



**Gold Coast  
Health Plan**<sup>SM</sup>  
A Public Entity

# Pharmacy Newsletter

AUGUST 2018

**Q2** 2018

# Table of Contents

SECTION 1: A Message from the Gold Coast Health Plan (GCHP) Pharmacy Director ..... 3

SECTION 2: Prior Authorization and Appeals Process ..... 4

SECTION 3: Pharmacy Department Update ..... 5

SECTION 4: Formulary Changes ..... 6

SECTION 5: Alerts from the U.S. Food and Drug Administration (FDA): New FDA Drug Approvals,  
 FDA Safety Labeling Changes, Drug Shortages, FDA Drug Safety Communications ..... 7



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](mailto:afreese@goldchp.org) or 1-805-437-5652.

**Pharmacy Director:**  
Anne Freese, Pharm. D.

**Chief Medical Officer:**  
Nancy R. Wharfield, MD

**Editor-in-Chief:**  
Steven Lalich

**Copy Editor:**  
Susana Enriquez-Euyoque

# 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,

A handwritten signature in black ink, appearing to read 'Anne Freese'.

Anne Freese, Pharm.D.  
Director of Pharmacy

# Prior Authorization and Appeal Process

## Definitions

**Prior Authorization (PA)** – A prior authorization is an attempt by the provider to request authorization for a drug that requires prior authorization, has not met the criteria of a step therapy, or exceeds a formulary utilization managed edit, such as an age restriction or quantity limit. A Notice of Action letter is sent to the prescribing provider and member if the request is denied containing information regarding how to appeal the denial. All prior authorization requests will be reviewed and a determination made within 24 hours of receipt of the documentation.

**Appeal** – An appeal is an attempt by the provider to request authorization for a drug when the initial prior authorization request was denied and the appeal was requested within 60 days of the initial denial. An appeal response letter is sent to the prescribing provider and member and if denied, contains information regarding how to request a State Fair Hearing. All appeals will be reviewed within 30 days unless it is determined to be urgent and it will be reviewed within 72 hours.

**State Fair Hearing (SFH)** – A Gold Coast Health Plan (GCHP) member is entitled to a State Fair Hearing within 60 days of a denied appeal. Information regarding how to request an SFH is included within the appeal response letter sent to the prescribing provider and member.

## How to Submit a Prior Authorization

There are multiple ways to submit a prior authorization for GCHP members to the Plan's Pharmacy Benefit Manager (PBM) OptumRx:

1. Via phone at 1-855-297-2870
  - If your office staff typically calls the PBM to have a form sent to them, they may ask the OptumRx agent to send a form to the office to be completed and faxed back. Your staff is not required to provide the information verbally.
2. Via fax at 1-800-527-0531
3. Via ePA from your EHR system

[Click here](#) to obtain a prior authorization form from the OptumRx Provider Portal for GCHP.

## How to Submit an Appeal

There are multiple ways to submit an appeal for GCHP members to OptumRx:

1. Via phone at 1-888-403-3398
2. Via fax at 1-877-239-4565
3. Via mail sent to:

**OptumRx**  
c/o Appeals Coordinator  
P.O. Box 25184  
Santa Ana, CA 92799

## Tips to Help the Prior Authorization Process Work Smoothly:

- Ensure that the form is completed and has the physician's signature.
- Ensure that all writing is legible.
- Ensure that a diagnosis is listed.
- Ensure that all quantity limit requests state the directions and justification for the dosage.
- List all prior tried-and-failed medications: state doses, dates, and outcomes.
- List common drugs that might be used to treat the condition that are contraindicated in the member and state why.
- List all pertinent medical information such as allergies, co-morbid conditions, etc., that affected the selection of the particular drug product.
- Include chart notes, lab values / results, etc. to further document the medical necessity of the drug product requested.

### Common Reasons for Denials:

- There is no diagnosis included on the form.
- For quantity limit issues, here are the most common issues:
  - » There are no directions included in the documentation.
  - » There are no justifications for why the dose exceeds the daily limit or the dosage approved by the U.S. Food and Drug Administration (FDA).
- For step therapy issues, the most common issue is that the form did not state why the step 1 drugs were inappropriate or that they have been tried and failed.
- For continuing therapy issues, the request must state the length of time or duration that the member has been on the medication.

