for 11 drug classes. This should only affect new starts for members 22 years of age and older, for the time being. The 11 classes of drugs involved are: diuretics, antilipemic agents (including statins and omega-3 fatty acids), hypoglycemics, glucagon, antihypertensives, coronary vasodilators (nitrates and pulmonary arterial hypertension agents), cardiovascular agents (including antiarrhythmics and inotropes), anticoagulants, antiplatelets, niacin, vitamin B, and vitamin C products.

Phase II will reinstate PA requirements for the remaining 71 drug classes for new prescriptions and is not expected to go into effect until Phase I has been successfully implemented. The state Department of Health Care Services (DHCS) has stated it will give, at minimum, a 30-day advanced notice of the start of Phase II. Please look for additional information as it is released to be sure that you are up to date on the changes.

The DHCS website contains the most accurate, up-to-date information regarding Medi-Cal Rx. Make sure to bookmark this website today and sign up for the Medi-Cal Rx Subscription Services (MCRxSS). The website includes an 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.

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
EPSOLAY	*benzoyl peroxide*	Topical cream	Inflammatory lesions of rosacea in adults 18 years of age and older.
CAMZYOS	*mavacamten*	Oral capsule	Indicated in adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.
ERMEZA	*levothyroxine sodium*	Oral solution	Indicated in adult and pediatric patients, including neonates, for: • Hypothyroidism: as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. • Pituitary thyrotropin (Thyroid-Stimulating Hormone, TSH) suppression: as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
VOQUEZNA DUAL PAK	*amoxicillin; vonoprazan*	Oral capsule, oral tablet	Co-packaged product indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults.
TYVASO DPI	*treprostinil*	Inhalation powder	Indicated for the treatment of: • Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with Tyvaso establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). • Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with Tyvaso establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
FYLNETRA	*pegfilgrastim-pbbk*	Injection	Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
AMVUTTRA	*vutrisiran*	Injection	Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.
JEMPERLI	*dostarlimab-gxly*	Solution; Intravenous	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.
KORSUVA	*difelikefalin acetate*	Solution; Intravenous	Indicated for moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).
CAMCEVI KIT	*Leuprolide mesylate*	Subcutaneous emulsion	Gonadotropin-releasing hormone (gnrh) agonist Indicated for the treatment of adult patients with advanced prostate cancer.
TWYNEO	*tretinoin; benzoyl peroxide*	Topical cream	Indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.
BYOOVIZ	*ranibizumab-nuna*	Solution; Intravitreal	Indicated for the treatment of patients with: • Neovascular (wet) age-related macular degeneration (AMD). • Macular edema following retinal vein occlusion (RVO). • Myopic choroidal neovascularization (mCNV).
SEGLENTIS	*celecoxib; tramadol hydrochloride*	Oral tablet	Indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
TASCENSO ODT	*fingolimod*	Orally disintegrating tablet	Indicated for treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg.
JEVTANA	*cabazitaxel*	Solution; Intravenous	Indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.
LYVISPAH	*baclofen*	Oral granule	Indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. May also be of some value in patients with spinal cord injuries and other spinal cord diseases.
SYMTUZA	*darunavir; cobicistat; emtricitabine; tenofovir alafenamide*	Oral tablet	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg: • Who have no prior antiretroviral treatment history or • Who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least six months and have no known substitutions associated with resistance to darunavir or tenofovir.
IBSRELA	*tenapanor*	Oral tablet	Indicated in the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.
TLANDO	*testosterone undecanoate*	Oral capsule	Testosterone replacement therapy in adult males for conditions associated with deficiency or absence of endogenous testosterone.

