



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

**Pharmacy
Newsletter** **Q4** 2020

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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.

Pharmacy Director:
Anne Freese, Pharm. D.
Chief Medical Officer:
Nancy R. Wharfield, MD
Editor-in-Chief:
Susana Enriquez-Euyoque
Copy Editor:
Calley Cederlof

A Message from the Gold Coast Health Plan Pharmacy Director



Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to GCHP's formulary, new drug approvals, and safety labeling changes.

Our goal is to provide all medically-necessary pharmaceuticals in the most economical way possible. GCHP's formulary was developed by the Pharmacy & Therapeutics (P & T) Committee. It is reviewed and updated quarterly due to advances in therapeutic treatment regimens and newly-approved products by the U.S. Food and Drug Administration (FDA).

We want to ensure that all drugs are available to our members when the drugs are indicated. To help manage drug utilization, the formulary employs several mechanisms: Step therapy protocols, prior authorizations, quantity limits, and age restrictions. Any drug that is limited or is not listed may be available via prior authorization.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and our members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me.

Sincerely,

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

Anne Freese, Pharm.D.
Director of Pharmacy

Medi-Cal RX

Starting Jan. 1, 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.

DHCS has a [website](#) that contains the most accurate, up-to-date information regarding Medi-Cal Rx. Please 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.

Information about Medi-Cal Rx can also be found [here](#) on the Gold Coast Health Plan (GCHP) website.

Nature-Throid, WP Thyroid and Westthroid Recall

On Aug. 25, [RLC Labs announced a voluntary, consumer-level recall](#) of all unexpired lots of Nature-Throid and WP Thyroid tablets because some lots contain less than the required 90% of the active ingredient.

Patients using these medications may not be receiving the full expected dose and may experience symptoms that would normally indicate a dose adjustment may be required. However, this may be related to not receiving the full amount of the active ingredient.

Additional information regarding the recall can be found on the [U.S. Food and Drug Administration \(FDA\) website](#).



Formulary Changes

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

Additions

Drug	Formulary Status / Change
MYCAPSSA (<i>octreotide acetate</i>)	Add with a PA.
KYNMOBI (<i>apomorphine hydrochloride</i>)	Add with a PA.
TABRECTA (<i>capmatinib hydrochloride</i>)	Add with a PA.
RETEVMO (<i>selpercatinib</i>)	Add with a PA.
QINLOCK (<i>ripretinib</i>)	Add with a PA.
NEXLIZET (<i>bempedoic acid; ezetimibe</i>)	Add with a PA.
ISTURISA (<i>osilodrostat</i>)	Add with a PA.
ZEPOSIA (<i>ozanimod</i>)	Add with a PA.
FINTEPLA (<i>fenfluramine hydrochloride</i>)	Add with a PA.
LYUMJEV (<i>insulin lispro-aabc</i>)	Add to formulary in same fashion as Humalog.
TRUXIMA (<i>rituximab-abbs</i>)	Add to formulary in same fashion as Rituxan.
AVSOLA (<i>infliximab-axxq</i>)	Add to formulary in same fashion as Remicade.