## Pharmacy Department

### Have a Formulary Suggestion?

GCHP has developed a generic-first formulary that serves to provide all medically-necessary medications in the most cost effective manner. Over the past year, GCHP has worked to ensure that its formulary is aligned with current medical practice and offers prescribers enough flexibility to treat their patients without undue restrictions.

To that end, if you or one of your fellow prescribers sees an area of the formulary that should be reviewed or would like to make any suggestions, please contact the GCHP Pharmacy Director, Annie Freese, via email at [afreese@goldchp.org](mailto:afreese@goldchp.org) or via regular mail by writing to GCHP at the following address:

Pharmacy Director  
711 E. Daily Dr. Suite 106  
Camarillo, CA 93010

### Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

● [GCHP Formulary](#)

● [List of Participating Pharmacies](#)

● [Provider Resources](#)



# Formulary Changes

The following changes to GCHP's formulary are effective as of July 1:

## Additions

| Drug  | Formulary Status/Change                                      |
|---|--|
| QVAR REDIHALER<br>( <i>beclomethasone dipropionate</i> )<br>40 mcg/actuation and 80 mcg/actuation | Add to formulary.  |
| FIRVANQ KIT<br>( <i>vancomycin hydrochloride</i> )<br>50mg/ml oral solution                       | Add with age limit <12 years.                                |
| IMBRUVICA<br>( <i>ibrutinib</i> )<br>140mg, 280mg, 420mg and 560mg oral tablet                    | Add to formulary with PA.                                    |
| MAKENA AUTOINJECTOR<br>( <i>hydroxyprogesterone caproate</i> )<br>275mg/1.1ml                     | Add all formulations of Makena to formulary with no PA.      |
| CALQUENCE<br>( <i>acalabrutinib</i> )<br>Oral capsule   | Add to formulary with PA.                                    |
| LONHALA MAGNAIR KIT<br>( <i>glycopyrrolate</i> )<br>Oral inhalation                               | Add to formulary with PA.                                    |
| ERLEADA<br>( <i>apalutamide</i> )<br>Oral tablet  | Add to formulary with PA.                                    |
| ORENITRAM<br>( <i>treprostinil</i> )<br>Oral tablet   | Add to formulary with PA.                                    |
| CRYSVITA<br>( <i>burosumab-twza</i> )<br>SubQ injection   | Add to formulary with PA.                                    |
| XIFAXAN<br>( <i>rifaximin</i> )<br>oral tablet  | Add to formulary with PA.                                    |
| SHINGRIX<br>( <i>Zoster Vaccine, Recombinant</i> )  | Add to formulary with age restriction of 50 years and older. |

## Removals

| Drug   | Formulary Status/Change                    |
|--|--|
| Sensipar<br>( <i>cinacalcet</i> ) Tablets                            | Brand removed due to generic availability. |
| Ritalin LA<br>( <i>methylphenidate hydrochloride</i> ) 10mg capsules | Brand removed due to generic availability. |



# 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   |
|------------|--|----------------|---|
| TROGARZO   | <i>ibalizumab-uiyk</i>   | IV injection   | TROGARZO, a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.   |
| ILUMYA     | <i>tildrakizumab-asmn</i>                                      | SubQ injection | ILUMYA is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.  |
| SYMFI      | <i>efavirenz, lamivudine and tenofovir disoproxil fumarate</i> | Oral tablets   | SYMFI is three-drug combination of efavirenz (EFV), a non-nucleoside reverse transcriptase inhibitor, and lamivudine (3TC) and tenofovir disoproxil fumarate (TDF), both nucleo(t)side reverse transcriptase inhibitors and is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.  |
| PEMETREXED | <i>pemetrexed</i>  | IV injection   | PEMETREXED is an antimetabolite (Antifolate) anti-neoplastic agent indicated for the treatment of: <ul style="list-style-type: none"> <li>• Mesothelioma<br/>Initial treatment of unresectable malignant pleural mesothelioma (in combination with cisplatin) or in patients who are not otherwise candidates for curative surgery.</li> <li>• Non-small cell lung cancer (NSCLC), nonsquamous<br/>Initial treatment of locally advanced or metastatic nonsquamous NSCLC (in combination with cisplatin); maintenance treatment of locally advanced or metastatic nonsquamous NSCLC if no progression after four cycles of initial platinum-based first-line therapy; single-agent treatment (after prior chemotherapy) of recurrent / metastatic nonsquamous NSCLC.</li> </ul> |
| TAVALISSE  | <i>fostatinib disodium hexahydrate</i>                         | Oral tablets   | TAVALISSE is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.   |

