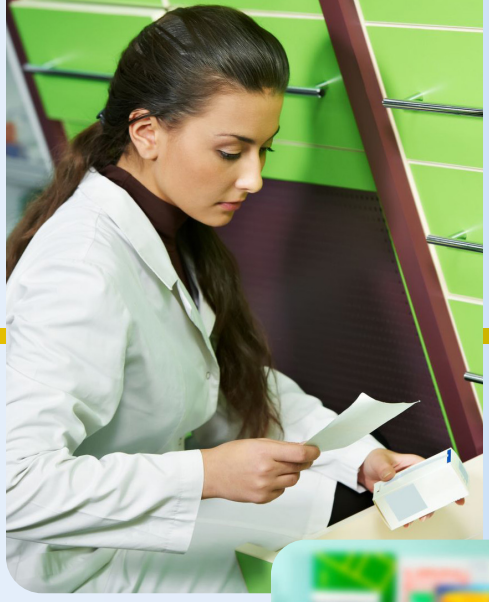

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

MARCH 2020

Q2 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 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

Formulary Changes

The following changes to GCHP's formulary are effective April 1, 2020:

Additions

Drug	Formulary Status / Change
AYVAKIT *(avapritinib)*	Added to formulary with PA.
BRUKINSA *(zanubrutinib)*	Added to formulary with PA.
PRETOMANID	Added to formulary with PA.
OXBRYTA *(voxelotor)*	Added to formulary with PA.
RUXIENCE *(rituximab-pvvr)*	Added to formulary.
ZIEXTENZO *(pegfilgrastim-bmez)*	Added to formulary.
DRYSOL *(aluminum chloride)*	Added to formulary.
IMIQUIMOD 5% topical cream	PA requirement removed.

Removals

Drug	Formulary Status / Change
Myrbetriq *(Mirabegron)* Extended-Release Tablets, 25 mg	Generic now available. Brand name removed from formulary.
Eliquis *(Apixaban)*Tablets, 2.5 mg and 5 mg	Generic now available. Brand name removed from formulary.
Jadenu *(Deferasirox)* Tablets, 90 mg, 180 mg, 360 mg	Generic now available. Brand name removed from formulary.
Nuvaring *(Etonogestrel and Ethinyl Estradiol)* Vaginal Ring, 0.120 mg / 0.015 mg per day	Generic now available. Brand name removed from formulary
Afinitor *(Everolimus)* Tablets, 2.5 mg, 5 mg, 7.5 mg, and 10 mg	Generic now available. Brand name removed from formulary.
Gilenya *(Fingolimod)* Capsules, 0.5 mg	Generic now available. Brand name removed from formulary.
Carafate *(Sucralfate)* Oral Suspension, 1 g / 10 mL	Generic now available. Brand name removed from formulary.
Apriso *(Mesalamine)* Extended-Release Capsules, USP 0.375 g	Generic now available. Brand name removed from formulary.
Digoxin Oral Solution, 0.05 mg/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
TRIJARDY XR	EMPAGLIFLOZIN; LINAGLIPTIN; METFORMIN HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	TRIJARDY XR is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
TAZVERIK	TAZEMETOSTAT	TABLET; ORAL	TAZVERIK is a methyltransferase inhibitor indicated for the treatment of adults and pediatric patients 16 years of age and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
TEPEZZA	TEPROTUMUMAB-TRBW	INJECTABLE; INJECTION	TEPEZZA is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease.
MONOFERRIC	FERRIC DERISOMALTOSE	INJECTABLE; INJECTION	MONOFERRIC is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients: • Who have intolerance to oral iron or have had unsatisfactory response to oral iron. • Who have non-hemodialysis dependent chronic kidney disease.
VALTOCO	DIAZEPAM	SPRAY; NASAL	VALTOCO is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.
NUMBRINO	COCAINE HYDROCHLORIDE	SOLUTION; NASAL	NUMBRINO (cocaine hydrochloride) nasal solution is an ester local anesthetic indicated for the introduction of local anesthesia of the mucous membranes for diagnostic procedures and surgeries on or through the nasal cavities of adults.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
AYVAKIT	AVAPRITINIB	TABLET; ORAL	AYVAKIT is a kinase inhibitor indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
UBRELVY	UBROGEPANT	TABLET; ORAL	UBRELVY is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults.
ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	INJECTABLE; INJECTION	ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.
GENOSYL	NITRIC OXIDE	IMPLANT; IMPLANTATION	GENOSYL is a vasodilator indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.
TISSUEBLUE	BRILLIANT BLUE G	SOLUTION; OPHTHALMIC	TISSUEBLUE (Brilliant Blue G Ophthalmic Solution) 0.025% is a disclosing agent indicated to selectively stain the internal limiting membrane (ILM).
CAPLYTA	LUMATEPERONE TOSYLATE	CAPSULE; ORAL	CAPLYTA is an atypical antipsychotic indicated for the treatment of schizophrenia in adults.
DAYVIGO	LEMBOREXANT	TABLET; ORAL	DAYVIGO is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and / or sleep maintenance.
CONJUPRI	LEVAMLODIPINE	TABLET; ORAL	CONJUPRI is calcium channel blocker and may be used alone or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
PADCEV	ENFORTUMAB VEDOTIN-EJFV	INJECTABLE; INJECTION	PADCEV is a Nectin-4-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant / adjuvant, locally advanced or metastatic setting.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ARALZO	TAZAROTENE	LOTION; TOPICAL	ARAZLO is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.
NOURESS	CYSTEINE HYDROCHLORIDE	INJECTABLE; INJECTION	
VYONDYS 53	GOLODIRSEN	SOLUTION; INTRAVENOUS	
AVSOLA	INFLIXIMAB-AXXQ	INJECTABLE; INJECTION	
REDITREX	METHOTREXATE	SOLUTION; SUBCUTANEOUS	
POTASSIUM PHOSPHATES	POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC	SOLUTION; INTRAVENOUS	
OXBRYTA	VOXELOTOR	TABLET; ORAL	
EXSERVAN	RILUZOLE	FILM; ORAL	
CABAZITAXEL	CABAZITAXEL	INJECTABLE; INJECTION	
XCOPRI	CENOBAMATE	TABLET; ORAL	
GIVLAARI	GIVOSIRAN SODIUM	SOLUTION; SUBCUTANEOUS	
ADAKVEO	CRIZANLIZUMAB-TMCA	INJECTABLE; INJECTION	

