Gold Coast Health Plan℠
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Pharmacy Newsletter

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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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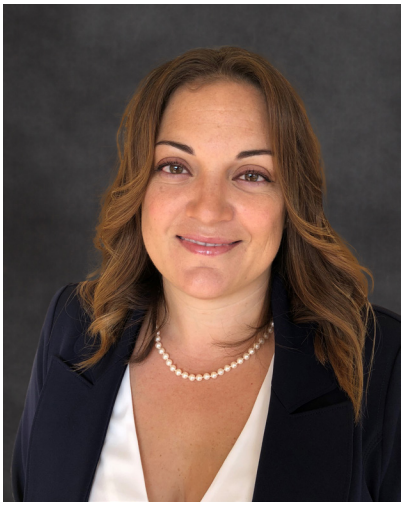
A Message from the Gold Coast Health Plan Pharmacy Director



Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to 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,

Anne Freese, Pharm.D.
Director of Pharmacy

Medi-Cal RX

Overview

On Jan. 7, 2019, Gov. Gavin Newsom issued Executive Order N-01-19, which requires the state Department of Health Care Services (DHCS) to transition all Medi-Cal pharmacy services from managed care (MC) to fee for service (FFS) by Jan. 1, 2021.

The Medi-Cal pharmacy benefits and services administered by DHCS in the FFS delivery system will be identified collectively as "Medi-Cal Rx."

Member Communication

The member communication strategy as outlined by DHCS is as follows:

- DHCS will send a 90-day AND a 60-day written notice to members.
- GCHP will send a 30-day written notice to members.
- GCHP will send new ID cards to members.
- GCHP will conduct a telephone outreach campaign to members in November and/or December 2020.

Transition Policy

DHCS will offer a transition period for members to prevent any disruption. The full policy is available here.

Listed below are a few basic elements of that policy.

- DHCS will use "grandfathering" and defined "look back" periods to allow members to continue using medications that they were previously using.
- DHCS will gather approved prior authorization information from Managed Care Plans (MCP) and honor those authorizations until the expiration or one year from the date of dispensing, whichever is sooner.
- Submitting providers, (e.g., pharmacies, prescribing providers, etc.) will receive communication of the prior authorization requirements.

Gold Coast Health Plan's Role

GCHP will be responsible for:

- Overseeing and maintaining all activities necessary for enrolled Medi-Cal beneficiary care coordination and related activities, consistent with contractual obligations.
- Providing oversight and management of all clinical aspects of pharmacy adherence, including providing disease and medication management.
- Processing and payment of all pharmacy services billed on medical and institutional claims.
- Participating in meetings related to the Medi-Cal Global Drug Utilization Review Board and other department-driven pharmacy committee meetings.