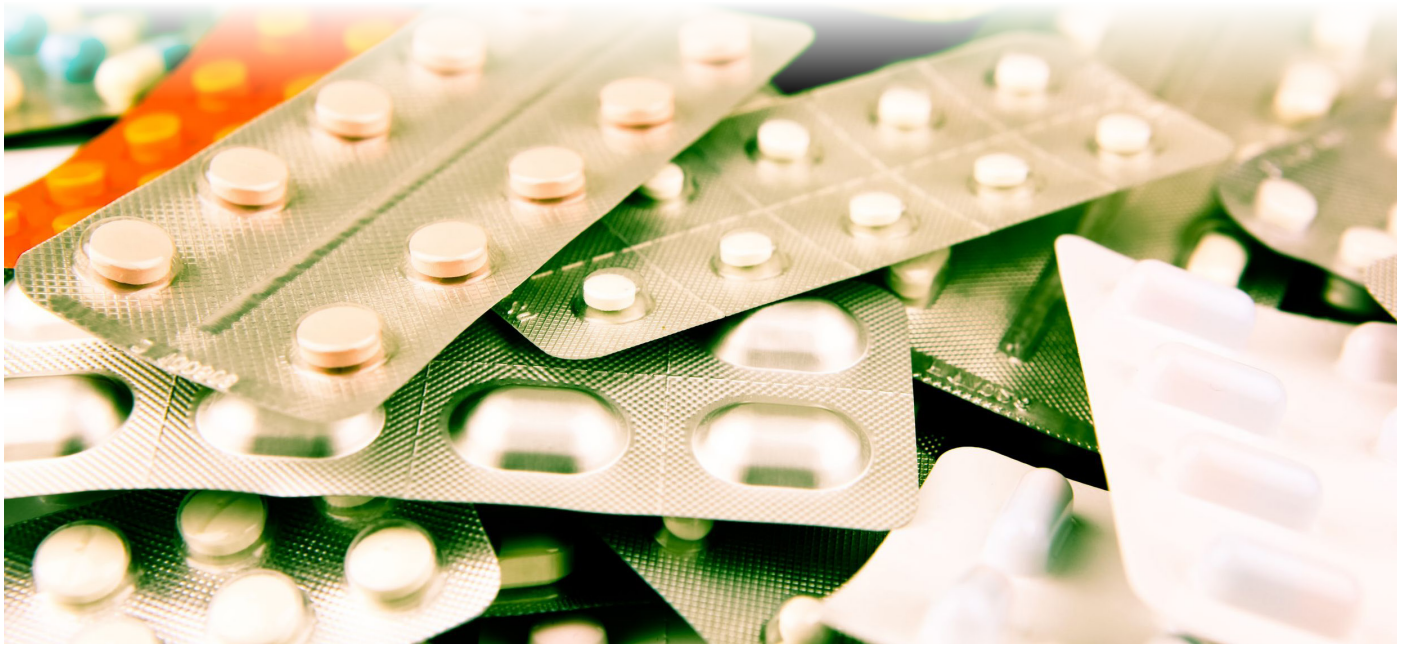
FDA Safety Labeling Changes

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
OPTIRAY 160 *(ioversol)* OPTIRAY 240 *(ioversol)* OPTIRAY 300 *(ioversol)* OPTIRAY 320 *(ioversol)* OPTIRAY 350 *(ioversol)*	Boxed Warning	RISKS WITH INADVERTENT INTRATHECAL ADMINISTRATION FOR INTRA-ARTERIAL AND INTRAVENOUS USE ONLY Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.
OPZELURA *(ruxolitinib phosphate)*	Boxed Warning	MORTALITY In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing an oral JAK inhibitor to tumor necrosis factor (TNF) blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor. MALIGNANCIES Malignancies were reported in patients treated with OPZELURA. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with an oral JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE) In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke. THROMBOSIS Thromboembolic events were observed in trials with OPZELURA. Thrombosis, including pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately.

Drug	Type of Change	Change
INTRALIPID 10% INTRALIPID 20% INTRALIPID 30%	Contraindications	INTRALIPID is contraindicated in patients with known hypersensitivity to egg, soybean, peanut protein, or to any of the active ingredients or excipients of INTRALIPID.
KRYSTEXXA *(pegloticase)*	Contraindications	KRYSTEXXA is contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency and in patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.
LEVEMIR *(insulin detemir recombinant)* LEVEMIR FLEXPEN *(insulin detemir recombinant)* LEVEMIR FLEXTOUCH *(insulin detemir recombinant)* LEVEMIR PENFILL *(insulin detemir recombinant)*	Contraindications	LEVEMIR is contraindicated: • During episodes of hypoglycemia. • In patients with hypersensitivity to insulin detemir or any of the excipients in LEVEMIR. Reactions have included anaphylaxis.
LO LOESTRIN FE *(ethinyl estradiol)* LOESTRIN 21 1.5/30 *(ethinyl estradiol; norethindrone acetate)* LOESTRIN 21 1/20 *(ethinyl estradiol; norethindrone acetate)* LOESTRIN 24 FE *(ethinyl estradiol; norethindrone acetate)* LOESTRIN FE 1.5/30 *(ethinyl estradiol; norethindrone acetate)* LOESTRIN FE 1/20 *(ethinyl estradiol; norethindrone acetate)*	Contraindications	LOESTRIN is contraindicated in females with a current diagnosis of, or history of, breast cancer, which may be hormone sensitive.
LOPRESSOR HCT *(hydrochlorothiazide; metoprolol tartrate)*	Contraindications	LOPRESSOR HCT is contraindicated in patients with: • Cardiogenic shock or decompensated heart failure. • Sinus bradycardia, sick sinus syndrome, and greater than first-degree block unless a permanent pacemaker is in place. • Anuria. • Hypersensitivity to metoprolol tartrate or hydrochlorothiazide or to other sulfonamide- derived drugs.
NITROMIST *(nitroglycerin)*	Contraindications	NITROMIST is contraindicated in patients with acute circulatory failure or shock.