Removals

Drug	Formulary Status / Change
Cloderm (<i>clocortolone Pivalate</i>) USP, 0.1% Cream	Brand removed from formulary due to generic availability.
Actigall (<i>ursodiol</i>) USP, 200 mg, 400 mg Capsules	Brand removed from formulary due to generic availability.
Desonate (<i>desonide</i>) Gel 0.05%	Brand removed from formulary due to generic availability.
Taclonex (<i>calcipotriene and betamethasone dipropionate</i>) Topical Suspension 0.005%/0.064%	Brand removed from formulary due to generic availability.
Noxafil (<i>posaconazole</i>) Oral Suspension, 200 mg/5 mL (40 mg/mL)	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
LYUMJEV	<i>Insulin lispro-aabc</i>	Injectable; injection	Rapid-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.
FINTEPLA	<i>Fenfluramine hydrochloride</i>	Solution; oral	Serotonin 5ht-2 receptor agonist indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.
PHESGO	<i>Pertuzumab; trastuzumab; hyaluronidase-zzxf</i>	Injectable; subcutaneous	Combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase, indicated for: <ul style="list-style-type: none"> • Use in combination with chemotherapy as: <ul style="list-style-type: none"> » Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. » Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. • Use in combination with docetaxel for treatment of patients with HER2 positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
ZEPZELCA	<i>Lurbinectedin</i>	Powder; intravenous	Alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.
MYCAPSSA	<i>Octreotide acetate</i>	Capsule, delayed release; oral	Somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.
TIVICAY PD	<i>Dolutegravir sodium</i>	Tablet, for suspension; oral	Human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but INSTI-naïve) at least 4 weeks of age and weighing at least 3 kg.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
RUKOBIA	<i>Fostemsavir</i>	Tablet, extended release; oral	Human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s) indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
UPLIZNA	<i>Inebilizumab-cdon</i>	Injectable; injection	CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
DOJOLVI	<i>Triheptanoin</i>	Liquid; oral	Medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).
NYVEPRIA	<i>Pegfilgrastim-apgf</i>	Injectable; injection	Leukocyte growth factor 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.
SEMGLEE	<i>Insulin glargine</i>	Injectable; injection	Long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
GIMOTI	<i>Metoclopramide hydrochloride</i>	Spray, metered; nasal	Dopamine-2 (D2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.
TRALEMENT	<i>Cupric sulfate; manganese sulfate; selenious acid; zinc sulfate</i>	Solution; intravenous	A combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.
BYFAVO	<i>Remimazolam</i>	Injectable; injection	Benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.
QWO	<i>Collagenase clostridium histolyticum-aaes</i>	Injectable; injection	A combination of bacterial collagenases indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.
HULIO	<i>Adalimumab-fkjp</i>	Injectable; injection	Tumor necrosis factor (TNF) blocker indicated for treatment of: <ul style="list-style-type: none"> • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Adult Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
INQOVI	<i>Decitabine; cedazuridine</i>	Tablet; oral	A combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
UPNEEQ	<i>Oxymetazoline hydrochloride</i>	Solution; ophthalmic	Indicated for the treatment of acquired blepharoptosis in adults.
WYNZORA	<i>Calcipotriene / betamethasone dipropionate</i>	Cream; topical	Corticosteroid indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.
XYWAV	<i>Calcium; magnesium; potassium; sodium oxybates</i>	Solution; oral	Central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
BREZTRI AERO-SPHERE	<i>Budesonide; formoterol fumarate; glycopyrrolate</i>	Aerosol, metered; inhalation	An inhaled corticosteroid (ICS); glycopyrrolate, an anticholinergic; and formoterol fumarate, a long-acting beta2-adrenergic agonist (LABA), indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
XEGLYZE	<i>Abametapir</i>	Lotion; topical	Pediculicide topical treatment of head lice infestation in patients 6 months of age and older.
VASOPRESSIN	<i>Vasopressin</i>	Solution; intravenous	Indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.
XTANDI	<i>Enzalutamide</i>	Tablet; oral	Androgen receptor inhibitor indicated for the treatment of patients with: <ul style="list-style-type: none"> • Castration-resistant prostate cancer. • Metastatic castration-sensitive prostate cancer.
BLENREP	<i>Belantamab mafodotin-blmf</i>	Gel; vaginal	B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
LAMPIT	<i>Nifurtimox</i>	Tablet; oral	Nitrofurantoin indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by <i>Trypanosoma cruzi</i> . This indication is approved under accelerated approval based on the number of treated patients who became immunoglobulin G (igg) antibody negative or who showed an at least 20% decrease in optical density on two different igg antibody tests against antigens of <i>T. Cruzi</i> . Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
OLINVYK	<i>Oliceridine</i>	Injectable; intravenous	Opioid agonist indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.
EVRYSDI	<i>Risdiplam</i>	For solution; oral	Survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.
VILTEPSO	<i>Viltolarsen</i>	Solution; intravenous	Antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
ENSPRYNG	<i>Satralizuma</i>	Injectable; injection	Interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
CYSTADROPS	<i>Cysteamine hydrochloride</i>	Solution / drops; ophthalmic	Cystine-depleting agent indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis.
WINLEVI	<i>Clascoterone</i>	Cream; topical	Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.
XARACOLL	<i>Bupivacaine hci</i>	Implant; subcutaneous	Indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair.
ONUREG	<i>Azacitidine</i>	Tablet; oral	Nucleoside metabolic inhibitor 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.