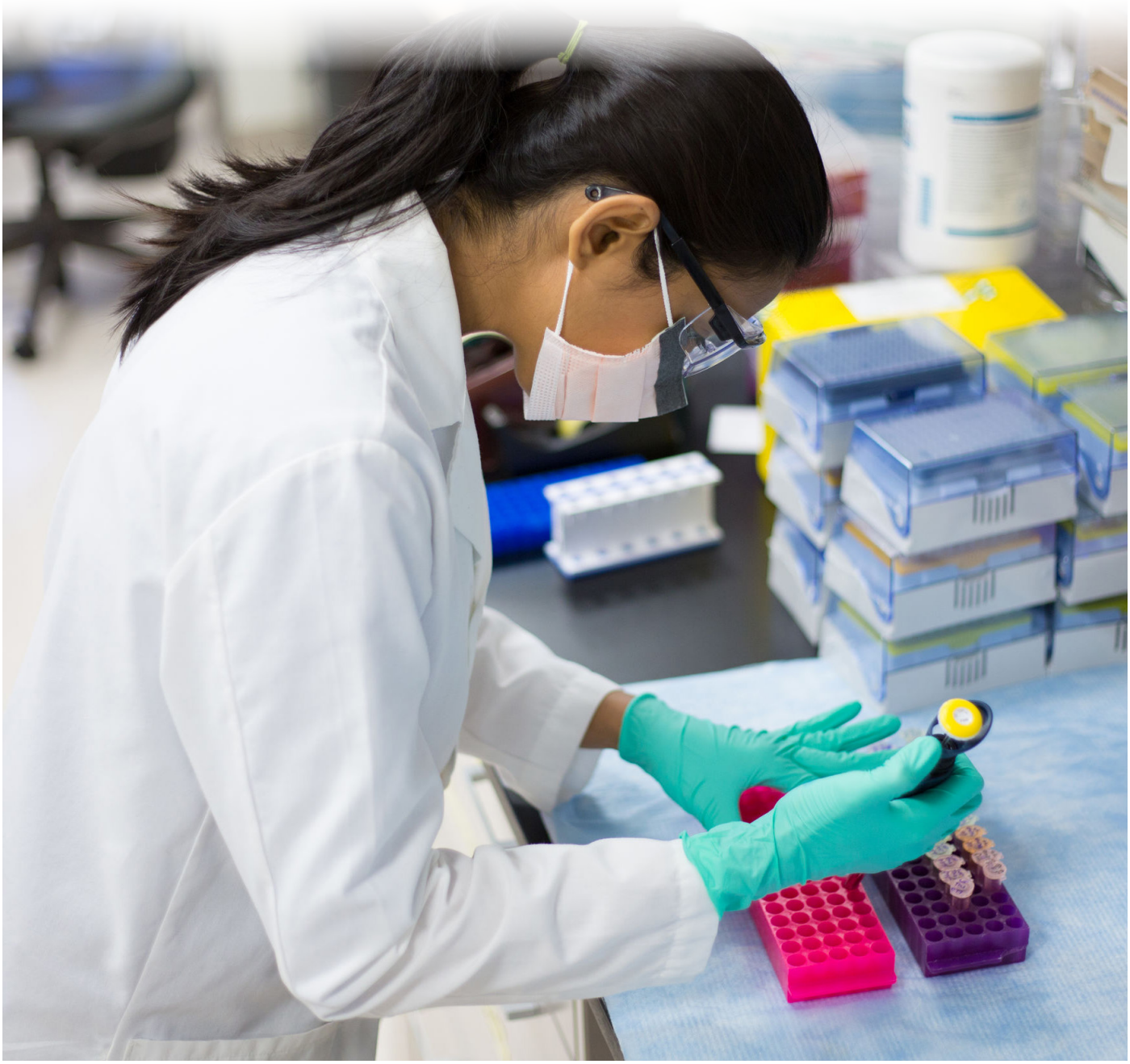
GCHP will have access to Pharmacy Benefit Manager (PBM) liaisons who may assist the Plan and its providers with care coordination and clinical issues.

Training

DHCS, in collaboration with its PBM, Magellan Medicaid Administration, Inc., will provide a series of trainings and education materials. As soon as these materials are made available, GCHP will be reaching out to providers to ensure they have access to the materials and are aware of the new system(s) and processes that will be in place for Medi-Cal Rx.

Helpful Resources:

- Medi-Cal Rx website: DHCS' dedicated website for more information about Medi-Cal RX.
- Medi-Cal Rx Frequently Asked Questions (FAQs): Additional guidance and clarification to Medi-Cal beneficiaries, providers, plan partners, and other interested parties.
- DHCS invites stakeholders to submit questions and/or comments regarding Medi-Cal Rx via email to rxcarveout@dhcs.ca.gov.



Formulary Changes

The following changes to GCHP formulary are effective July 1:

Additions

Drug	Formulary Status / Change
XCOPRI (cenobamate)	Added with PA.
VALTOCO *(diazepam)*	Added with PA.
NEXLETOL *(bempedoic acid)*	Added with PA.
RIOMET ER *(metformin hydrochloride)* oral solution 500 mg/5 ml	Added to formulary.
TRIJARDY XR *(empagliflozin; linagliptin; metformin hydrochloride)* Extended-release oral tablets 5 mg/2.5 mg/ 1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/2.5 mg/1000 mg and 25 mg/5 mg/1000 mg	Added with step therapy requirement of previous use of metformin.
TAZVERIK *(tazemetostat)*	Added with PA.
KOSELUGO *(selumetinib)*	Added with PA.
TUKYSA *(tucatinib)*	Added with PA.
PEMAZYRE *(pemigatinib)*	Added with PA.

Removals

Drug	Formulary Status / Change
Azesco (prenatal vitamins)	Removed high cost prenatal vitamin from formulary. There are many remaining formulary options.
Nexium (Esomeprazole Magnesium) Delayed-Release for Oral Suspension, 10 mg, 20 mg, 40 mg	Generic now available. Brand name removed from formulary.
Riomet (Metformin Hydrochloride) Oral Solution, 500 mg/5 mL	Generic now available. Brand name removed from formulary.