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
LEVEMIR *(insulin detemir recombinant)*	Contraindications	LEVEMIR is contraindicated during episodes of hypoglycemia.
XARELTO *(rivaroxaban)*	Boxed Warning	**Use in Patients with Renal Impairment** Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE In patients with CrCl <30 mL/min, rivaroxaban exposure and pharmacodynamic effects are increased compared to patients with normal renal function. There are limited clinical data in patients with CrCl 15 to <30 mL/min; therefore, observe closely and promptly evaluate any signs or symptoms of blood loss in these patients. There are no clinical data in patients with CrCl <15 mL/min (including patients on dialysis); therefore, avoid the use of XARELTO in these patients. Discontinue XARELTO in patients who develop acute renal failure while on treatment. Prophylaxis of Deep Vein Thrombosis following hip or knee replacement surgery in patients with CrCl <30 mL/min, rivaroxaban exposure and pharmacodynamic effects are increased compared to patients with normal renal function. There are limited clinical data in patients with CrCl 15 to <30 mL/min; therefore, observe closely and promptly evaluate any signs or symptoms of blood loss in these patients. There are no clinical data in patients with CrCl <15 mL/min (including patients on dialysis); therefore, avoid the use of XARELTO in these patients. Discontinue XARELTO in patients who develop acute renal failure while on treatment. Prophylaxis of Venous Thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding in patients with CrCl <30 mL/min, rivaroxaban exposure and pharmacodynamic effects are increased compared to patients with normal renal function. There are limited clinical data in patients with CrCl 15 to <30 mL/min; therefore, observe closely and promptly evaluate any signs or symptoms of blood loss in these patients. There are no clinical data in patients with CrCl <15 mL/min (including patients on dialysis); therefore, avoid the use of XARELTO in these patients. Discontinue XARELTO in patients who develop acute renal failure while on treatment.
INCRELEX *(mecasermin recombinant)*	Contraindications	INCRELEX is contraindicated in pediatric patients with malignant neoplasia or a history of malignancy.

Drug	Type of Change	Change
ZEPATIER *(elbasvir; grazoprevir)*	Contraindications	ZEPATIER is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of hepatic decompensation due to the risk of hepatic decompensation.
TOPOTECAN HYDROCHLORIDE	Contraindications	TOPOTECAN Injection is contraindicated in patients who have a history of severe hypersensitivity reactions to TOPOTECAN. Reactions have included anaphylactoid reactions.
TAXOTERE *(docetaxel)*	Boxed Warning	Treatment-related mortality associated with TAXOTERE is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive TAXOTERE as a single agent at a dose of 100 mg/m2. Avoid the use of TAXOTERE in patients with bilirubin > upper limit of normal (ULN), or patients with AST and/or ALT >1.5 × ULN concomitant with alkaline phosphatase >2.5 × ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of severe neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 × ULN also had a higher rate of febrile neutropenia. Measure bilirubin, AST or ALT, and alkaline phosphatase prior to each cycle of TAXOTERE. Do not administer TAXOTERE to patients with neutrophil counts of <1500 cells/mm3. Monitor blood counts frequently as neutropenia may be severe and result in infection. Do not administer TAXOTERE to patients who have a history of severe hypersensitivity reactions to TAXOTERE or to other drugs formulated with polysorbate 80. Severe hypersensitivity reactions have been reported in patients despite dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the TAXOTERE infusion and administration of appropriate therapy. Severe fluid retention occurred in 6.5% (6/92) of patients despite use of dexamethasone premedication. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites).
PARICALCITOL	Contraindications	PARICALCITOL injection is contraindicated in patients with known hypersensitivity to PARICALCITOL or any inactive ingredient in PARICALCITOL injection. Hypersensitivity adverse reactions have been reported [e.g., angioedema (including laryngeal edema) and urticaria].