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
NEOSPORIN (<i>bacitracin zinc; neomycin sulfate; polymyxin b sulfate</i>)	Contraindications	LUMI-SPORYN is contraindicated in individuals who have shown hypersensitivity to any of its components.
VESICARE (<i>solifenacin succinate</i>)	Contraindications	Contraindicated in patients who have demonstrated hypersensitivity to solifenacin succinate or the inactive ingredients in VESICARE. Reported adverse reactions have included anaphylaxis and angioedema.
TYSABRI (<i>natalizumab</i>)	Boxed Warning	Risk factors for the development of PML include the presence of anti-JCV antibodies, duration of therapy, and prior use of immunosuppressants.
TEKTURNA (<i>aliskiren hemifumarate</i>)	Contraindications	TEKTURNA is contraindicated in pediatric patients less than 2 years of age because of the risk of high aliskiren exposures identified in juvenile animals due to immaturity of transporters and metabolic enzymes.
CAMPATH (<i>alemtuzumab</i>)	Boxed Warning	<p>Infusion-Related Reactions: CAMPATH administration can result in serious, including fatal, infusion-related reactions. Carefully monitor patients during infusions and withhold CAMPATH for Grade 3 or 4 infusion-related reactions. Gradually escalate CAMPATH to the recommended dose at the initiation of therapy and after interruption of therapy for seven or more days.</p> <p>Immunosuppression / Infections: Serious, including fatal, bacterial, viral, fungal, and protozoan infections can occur in patients receiving CAMPATH. Administer prophylaxis against <i>Pneumocystis jirovecii</i> pneumonia (PCP) and herpes virus infections.</p>
RETACRIT (<i>epoetin alfa-epbx</i>)	Contraindications	RETACRIT from multiple-dose vials contains benzyl alcohol and is contraindicated in: <ul style="list-style-type: none"> • Neonates, infants, pregnant women, and lactating women.
EMFLAZA (<i>deflazacort</i>)	Boxed Warning	<p>PATIENT COUNSELING INFORMATION</p> <p>EMFLAZA may be taken with or without food. Do not take EMFLAZA with grapefruit juice.</p> <p>The EMFLAZA Oral Suspension dose may be placed in 3-4 ounces of juice (except grapefruit juice) or milk, mixed thoroughly, and immediately administered.</p>
POTASSIUM CHLORIDE IN DEXTROSE 5% IN PLASTIC CONTAINER	Contraindications	POTASSIUM CHLORIDE IN DEXTROSE injection is contraindicated in patients with: <ul style="list-style-type: none"> • Known hypersensitivity to potassium chloride and/or dextrose. • Clinically significant hyperkalemia. • Clinically significant hyperglycemia.

Drug	Type of Change	Change
JULUCA (<i>dolutegravir sodium; rilpivirine hydrochloride</i>)	Contraindications	JULUCA is contraindicated in patients: <ul style="list-style-type: none">• With previous hypersensitivity reaction to dolutegravir or rilpivirine.• Receiving dofetilide due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events.• Receiving other co-administered drugs that significantly decrease rilpivirine plasma concentrations.
XYREM (<i>sodium oxybate</i>)	Contraindications	XYREM is contraindicated for use in: <ul style="list-style-type: none">• Combination with sedative hypnotics.• Combination with alcohol.• Patients with succinic semialdehyde dehydrogenase deficiency.