FDA Alerts

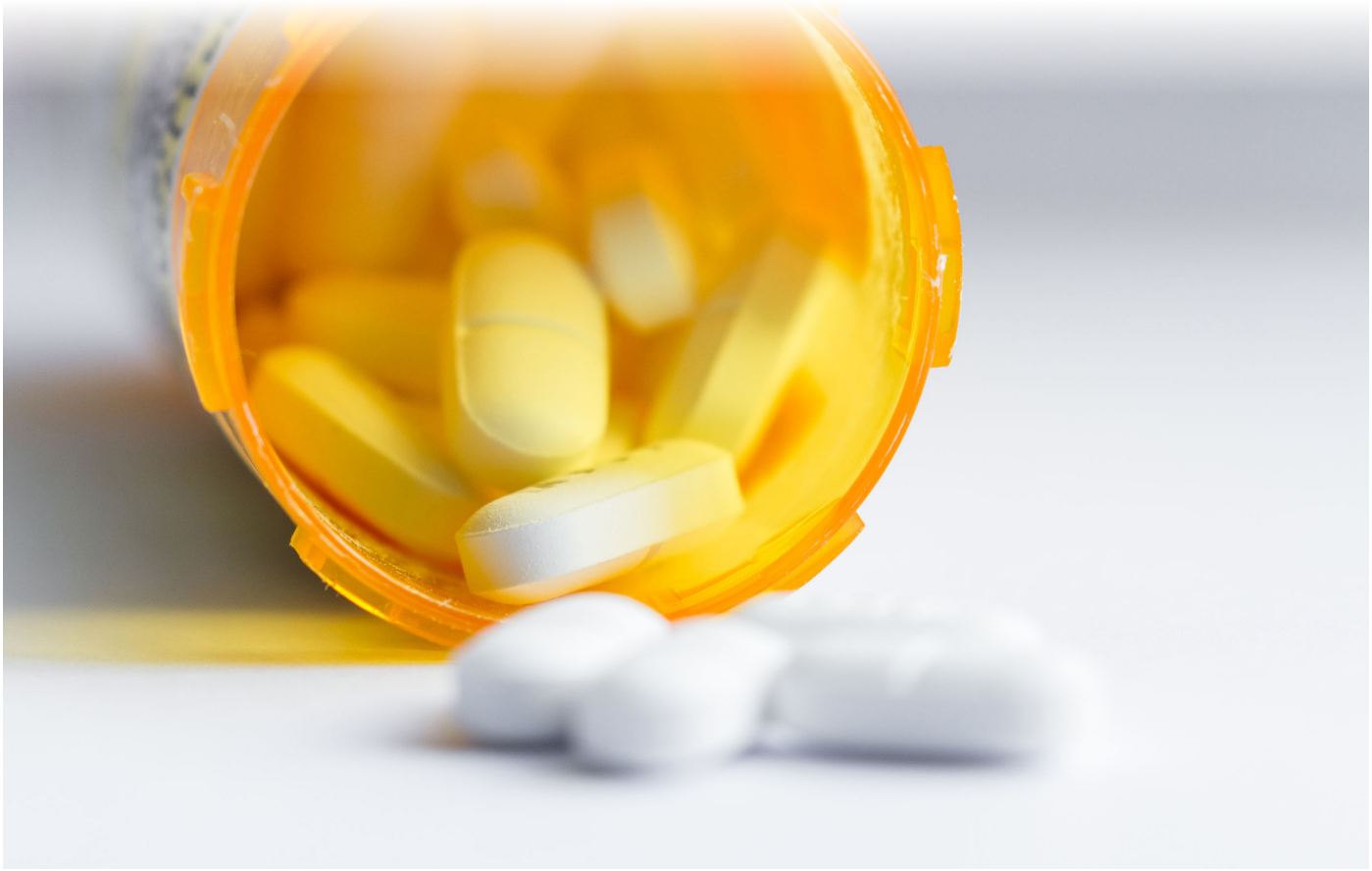
FDA New Drug Approvals

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
DURYSTA	*bimatoprost*	Implant	Indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).
ISTURISA	*osilodrostat*	Tablet; oral	For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
FLUORESCEIN SODIUM; BENOXINATE HYDROCHLORIDE	*fluorescein sodium; benoxinate hydrochloride*	Solution; ophthalmic	Indicated for procedures in adult and pediatric patients requiring a disclosing agent in combination with a topical ophthalmic anesthetic.
PULMOTECH MAA	*technetium tc99m albumin aggregated*	Injectable	Indicated for: • Lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients. • Scintigraphy of peritoneovenous shunt as an aid in the evaluation of its patency in adults.
ZEPOSIA	*ozanimod*	Capsule; oral	For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
TRIFERIC AVNU	*ferric pyrophosphate citrate*	Solution; intravenous	For the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).
LEVONORGESTREL AND ETHINYL ESTRADIOL	*ethinyl estradiol; levonorgestrel*	Tablet; oral	Birth Control.
DOLUTEGRAVIR; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	*dolutegravir; lamivudine; tenofovir disoproxil fumarate*	Tablet; oral	HIV-1 infection in adults and pediatric patients weighing at least 40 kg.
Helium, USP	*n/a*	Gas; inhalation	
JELMYTO	*mitomycin*	Solution; pyelocalyceal	Indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).
TRODELVY	*sacituzumab govitecan-hziy*	Injectable	Adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.
ONGENTYS	*opicapone*	Capsule; oral	Adjunctive treatment to levodopa / carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
BAFIERTAM	*monomethyl fumarate*	Capsule, delayed release; oral	Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
MILPROSA	*progesterone*	System; vaginal	Support embryo implantation and early pregnancy (up to 10 weeks post-embryo transfer) by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women.
FENSOLVI	*leuprolide acetate*	Injectable	Treatment of pediatric patients 2 years of age and older with central precocious puberty.
DARZALEX FASPRO	*daratumumab; hyaluronidase-fihj*	Injectable	Multiple myeloma.
ELYXYB	*celecoxib*	Solution; oral	Acute treatment of migraine with or without aura in adults.
TABRECTA	*capmatinib hydrochloride*	Tablet; oral	Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
RETEVMO	*selpercatinib*	Capsule; oral	Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC). • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
QINLOCK	*ripretinib*	Tablet; oral	Adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib.
FERRIPROX	*deferiprone*	Tablet; oral	Patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.
IMPEKLO	*clobetasol propionate*	Lotion; topical	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, in patients 18 years of age or older.
CERIANNA	*fluoroestradiol f18*	Injectable	Indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.
KYNMOBI	*apomorphine hydrochloride*	Film; sublingual	Acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
PHEXXI	*lactic acid; citric acid; potassium bitartrate*	Gel; vaginal	Prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.