| Brand Name                                   | Generic Name   | Dosage Form    | Summary of Indication and Mechanism of Action  |
|--|--|----------------|--|
| CRYSVITA                                     | <i>burosumab-twza</i>  | SubQ injection | CRYSVITA is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.  |
| AKYNZEO                                      | <i>netupitant and palonosetron</i>   | Oral capsules  | AKYNZEO capsules is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.  |
| AKYNZEO                                      | <i>netupitant and palonosetron</i>   | IV injection   | AKYNZEO for injection is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.  |
| JYNARQUE                                     | <i>tolvaptan</i>   | Oral tablets   | JYNARQUE is a vasopressin antagonist indicated for the treatment of clinically-significant hypervolemic and euvoletic hyponatremia (serum sodium of less than 125 meq/l or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and syndrome of inappropriate secretion of antidiuretic hormone (siadh).           |
| HYDROCODONE BITARTRATE AND GUAIFENESIN       | <i>hydrocodone bitartrate and guaifenesin</i>  | Oral tablets   | Hydrocodone bitartrate and guaifenesin tablets is a combination of hydrocodone, an opioid agonist; and guaifenesin, an expectorant, indicated for the symptomatic relief of cough and to loosen mucus associated with the common cold in patients 18 years of age and older.   |
| PLENVU                                       | <i>polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride</i> | Oral solution  | PLENVU is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults.   |
| LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | <i>lamivudine and tenofovir disoproxil fumarate</i>  | Oral tablets   | Lamivudine and tenofovir disoproxil fumarate tablets is a two-drug combination of lamivudine (3TC) and tenofovir disoproxil fumarate (TDF), both nucleo(t)side reverse transcriptase inhibitors and is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg. |



| Brand Name                                       | Generic Name                              | Dosage Form              | Summary of Indication and Mechanism of Action  |
|--|---|--------------------------|--|
| RETACRIT<br>biosimilar to<br>EPOGEN /<br>PROCRIT | <i>epoetin alfa-epbx</i>                  | IV and SubQ<br>injection | RETACRIT is an erythropoiesis-stimulating agent (ESA) indicated for: <ul style="list-style-type: none"> <li>• Treatment of anemia due to: <ul style="list-style-type: none"> <li>▸ Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.</li> <li>▸ Zidovudine in patients with HIV-infection.</li> <li>▸ The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.</li> </ul> </li> <li>• Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery.</li> </ul> |
| BENDAMUSTINE<br>HYDROCHLO-<br>RIDE               | <i>bendamustine<br/>hydrochloride</i>     | IV injection             | Bendamustine Hydrochloride Injection is an alkylating drug indicated for treatment of patients with: <ul style="list-style-type: none"> <li>• Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established.</li> <li>• Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.</li> </ul>  |
| LUCEMYRA   | <i>lofexidine</i>                         | Oral tablets             | LUCEMYRA is a central alpha-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.   |
| AIMOVIG  | <i>erenumab-aooe</i>                      | SubQ injection           | AIMOVIG is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of migraine in adults.   |
| LOKELMA  | <i>sodium zirconium<br/>cyclosilicate</i> | Oral suspension          | LOKELMA is a potassium binder indicated for the treatment of hyperkalemia in adults.   |
| DOPTELET   | <i>avatrombopag</i>                       | Oral tablets             | DOPTELET (avatrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.  |
| YONSA  | <i>abiraterone<br/>acetate</i>            | Oral tablets             | YONSA is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).   |
| PROGRAF<br>Granules                              | <i>tacrolimus</i>                         | Oral suspension          | PROGRAF is a calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving allogeneic liver, kidney or heart transplants, in combination with other immunosuppressants.   |