Drug	Type of Change	Change
NUVARING *(ethinyl estradiol; etonogestrel)*	Contraindications	NUVARING is contraindicated in females who are known to have or develop current diagnosis of, or history of, breast cancer, which may be hormone-sensitive.
PERIKABIVEN IN PLASTIC CONTAINER *(amino acids; calcium chloride; dextrose; magnesium sulfate; potassium chloride; sodium acetate; sodium glycerophosphate; soybean oil)*	Contraindications	The use of PERIKABIVEN is contraindicated in: • Neonates (28 days of age or younger) receiving concomitant treatment with ceftriaxone, even if separate infusion lines are used, due to the risk of fatal ceftriaxone calcium salt precipitation in the neonate's bloodstream. • Patients with known hypersensitivity to egg, soybean proteins, peanut proteins, or to any of the active ingredients or excipients. • Patients with severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentration >1,000 mg/dL). • Patients with inborn errors of amino acid metabolism. • Patients with cardiopulmonary instability (including pulmonary edema, cardiac insufficiency, myocardial infarction, acidosis and hemodynamic instability requiring significant vasopressor support. • Patients with hemophagocytic syndrome.
PRAVACHOL *(pravastatin sodium)*	Contraindications	PRAVACHOL is contraindicated in patients with acute liver failure or decompensated cirrhosis or those with hypersensitivity to any pravastatin or any excipients in PRAVACHOL.
QSYMIA *(phentermine hydrochloride; topiramate)*	Contraindications	QSYMIA is contraindicated in patients: • Taking or within 14 days of stopping a monoamine oxidase inhibitor. • With known hypersensitivity to phentermine, topiramate or other component of QSYMIA, or idiosyncrasy to the sympathomimetic amines.



Drug	Type of Change	Change
SAFYRAL *(drospirenone; ethinyl estradiol; levomefolate calcium)*	Contraindications	SAFYRAL is contraindicated in females who are known to have or develop current diagnosis of, or history of, breast cancer, which may be hormone-sensitive.
TRESIBA *(insulin degludec)*	Contraindications	TRESIBA is contraindicated: • During episodes of hypoglycemia. • In patients with hypersensitivity to insulin degludec or any of the excipients in TRESIBA.
EFFEXOR XR *(venlafaxine hydrochloride)*	Boxed Warning / Contraindications	**Boxed Warning** **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS** Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. **Closely monitor all antidepressant-treated patients for clinical worsening, and emergence of suicidal thoughts and behaviors.** EFFEXOR XR is contraindicated in patients: • With known hypersensitivity to venlafaxine hydrochloride, desvenlafaxine succinate or to any excipients in the formulation. • Taking, or within 14 days of stopping, MAOIs (including the MAOIs linezolid and intravenous methylene blue) because of the risk of serotonin syndrome.

Drug	Type of Change	Change
ARTHROTEC *(diclofenac sodium; misoprostol)*	Boxed Warning / Contraindications	**Boxed Warning** **WARNING: RISK OF UTERINE RUPTURE, ABORTION, PREMATURE BIRTH, BIRTH DEFECTS; SERIOUS CARDIOVASCULAR EVENTS; AND SERIOUS GASTROINTESTINAL EVENTS** Uterine Rupture, Abortion, Premature Birth, and Birth Defects • Administration of misoprostol, a component of ARTHROTEC, to pregnant women can cause uterine rupture, abortion, premature birth, or birth defects. Uterine rupture has occurred when misoprostol was administered in pregnant women to induce labor or an abortion. • ARTHROTEC is contraindicated in pregnancy and not recommended in women of childbearing potential. Patients must be advised of the abortifacient property and warned not to give the drug to others. • If ARTHROTEC is prescribed, verify the pregnancy status of females of reproductive potential prior to initiation of treatment and advise them to use effective contraception during treatment. **Cardiovascular Thrombotic Events** • NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. • ARTHROTEC is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. **Gastrointestinal Bleeding, Ulceration, and Perforation** • NSAIDs cause an increased risk of serious gastrointestinal (GI) Adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. ARTHROTEC is contraindicated in the following patients: • Pregnancy. Use of misoprostol, a component of ARTHROTEC, during pregnancy can result in maternal and fetal harm, including uterine rupture, abortion, premature birth, or birth defects. • In the setting of coronary artery bypass graft (CABG) surgery. • Active gastrointestinal bleeding.