VESICARE LS	*solifenacin succinate*	Suspension; oral	Treatment of neurogenic detrusor overactivity in pediatric patients 2 years of age and older.
ARTESUNATE	*artesunate*	Powder; intravenous	Initial treatment of severe malaria in adult and pediatric patients.
TAUVID	*flortaucipir f18*	Injectable	Positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD).
ZILXI	*minocycline*	Foam; topical	Inflammatory lesions of rosacea in adults.
ARTESUNATE	*artesunate*	Injectable; injection	
ORIAHNN	*elagolix; estradiol norethindrone acetate; elagolix*	Capsule; oral	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.



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
FIRMAGON *(degarelix acetate)*	Contraindications	FIRMAGON is contraindicated in patients with history of severe hypersensitivity to degarelix or to any of the product components.
BYDUREON BCISE *(exenatide)*	Contraindications	BYDUREON BCISE is contraindicated in patients with: • A history of drug-induced immune-mediated thrombocytopenia from exenatide products. Serious bleeding, which may be fatal, from drug-induced immune-mediated thrombocytopenia has been reported with exenatide use.
BYETTA *(exenatide synthetic)*	Contraindications	BYETTA is contraindicated in patients with: • A history of drug-induced immune-mediated thrombocytopenia from exenatide products. Serious bleeding, which may be fatal, from drug-induced immune-mediated thrombocytopenia has been reported with exenatide use.
CALOMIST *(cyanocobalamin)*	Contraindications	CALOMIST is contraindicated in patients with sensitivity to cobalt, vitamin B12, or any component of this product. Reactions following administration of parenteral vitamin B12 have included: anaphylactic shock, death, and angioedema.
DEXTROSE 5% AND ELECTROLYTE NO. 48 IN PLASTIC CONTAINER	Contraindications	DEXTROSE 5% and ELECTROLYTE NO. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is contraindicated in patients with: • A known hypersensitivity to the product. • Clinically significant hyperglycemia.
DOCETAXEL *(docetaxel)*	Contraindications	DOCETAXEL Injection is contraindicated in patients with: • Neutrophil counts of <1500 cells/mm3.
EVOTAZ *(atazanavir sulfate; cobicistat)*	Contraindications	The concomitant use of EVOTAZ and the following drugs in Table 1, are contraindicated due to the potential for serious and/or life-threatening events or loss of therapeutic effect: • When co-administered with drugs that strongly induce CYP3A and may lead to lower exposure and loss of efficacy of EVOTAZ (see Table 1). **Table 1: Drugs Contraindicated with EVOTAZ** *Table formatting has changed; please refer to the label.* *In the Antigout drug class, the following language is added after colchicine:* '(when used in patients with hepatic and/or renal impairment).' *In Lipid-modifying Agents,* 'lomitapide' *added to lovastatin and simvastatin.*
FARXIGA *(dapagliflozin propanediol)*	Contraindications	• History of a serious hypersensitivity reaction to FARXIGA, such as anaphylactic reactions or angioedema. • Patients who are being treated for glycemic control without established CVD or multiple CV risk factors with severe renal impairment, (eGFR less than 30 mL/min/1.73 m2). • Patients on dialysis.