| Brand Name             | Generic Name                     | Dosage Form    | Summary of Indication and Mechanism of Action  |
|------------------------|----------------------------------|----------------|--|
| HALOBETASOL PROPIONATE | <i>halobetasol propionate</i>    | Topical foam   | Halobetasol Propionate Topical Foam is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.   |
| PALYNZIQ               | <i>pegvaliase-pqpz</i>           | SubQ injection | Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.   |
| IMVEXXY                | <i>estradiol vaginal inserts</i> | Vaginal insert | IMVEXXY is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.   |
| CONSENSI               | <i>amlodipine and celecoxib</i>  | Oral tablets   | CONSENSI is a combination of amlodipine besylate, a calcium channel blocker, and celecoxib, a non-steroidal anti-inflammatory drug (NSAID), indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions. |



## FDA Safety Labeling Changes

This section includes all 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  |
|--|------------------|---|
| ADEMPAS<br>(riociguat)                     | Contraindication | Based on data from animal reproduction studies, Adempas may cause fetal harm when administered to a pregnant woman and is contraindicated in females who are pregnant. Adempas was consistently shown to have teratogenic effects when administered to animals. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.  |
| AFINITOR/ AFINITOR DISPERZ<br>(everolimus) | Contraindication | AFINITOR/AFINITOR DISPERZ is contraindicated in patients with clinically significant hypersensitivity to everolimus or to other rapamycin derivatives.  |
| PARNATE<br>(tranylcypromine sulfate)       | Boxed Warning    | <p><b>WARNING: SUICIDAL THOUGHTS AND BEHAVIORS and HYPERTENSIVE CRISIS WITH SIGNIFICANT TYRAMINE USE</b></p> <p><b>Suicidal Thoughts and Behaviors</b><br/>Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. PARNATE is not approved for use in pediatric patients.</p> <p><b>Hypertensive Crisis with Significant Tyramine Use</b><br/>Excessive consumption of foods or beverages with significant tyramine content or the use of certain drugs with PARNATE or after PARNATE discontinuation can precipitate hypertensive crisis. Monitor blood pressure and allow for medication-free intervals between administration of PARNATE and interacting drugs. Instruct patients to avoid ingestion of foods and beverages with high tyramine content.</p> |
| KYBELLA®<br>(deoxycholic acid)             | Contraindication | KYBELLA® (deoxycholic acid) injection is contraindicated in the presence of infection at the injection sites.   |
| NITROSTAT<br>(nitroglycerin)               | Contraindication | <p>Do not use NITROSTAT in patients who are taking PDE-5 Inhibitors, such as avanafil, sildenafil, tadalafil, vardenafil hydrochloride. Concomitant use can cause severe hypotension, syncope, or myocardial ischemia.</p> <p>Do not use NITROSTAT in patients who are taking the soluble guanylate cyclase stimulators, such as riociguat. Concomitant use can cause hypotension.</p>  |

| Drug  | Type of Change                     | Change  |
|---|------------------------------------|---|
| VIDEX / VIDEX EC<br>( <i>didanosine</i> )     | Boxed Warning and Contraindication | <p><b>WARNING: PANCREATITIS, LACTIC ACIDOSIS and HEPATOMEGALY with STEATOSIS</b></p> <p>Coadministration of VIDEX and stavudine is contraindicated because of increased risk of serious and/or life-threatening events. Suspend treatment if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occurs.</p> <p>Contraindication:<br/>Videx is contraindicated when coadministered with the following medications:<br/>Stavudine: Coadministration of didanosine and stavudine is contraindicated because of the potential for serious and/or life-threatening events notably pancreatitis, lactic acidosis, hepatotoxicity, and peripheral neuropathy.</p>  |
| ZYDELIG<br>( <i>idelalisib</i> )              | Boxed Warning                      | <p><b>WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, INFECTIONS, and INTESTINAL PERFORATION</b></p> <p>Fatal and/or serious hepatotoxicity occurred in 16% to 18% of Zydelig-treated patients...</p> <p>Fatal and/or serious and severe diarrhea or colitis occurred in 14% to 20% of Zydelig-treated patients...</p> <p>Fatal and/or serious infections occurred in 21% to 48% of Zydelig-treated patients.</p>  |
| ZOMACTON<br>( <i>somatropin recombinant</i> ) | Contraindication                   | <p>ZOMACTON is contraindicated in patients with:</p> <ul style="list-style-type: none"> <li>• Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin.</li> <li>• Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of death.</li> <li>• Active malignancy due to an increased risk of second neoplasm.</li> <li>• Hypersensitivity to ZOMACTON, any of its excipients, or its accompanying diluents. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.</li> <li>• Active proliferative or severe non-proliferative diabetic retinopathy.</li> <li>• Pediatric patients with closed epiphyses.</li> </ul> |