Drug	Type of Change	Change
KALETRA *(lopinavir; ritonavir)*	Contraindications	KALETRA is contraindicated with drugs that are potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance Anticancer agents: apalutamide.
NORVIR *(ritonavir)*	Contraindications	NORVIR is contraindicated with drugs that are potent CYP3A inducers where significantly reduced ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance Anticancer agents: apalutamide.
DOXORUBICIN HYDROCHLORIDE	Contraindications	**Cardiomyopathy:** Myocardial damage, including acute left ventricular failure, can occur with DOXORUBICIN HYDROCHLORIDE. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 1% - 20% for cumulative doses ranging from 300 mg/m2 to 500 mg/m2 when DOXORUBICIN HYDROCHLORIDE is administered every three weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with DOXORUBICIN HYDROCHLORIDE. **Secondary Malignancies:** Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including DOXORUBICIN HYDROCHLORIDE. **Extravasation and Tissue Necrosis:** Extravasation of DOXORUBICIN HYDROCHLORIDE can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area.
STAVZOR *(valproic acid)*	Contraindications	For use in prophylaxis of migraine headaches STAVZOR is contraindicated in women who are pregnant and in women of childbearing potential who are not using effective contraception.
OTREXUP *(methotrexate)*	Contraindications	OTREXUP can cause embryo-fetal toxicity and fetal death when administered during pregnancy.
DOCETAXEL	Contraindications	DOCETAXEL injection is contraindicated in patients with neutrophil counts of <1500 cells/mm3.
FUSILEV *(levoleucovorin calcium)*	Contraindications	FUSILEV is contraindicated in patients who have had severe hypersensitivity to leucovorin products, folic acid or folinic acid.
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.

Drug	Type of Change	Change
OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN	Contraindications	OMECLAMOX-PAK is contraindicated in patients with known history of hypersensitivity to omeprazole or benzimidazoles, any macrolide antibacterial drug, or any penicillin. Hypersensitivity reactions to omeprazole may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticarial.
INVOKAMET / 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.
AVODART *(dutasteride)*	Contraindications	Dutasteride use is contraindicated in women who are pregnant.
ZYPITAMAG *(pitavastatin magnesium)*	Contraindications	ZYPITAMAG is contraindicated in the following conditions: • Known hypersensitivity to pitavastatin or any inactive ingredient in ZYPITAMAG. Hypersensitivity reactions including angioedema, rash, pruritus, and urticaria have been reported with pitavastatin. • 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.
VIBATIV *(telavancin hydrochloride)*	Boxed Warning	**Embryofetal Toxicity:** VIBATIV may cause fetal harm. In animal reproduction studies, adverse developmental outcomes were observed in three animal species at clinically relevant doses. Verify pregnancy status in females of reproductive potential prior to initiating VIBATIV. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VIBATIV and for twodays after the final dose.

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
Sodium Polystyrene Sulfonate Oral or Rectal Suspension	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. **Estimated Resupply Dates** • CMP Pharma has SPS Suspension on allocation and the company is shipping supplies regularly.
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 in 100- and 300-count bottles on back order and the company estimates a release date of mid-March 2020 for the 100-count bottles and late-March 2020 for the 300-count bottles. The immediate-release 500 mg tablets in 100- and 300-count bottles are on back order and the company estimates a release date of late-February 2020 for the 100-count and late-March 2020 for the 300-count bottles. • Teva has sulfasalazine immediate-release 500 mg tablets in 100-, 500-, and 1,000-count bottles on back order and the company estimates a release date of early-March 2020.
Venlafaxine Hydrochloride Extended-Release Capsules	Teva Zydus	• Pfizer has Effexor XR capsules available. • Teva did not provide a reason for the shortage. • Zydus did not provide a reason for the shortage. Zydus has discontinued the 30-count presentations. **Estimated Resupply Dates** • Teva has most venlafaxine extended-release capsules on back order and the company estimates a release date in late-February 2020. • Zydus has all venlafaxine extended-release capsules on allocation.

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 late-March 2020. • Torrent has anagrelide 0.5 mg and 1 mg capsules on allocation.
Nizatidine Capsules	Glenmark Mylan Teva	• Glenmark did not provide a reason for the shortage. • Mylan discontinued nizatidine capsules. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Glenmark has nizatidine capsules on back order and the company cannot estimate a release date. • Teva has nizatidine capsules on back order and the company estimates a release date of late-March 2020.

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
Belviq / Belviq XR *(lorcaserin)*	The U.S. Food and Drug Administration (FDA) has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc., has submitted a request to voluntarily withdraw the drug.

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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