Drug	Type of Change	Change
FERRLECIT *(sodium ferric gluconate complex)*	Contraindications	FERRLECIT is contraindicated in patients with known hypersensitivity to sodium ferric gluconate or any of its components. Reactions have included anaphylaxis.
FIRMAGON *(degarelix acetate)*	Contraindications	FIRMAGON is contraindicated in patients with history of severe hypersensitivity to degarelix or to any of the product components.
FORTESTA *(testosterone)*	Contraindications	FORTESTA is contraindicated in women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
FUSILEV *(levoleucovorin calcium)*	Contraindications	FUSILEV is contraindicated in patients who have had severe hypersensitivity to leucovorin products, folic acid or folinic acid.
INVOKAMET *(canagliflozin; metformin hydrochloride)* INVOKAMET XR *(canagliflozin; metformin hydrochloride)*	Contraindications	INVOKAMET / INVOKAMET XR is contraindicated in patients: With severe renal impairment (eGFR less than 30 mL/min/1.73 m2) or on dialysis.
LUPRON DEPOT *(leuprolide acetate)*	Contraindications	LUPRON DEPOT 11.25 mg is contraindicated in women with the following: • Hypersensitivity to gonadotropin-releasing hormone (GnRH), GnRH agonist analogs, including leuprolide acetate, or any of the excipients in LUPRON DEPOT 11.25 mg. • Undiagnosed abnormal uterine bleeding. • Pregnancy. When norethindrone acetate is administered with LUPRON DEPOT 11.25 mg, the contraindications to the use of norethindrone acetate also apply to this combination regimen. Refer to the norethindrone acetate prescribing information for a list of contraindications for norethindrone acetate.
MANNITOL 25%	Contraindications	Mannitol Injection is contraindicated in patients with: • Known hypersensitivity to mannitol. • Anuria. • Severe hypovolemia. • Pre-existing severe pulmonary vascular congestion or pulmonary edema. • Active intracranial bleeding except during craniotomy.
MYFORTIC *(mycophenolic acid)*	Boxed Warning	**WARNING: EMBRYO-FETAL TOXICITY, MALIGNANCIES, AND SERIOUS INFECTIONS** • Use during pregnancy is associated with increased risks of pregnancy loss and congenital malformations. Avoid if safer treatment options are available. Females of reproductive potential must be counseled regarding pregnancy prevention and planning.
NEOSPORIN *(bacitracin zinc; neomycin sulfate; polymyxin b sulfate)*	Contraindications	LUMI-SPORYN is contraindicated in individuals who have shown hypersensitivity to any of its components.