| Drug  | Type of Change   | Change  |
|---|------------------|---|
| BUNAVAIL<br>(buprenorphine hydrochloride;<br>naloxone hydrochloride);<br>SUBOXONE<br>(buprenorphine hydrochloride;<br>naloxone hydrochloride);<br>ZUBSOLV<br>(buprenorphine hydrochloride;<br>naloxone hydrochloride) | Contraindication | Contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone.  |
| DOLOPHINE<br>HYDROCHLORIDE<br>(methadone hydrochloride);<br>methadone hydrochloride   | Boxed Warning    | <p>Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants</p> <p>Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.</p> <ul style="list-style-type: none"> <li>• Reserve concomitant prescribing of DOLOPHINE Tablets and benzodiazepines or other CNS depressants for use in patients for whom alternatives to benzodiazepines or other CNS depressants are inadequate.</li> <li>• Limit dosages and durations to the minimum required for patients being treated for pain.</li> <li>• Follow patients for signs and symptoms of respiratory depression and sedation. If the patient is visibly sedated, evaluate the cause of sedation, and consider delaying or omitting the daily methadone dose.</li> </ul> |
| OCALIVA<br>(obeticholic acid)   | Boxed Warning    | <p>WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS</p> <ul style="list-style-type: none"> <li>• In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with primary biliary cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.</li> <li>• The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.</li> </ul>   |
| SUBUTEX<br>(buprenorphine hydrochloride)  | Contraindication | Contraindicated in patients with a history of hypersensitivity to buprenorphine.  |

| Drug   | Type of Change   | Change   |
|--|------------------|--|
| FERAHEME<br>(ferumoxytol)                        | Boxed Warning    | Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving Feraheme. Initial symptoms may include hypotension, syncope, unresponsiveness, cardiac / cardiorespiratory arrest.<br><br>Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.   |
| DORYX<br>(doxycycline hyclate)                   | Contraindication | The drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.  |
| ZYTIGA<br>(abiraterone acetate)                  | Contraindication | Pregnancy<br>ZYTIGA can cause fetal harm and potential loss of pregnancy.  |
| NUVARING<br>(ethinyl estradiol;<br>etonogestrel) | Contraindication | Hypersensitivity, including anaphylaxis and angioedema, to any of the components of NuvaRing.  |
| NORDITROPIN<br>(somatropin recombinant)          | Contraindication | NORDITROPIN is contraindicated in patients with: <ul style="list-style-type: none"> <li>• Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin.</li> <li>• Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of sudden death.</li> <li>• Hypersensitivity to NORDITROPIN or any of its excipients.</li> </ul> |
| ALTOPREV<br>(lovastatin)                         | Contraindication | The use of Altoprev is contraindicated in the following conditions: <ul style="list-style-type: none"> <li>• Pregnancy.</li> <li>• Lactation. Because another drug in this class passes into breast milk, and because statins have the potential to cause serious adverse reactions in breastfed infants, women who require Altoprev treatment should not breastfeed their infants.</li> </ul>   |
| SKYLA<br>(levonorgestrel)                        | Contraindication | The use of Skyla is contraindicated when one or more of the following conditions exist: <ul style="list-style-type: none"> <li>• Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity</li> </ul>   |