Drug	Type of Change	Change
ARTHROTEC (<i>diclofenac sodium; misoprostol</i>)	Boxed Warning	<p>ARTHROTEC CONTAINS DICLOFENAC SODIUM AND MISOPROSTOL. ADMINISTRATION OF MISOPROSTOL TO WOMEN WHO ARE PREGNANT CAN CAUSE ABORTION, PREMATURE BIRTH, BIRTH DEFECTS, OR UTERINE RUPTURE. UTERINE RUPTURE HAS BEEN REPORTED WHEN MISOPROSTOL WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION. THE RISK OF UTERINE RUPTURE INCREASES WITH ADVANCING GESTATIONAL AGES AND WITH PRIOR UTERINE SURGERY, INCLUDING CESAREAN DELIVERY. ARTHROTEC SHOULD NOT BE TAKEN BY PREGNANT WOMEN.</p> <p>PATIENTS MUST BE ADVISED OF THE ABORTIFACIENT PROPERTY AND WARNED NOT TO GIVE THE DRUG TO OTHERS. ARTHROTEC should not be used in women of childbearing potential unless the patient requires nonsteroidal anti-inflammatory drug (NSAID) therapy and is at a high risk of developing gastric or duodenal ulceration or for developing complications from gastric or duodenal ulcers associated with the use of the NSAID. In such patients, ARTHROTEC may be prescribed if the patient:</p> <ul style="list-style-type: none"> • Has had a negative serum pregnancy test within two weeks prior to beginning therapy. • Is capable of complying with effective contraceptive measures. • Has received both oral and written warnings of the hazards of misoprostol, the risk of possible contraception failure, and the danger to other women of childbearing potential should the drug be taken by mistake. • Will begin ARTHROTEC only on the second or third day of the next normal menstrual period. <p>Cardiovascular Thrombotic Events Risk</p> <ul style="list-style-type: none"> • Nonsteroidal anti-inflammatory drugs (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. <p>Gastrointestinal Bleeding, Ulceration, and Perforation Risk</p> <ul style="list-style-type: none"> • 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.

Drug	Type of Change	Change
HEPARIN SODIUM	Contraindications	The use of HEPARIN SODIUM is contraindicated in patients: <ul style="list-style-type: none"> • With history of heparin-induced thrombocytopenia (HIT) (with or without Thrombosis). • With a known hypersensitivity to heparin or pork products (e.g., anaphylactoid reactions). • In whom suitable blood coagulation tests — e.g., the whole blood clotting time, partial thromboplastin time, etc., — cannot be performed at appropriate intervals (this contraindication refers to full-dose heparin; there is usually no need to monitor coagulation parameters in patients receiving low-dose heparin). • With an uncontrollable active bleeding state, except when treating disseminated intravascular coagulation.
SUPREP BOWEL PREP KIT (<i>magnesium sulfate; potassium sulfate; sodium sulfate</i>)	Contraindications	SUPREP BOWEL PREP KIT is contraindicated in the following conditions: <ul style="list-style-type: none"> • Gastrointestinal obstruction or ileus. • Bowel perforation. • Toxic colitis or toxic megacolon gastric retention. • Hypersensitivity to any of the ingredients in SUPREP BOWEL PREP KIT.
CYCLOSET (<i>bromocriptine mesylate</i>)	Contraindications	Contraindicated in: <ul style="list-style-type: none"> • Postpartum patients. Serious and life-threatening adverse reactions have been reported with bromocriptine use in this population. • Lactating patients. CYCLOSET contains bromocriptine which inhibits lactation.
VARUBI (<i>rolapitant hydrochloride</i>)	Contraindications	VARUBI is contraindicated in pediatric patients less than 2 years of age because of irreversible impairment of sexual development and fertility observed in juvenile rats at clinically relevant dosages.



Drug	Type of Change	Change
MARCAINE HYDROCHLORIDE <i>(bupivacaine hydrochloride),</i> MARCAINE HYDROCHLORIDE WITH EPINEPHRINE <i>(bupivacaine hydrochloride; epinephrine bitartrate)</i>	Boxed Warning / Contraindications	<p>Boxed Warning: WARNING: RISK OF CARDIAC ARREST WITH USE OF MARCAINE IN OBSTETRICAL ANESTHESIA</p> <p>There have been reports of cardiac arrest with difficult resuscitation or death during use of MARCAINE for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of MARCAINE is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.</p> <p>Contraindications: MARCAINE / MARCAINE WITH EPINEPHRINE is contraindicated in:</p> <ul style="list-style-type: none"> • Obstetrical paracervical block anesthesia. Its use in this technique has resulted in fetal bradycardia and death. • Intravenous regional anesthesia (Bier Block). • Patients with a known hypersensitivity to bupivacaine or to any local anesthetic agent of the amide-type or to other components of MARCAINE / MARCAINE WITH EPINEPHRINE.