Drug	Type of Change	Change
NIKITA *(pitavastatin sodium)*	Contraindications	NIKITA is contraindicated in the following conditions: • Known hypersensitivity to pitavastatin or any inactive ingredient in NIKITA. Hypersensitivity reactions including angioedema, rash, pruritus, and urticaria have been reported with NIKITA. • Concomitant use of cyclosporine. • Active liver disease including unexplained persistent elevations of hepatic transaminase levels. • Pregnancy. • Lactation. It is not known if pitavastatin is present in human milk; however, another drug in this class passes into breast milk. Since HMG-CoA reductase inhibitors have the potential for serious adverse reactions in breastfed infants, females who require pitavastatin treatment should not breastfeed their infants.
RASUVO *(methotrexate)*	Boxed Warning	Methotrexate can cause embryo-fetal toxicity, including fetal death. Use is contraindicated during pregnancy. Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females and males of reproductive potential to use effective contraception during and after treatment with RASUVO.
SINGULAIR *(montelukast sodium)*	Boxed Warning	**WARNING: SERIOUS NEUROPSYCHIATRIC EVENTS** Serious neuropsychiatric (NP) events have been reported with the use of SINGULAIR. The types of events reported were highly variable, and included, but were not limited to, agitation, aggression, depression, sleep disturbances, suicidal thoughts and behavior (including suicide). The mechanisms underlying NP events associated with SINGULAIR use are currently not well understood. Because of the risk of NP events, the benefits of SINGULAIR may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with alternative therapies. Reserve use of SINGULAIR for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. In patients with asthma or exercise-induced bronchoconstriction, consider the benefits and risks before prescribing SINGULAIR. Discuss the benefits and risks of SINGULAIR with patients and caregivers when prescribing SINGULAIR. Advise patients and/or caregivers to be alert for changes in behavior or new NP symptoms when taking SINGULAIR. If changes in behavior are observed, or if new NP symptoms or suicidal thoughts and/or behavior occur, advise patients to discontinue SINGULAIR and contact a health care provider immediately.

Drug	Type of Change	Change
VOGELXO *(testosterone)*	Contraindications	VOGELXO is contraindicated in women who are pregnant. VOGELXO can cause virilization of the female fetus when administered to a pregnant woman. Pregnant women need to be aware of the potential for skin transfer of testosterone from men treated with VOGELXO. If a pregnant woman is exposed to VOGELXO, she should be apprised of the potential hazard to the fetus.
FARXIGA *(dapagliflozin propanediol)*	Contraindications	• History of a serious hypersensitivity reaction to FARXIGA, such as anaphylactic reactions or angioedema. • Patients who are being treated for glycemic control without established CVD or multiple CV risk factors with severe renal impairment, (eGFR less than 30 mL/min/1.73 m2). • Patients on dialysis.
NIKITA *(pitavastatin sodium)*	Contraindications	NIKITA is contraindicated in the following conditions: • Known hypersensitivity to pitavastatin or any inactive ingredient in NIKITA. Hypersensitivity reactions including angioedema, rash, pruritus, and urticaria have been reported with NIKITA. • Concomitant use of cyclosporine. • Active liver disease including unexplained persistent elevations of hepatic transaminase levels. • Pregnancy. • Lactation. It is not known if pitavastatin is present in human milk; however, another drug in this class passes into breast milk. Since HMG-CoA reductase inhibitors have the potential for serious adverse reactions in breastfed infants, females who require pitavastatin treatment should not breastfeed their infants.
VESICARE *(solifenacin succinate)*	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.

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
Sulfasalazine Enteric-Coated and Immediate-Release Tablets	• Greenstone • Teva	• Greenstone did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates:** • Greenstone has sulfasalazine enteric-coated 500 mg tablets and immediate-release 500 mg tablets in 100- and 300-count bottles on intermittent back order and the company is releasing supplies as they become available. • Teva has sulfasalazine immediate-release 500 mg tablets in 100-, 500-, and 1000-count bottles on intermittent back order and the company is releasing supplies as they become available.
Sulfasalazine Enteric-Coated and Immediate-Release Tablets	• CMP Pharma • Perrigo • Hikma	• CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products. They are using available powder to manufacture the suspension. • Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again. • Hikma is not currently marketing sodium polystyrene sulfonate suspension.
Methyldopa Tablets	• Accord • Mylan	• 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. **Estimated Resupply Dates:** • 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 back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Anagrelide Hydrochloride Capsules	• Shire (Takeda) • Teva • Torrent	• Shire (Takeda) did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. • Torrent has discontinued anagrelide 1 mg capsules. Torrent is working on relaunching anagrelide 0.5 mg capsules. **Estimated Resupply Dates:** • Takeda has Agrylin 0.5 mg capsules on allocation. • Teva has anagrelide 0.5 mg and 1 mg capsules on back order and the company estimates a release date of early June 2020. • Torrent has anagrelide 0.5 mg and 1 mg capsules on allocation.
Chloroquine Phosphate Tablets	• Rising	• Rising has chloroquine phosphate 250 mg and 500 mg tablets on allocation.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the prescription benefit for GCHP. Click here to access this information on the FDA's website.

Drug	Communications Summary
Hydroxychloroquine and chloroquine	FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.

Gold Coast Health Plan℠
A Public Entity

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JUNE 2020

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