| Drug  | Type of Change                     | Change  |
|---|------------------------------------|---|
| AQUAMEPHYTON<br>( <i>phytonadione</i> )                       | Boxed Warning and Contraindication | <p><b>WARNING: HYPERSENSITIVITY REACTIONS WITH INTRAVENOUS AND INTRAMUSCULAR USE</b></p> <p>Fatal hypersensitivity reactions, including anaphylaxis, have occurred during and immediately after INTRAVENOUS and INTRAMUSCULAR injection of AQUAMEPHYTON. Reactions have occurred despite dilution to avoid rapid infusion and upon first dose. Avoid the intravenous and intramuscular routes of administration unless the subcutaneous route is not feasible and the serious risk is justified.</p> <p>Contraindication:<br/>Hypersensitivity to phytonadione or any other component of this medication.</p>   |
| INVIRASE<br>( <i>saquinavir mesylate</i> )                    | Contraindication                   | <p>INVIRASE/ritonavir is contraindicated in patients receiving the following co-administered drugs; however, it should be noted that this list is not intended to be exhaustive.</p> <ul style="list-style-type: none"> <li>• Alpha 1-adrenoreceptor antagonist: alfuzonsin</li> <li>• Antiarrhythmics: amiodarone, bepridil, deofeilide, flecainide, lidocaine (systemic), propafenone, quinidine</li> <li>• Antidepressant: trazodone</li> <li>• Anti-infectives: clarithromycin, erythromycin, halofantrine, pentamidine</li> <li>• Antimycobacterial Agents: rifampin</li> <li>• Antipsychotics: lurasidone, clozapine, haloperidol, pimozide, sertindole, ziprasidone, phenothiazines (e.g., chlorpromazine, mesoridazine, thioridazine).</li> <li>• Ergot Derivatives: dihydroergotamine, ergonovine, ergotamine, methylergonovine</li> <li>• HIV-1 Protease Inhibitor: atazanavir</li> <li>• HMG-CoA Reductase Inhibitors: lovastatin, simvastatin</li> <li>• Immunosuppressant: tacrolimus</li> <li>• Non-nucleoside reverse transcriptase inhibitor (NNRTI): rilpivirine (concomitant use and switching from rilpivirine to INVIRASE/ritonavir without a washout period of at least 2 weeks is contraindicated)</li> <li>• PDE5 Inhibitors: sildenafil (Revatio®)[for treatment of pulmonary arterial hypertension]</li> <li>• Sedative / Hypnotics: triazolam, and orally administered midazolam</li> <li>• Tyrosine kinase inhibitors: dasatinib, sunatinib</li> <li>• Other drugs that are CYP3A substrates: disopyramide, quinine</li> </ul> |
| SOLU-MEDROL<br>( <i>methylprednisolone sodium succinate</i> ) | Contraindication                   | <p>SOLU-MEDROL Sterile Powder is contraindicated in systemic fungal infections and patients with known hypersensitivity to the product and its constituents. The SOLU-MEDROL 40 mg presentation includes lactose monohydrate produced from cow's milk. This presentation is therefore contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its components or other dairy products because it may contain trace amounts of milk ingredients.</p>  |