Drug	Type of Change	Change
KYPROLIS (<i>carfilzomib</i>)	Boxed Warning	<p>Cardiac Toxicities Death due to cardiac arrest has occurred within one day of KYPROLIS administration. In randomized, open-label, multicenter trials for combination therapies, the incidence of cardiac failure events was 8% and that of arrhythmias was 8% (majority of which were atrial fibrillation and sinus tachycardia).</p> <p>Tumor Lysis Syndrome Administer oral and intravenous fluids before administration of KYPROLIS in Cycle 1 and in subsequent cycles as needed. Consider uric acid-lowering drugs in patients at risk for Tumor Lysis Syndrome (TLS).</p> <p>Pulmonary Toxicity Acute Respiratory Distress Syndrome (ARDS) and acute respiratory failure have occurred in approximately 2% of patients who received KYPROLIS. In addition, acute diffuse infiltrative pulmonary disease, such as pneumonitis and interstitial lung disease, occurred in approximately 2% of patients who received KYPROLIS.</p> <p>Dyspnea Dyspnea was reported in 25% of patients treated with KYPROLIS.</p> <p>Hypertension Hypertension, including hypertensive crisis and hypertensive emergency, has been observed with KYPROLIS. In ASPIRE, the incidence of hypertension events was 17% in the KRd arm versus 9% in the Rd arm. In ENDEAVOR, the incidence of hypertension events was 34% in the Kd arm versus 11% in the Vd arm. In CANDOR, the incidence of hypertension events was 31% in the DKd arm versus 27% in the Kd arm. Some of these events have been fatal. Optimize blood pressure prior to starting KYPROLIS. Monitor blood pressure regularly in all patients while on KYPROLIS. If hypertension cannot be adequately controlled, withhold KYPROLIS and evaluate. Consider whether to restart KYPROLIS based on a benefit / risk assessment.</p>
ABRAXANE (<i>paclitaxel</i>)	Contraindications	<p>ABRAXANE is contraindicated in patients with:</p> <ul style="list-style-type: none"> • Baseline neutrophil counts of < 1,500 cells/mm³. • A history of severe hypersensitivity reaction to ABRAXANE.

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
Chloroquine Phosphate Tablets	<ul style="list-style-type: none"> • Rising • Sun Pharma 	<ul style="list-style-type: none"> • Rising did not provide a reason for the shortage. • Sun Pharma discontinued chloroquine tablets. <p>Estimated Resupply Dates:</p> <ul style="list-style-type: none"> • Rising has chloroquine phosphate 250 mg and 500 mg tablets available and the company is shipping to forecast.
Methyldopa Tablets	<ul style="list-style-type: none"> • Accord • Mylan • Teva 	<ul style="list-style-type: none"> • Accord has methyldopa temporarily unavailable due to shortage of raw ingredient. • Mylan discontinued the unit-dose presentations in 2019. They did not provide a reason for the shortage of the 100-count bottles. • Teva discontinued methyldopa tablets in 2018. <p>Estimated Resupply Dates:</p> <ul style="list-style-type: none"> • Accord has temporarily discontinued methyldopa presentations and the company cannot estimate when product will return. • Mylan has methyldopa 250 mg and 500 mg tablets in 100-count bottles on long-term back order 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
Naloxone	FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder.
Canagliflozin (Invokana, Invokamet, Invokamet XR)	FDA removed Boxed Warning about risk of leg and foot amputations for the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR). Based on a U.S. Food and Drug Administration (FDA) review of new data from three clinical trials, the FDA has removed the Boxed Warning about amputation risk from the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) prescribing information.



**Gold Coast
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A Public Entity

Pharmacy Newsletter

Q4 2020

SEPTEMBER 2020

For additional information, contact Pharmacy Relations at 888.531.0998.

Gold Coast Health Plan

711 East Daily Drive, Suite 106, Camarillo, CA 93010

www.goldcoasthealthplan.org