Drug	Type of Change	Change
ULTOMIRIS *(ravulizumab-cwvz)*	Boxed Warning	**Boxed Warning** **Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS REMS.**

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
Dicloxacillin Sodium Capsules	Sandoz Teva	• Sandoz discontinued dicloxacillin sodium capsules in January 2022. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Teva has dicloxacillin sodium 500 mg capsules on back order and the company estimates a release date of early-December 2022.
Colestipol Oral Tablets	Amneal	• Amneal did not provide a reason for the shortage. **Estimated Resupply Dates** • Amneal has colestipol 1-gram tablets on allocation.
Duloxetine Delayed Release Sprinkle Capsules	Sun Pharma	• Sun Pharma is not currently producing Drizalma Sprinkle capsules due to regulatory issues. • Sun Pharma is the sole supplier of duloxetine sprinkle capsules. • Other duloxetine delayed-release capsules are not affected by this shortage. **Estimated Resupply Dates** • Sun Pharma has Drizalma Sprinkle capsules unavailable, and the company cannot estimate when product will be available.
Varenicline Tablets	Pfizer	• Pfizer has Chantix on shortage due to a manufacturing delay to evaluate the active ingredient of the product. Pfizer has recalled all presentations of Chantix. More information on the recall can be found here. • The generic presentations are not affected by this shortage. **Estimated Resupply Dates** • Pfizer has Chantix on back order and the company cannot estimate a release date.
Cefixime Capsules	Ascend Lupin	• Ascend has discontinued cefixime capsules. • Lupin has cefixime capsules on shortage due to increased demand. **Estimated Resupply Dates** • Lupin has cefixime capsules available in limited supply.

Drug Product	Affected Manufacturers	Summary
Neomycin Sulfate Tablets	Akorn Teva X-Gen	• Akorn discontinued neomycin sulfate tablets in August 2022. • Teva did not provide a reason for the shortage. • X-gen has neomycin sulfate tablets on shortage due to manufacturing delays. **Estimated Resupply Dates** • Teva has neomycin sulfate tablets on back order and the company estimates a release date of late-October 2022. • X-gen has neomycin sulfate tablets on back order and the company estimates a release date of late-December 2022.
Diazepam Oral Solution	Hikma Lannett	• Hikma did not provide a reason for the shortage. • Lannett discontinued diazepam oral solution in January 2022. **Estimated Resupply Dates** • Hikma has diazepam 5 mg/mL 30 mL bottles on back order and the company estimated a release date in late-September 2022.
Dulaglutide Injection	Lilly USA	• Lilly has Trulicity on shortage due to increased demand. **Estimated Resupply Dates** • Lilly has all Trulicity presentations on intermittent back order and the company is releasing product as it becomes available.
Semaglutide Injection	Novo Nordisk	• Novo Nordisk has Ozempic on shortage due to increased demand. • Wegovy is on shortage due to increased demand and issues with contract manufacturers. Additional product supply information can be found here. **Estimated Resupply Dates** • Novo Nordisk has all Ozempic presentations on intermittent back order and the company is releasing product as it becomes available. • Novo Nordisk has all Wegovy presentations on back order and the company estimates a release date of late-2022.

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
UKONIQ *(umbralisib)*	Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine Ukoniq (umbralisib). Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL). Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq. As a result, we determined the risks of treatment with Ukoniq outweigh its benefits. Based upon this determination, the drug's manufacturer, TG Therapeutics, announced it was voluntarily withdrawing Ukoniq from the market for the approved uses in MZL and FL. Health care professionals should stop prescribing Ukoniq and switch patients to alternative treatments. Inform patients currently taking Ukoniq of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine. In limited circumstances in which a patient may be receiving benefit from Ukoniq, TG Therapeutics plans to make it available under expanded access.
COPIKTRA *(duvelisib)*	The U.S. Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood. Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Advise patients receiving Copiktra of the possible increased risk of death and higher risk of serious adverse events.

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For additional information, contact the
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