| Drug   | Type of Change                        | Change  |
|--|---------------------------------------|---|
| VARUBI<br>(rolapitant<br>hydrochloride)  | Contraindication                      | VARUBI is contraindicated in patients taking CYP2D6 substrates with a narrow therapeutic index, such as thioridazine and pimozide. VARUBI can significantly increase the plasma concentrations of thioridazine and pimozide, which may result in QT prolongation and Torsades de Pointes.   |
| TAZORAC<br>(tazarotene)  | Contraindication                      | TAZORAC Gel is contraindicated in: <ul style="list-style-type: none"> <li>• Pregnancy. Retinoids may cause fetal harm when administered to a pregnant female.</li> <li>• Individuals who have known hypersensitivity to any of its components.</li> </ul>   |
| E.E.S.<br>(erythromycin<br>ethylsuccinate);<br>ERYC (erythromycin);<br>ERYPED<br>(erythromycin<br>ethylsuccinate);<br>ERYTHROCIN<br>(erythromycin<br>lactobionate);<br>PCE<br>(erythromycin) | Contraindication                      | Do not use erythromycin concomitantly with HMG CoA reductase inhibitors (statins) that are extensively metabolized by CYP 3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.   |
| KISQALI FEMARA<br>CO-PACK<br>(COPACKAGED)<br>(letrozole; ribociclib<br>succinate)  | Contraindication                      | Known hypersensitivity to the active substance (letrozole), or to any of the excipients of FEMARA. Refer to FEMARA Prescribing Information.   |
| SAMSCA<br>(tolvaptan)  | Boxed Warning and<br>Contraindication | <p><b>WARNING: NOT FOR USE FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)</b></p> <p>Because of the risk of hepatotoxicity, tolvaptan should not be used for ADPKD outside of the FDA-approved REMS.</p> <p>Contraindication:<br/>Use in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) outside of FDA approved REMS</p> <p>Tolvaptan can cause serious and potentially fatal liver injury. Tolvaptan should not be prescribed or used outside of the FDA-approved Risk Evaluation and Mitigation Strategy (REMS) for ADPKD patients.</p> |
| LOPID<br>(gemfibrozil)   | Contraindication                      | <p>Combination therapy of gemfibrozil with simvastatin.</p> <p>Combination therapy of gemfibrozil with repaglinide.</p> <p>Combination therapy of gemfibrozil with dasabuvir.</p> <p>Combination therapy of gemfibrozil with selexipag.</p>   |

| Drug   | Type of Change                        | Change   |
|--|---------------------------------------|--|
| MAGNEVIST<br>(gadopentetate dimeglumine)                           | Contraindication                      | Magnevist is contraindicated in patients with history of severe hypersensitivity reactions to Gadopentetate dimeglumine.   |
| COMBIVIR<br>(lamivudine;<br>zidovudine)                            | Boxed Warning                         | Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including lamivudine and zidovudine (components of COMBIVIR). Discontinue COMBIVIR if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur.  |
| TRIZIVIR<br>(abacavir sulfate;<br>lamivudine;<br>zidovudine)       | Boxed Warning                         | Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including abacavir, lamivudine, and zidovudine (components of TRIZIVIR).   |
| K-TAB<br>(potassium chloride);<br>KLOR-CON<br>(potassium chloride) | Contraindication                      | Potassium chloride is contraindicated in patients on triamterene or amiloride.   |
| Cosyntropin  | Contraindication                      | Hypersensitivity to Cosyntropin injection, synthetic ACTH, or to any of the excipients.  |
| EXJADE<br>(deferasirox)  | Boxed Warning and<br>Contraindication | <p>Boxed Warning:<br/>Renal Failure</p> <ul style="list-style-type: none"> <li>Exjade can cause acute renal failure and death, particularly in patients with comorbidities and those who are in the advanced stages of their hematologic disorders.</li> <li>Evaluate baseline renal function prior to starting or increasing Exjade dosing in all patients. Exjade is contraindicated in adult and pediatric patients with eGFR less than 40 mL/min/1.73 m<sup>2</sup>. Measure serum creatinine in duplicate prior to initiation of therapy. Monitor renal function at least monthly. For patients with baseline renal impairment or increased risk of acute renal failure, monitor renal function weekly for the first month, then at least monthly. Reduce the starting dose in patients with pre-existing renal disease. During therapy, increase the frequency of monitoring and modify the dose for patients with an increased risk of renal impairment, including use of concomitant nephrotoxic drugs, and pediatric patients with volume depletion or overchelation.</li> </ul> <p>Contraindication:<br/>Exjade is contraindicated in patients with estimated GFR less than 40 mL/min/1.73m<sup>2</sup>.</p> |

| Drug  | Type of Change                        | Change  |
|---|---------------------------------------|---|
| JADENU<br>( <i>deferasirox</i> );<br>JADENU SPRINKLE<br>( <i>deferasirox</i> )  | Boxed Warning and<br>Contraindication | <p><b>WARNING: RENAL FAILURE, HEPATIC FAILURE, AND GASTROINTESTINAL HEMORRHAGE</b></p> <p>Renal Failure</p> <ul style="list-style-type: none"> <li>JADENU can cause acute renal failure and death...</li> <li>Evaluate baseline renal function prior to starting or increasing Jadenu dosing in all patients. JADENU is contraindicated in adult and pediatric patients with eGFR less than 40 mL/minute/1.73 m<sup>2</sup>. Measure serum creatinine in duplicate prior to initiation of therapy. Monitor renal function at least monthly. For patients with baseline renal impairment or increased risk of acute renal failure, monitor renal function weekly for the first month, then at least monthly. Reduce the starting dose in patients with pre-existing renal disease. During therapy, increase the frequency of monitoring and modify the dose for patients with an increased risk of renal impairment, including use of concomitant nephrotoxic drugs, and pediatric patients with volume depletion or overchelation.</li> </ul> <p>Contraindication:<br/>JADENU is contraindicated in patients with estimated GFR less than 40 mL/min/1.73 m<sup>2</sup>.</p> |
| DEXTROSE 20%<br>IN PLASTIC<br>CONTAINER;<br>DEXTROSE 30%<br>IN PLASTIC<br>CONTAINER;<br>DEXTROSE 40%<br>IN PLASTIC<br>CONTAINER;<br>DEXTROSE 50%<br>IN PLASTIC<br>CONTAINER;<br>DEXTROSE 70%<br>IN PLASTIC<br>CONTAINER | Contraindication                      | <p>The use of Dextrose Injection is contraindicated in patients:</p> <ul style="list-style-type: none"> <li>Who are severely dehydrated as hypertonic dextrose solution can worsen the patient's hyperosmolar state.</li> <li>With known hypersensitivity to dextrose.</li> </ul>   |
| BOTOX<br>( <i>onabotulinumtoxin</i> a)  | Contraindication                      | <p>Urinary Tract Infection or Urinary Retention</p> <p>Intradetrusor injection of BOTOX is contraindicated in patients with overactive bladder or detrusor overactivity associated with a neurologic condition who have a urinary tract infection. Intradetrusor injection of BOTOX is also contraindicated in patients with urinary retention and in patients with post-void residual (PVR) urine volume &gt;200 mL, who are not routinely performing clean intermittent self-catheterization (CIC).</p>   |

| Drug   | Type of Change   | Change   |
|--|------------------|--|
| PROLIA<br>(denosumab);<br>XGEVA<br>(denosumab)           | Contraindication | Denosumab is contraindicated in: <ul style="list-style-type: none"> <li>• Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with denosumab.</li> <li>• Pregnancy: Denosumab may cause fetal harm when administered to a pregnant woman. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with denosumab.</li> <li>• Hypersensitivity: Denosumab is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling, and urticaria.</li> </ul> |
| ELOCON<br>(mometasone furoate)                           | Contraindication | ELOCON Ointment is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation.   |
| PURINETHOL<br>(mercaptopurine)                           | Contraindication | Mercaptopurine should not be used in patients whose disease has demonstrated prior resistance to this drug. In animals and humans, there is usually complete cross-resistance between mercaptopurine and thioguanine.<br><br>Mercaptopurine should not be used in patients who have a hypersensitivity to mercaptopurine or any component of the formulation.  |
| PROGRAF<br>(tacrolimus)                                  | Boxed Warning    | Increased risk for developing serious infections and malignancies with PROGRAF or other immunosuppressants that may lead to hospitalization or death.  |
| CADUET<br>(amlodipine besylate;<br>atorvastatin calcium) | Contraindication | Pregnancy<br>• Lactation   |
| CIMZIA<br>(certolizumab pegol)                           | Contraindication | CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylactoid reaction, serum sickness, and urticarial.   |
| SYLVANT<br>(siltuximab)                                  | Contraindication | Severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT. Hypersensitivity reactions, including anaphylactic reaction, hypersensitivity, and drug hypersensitivity have been reported in patients treated with siltuximab.   |
| PREZCOBIX<br>(cobicistat; darunavir<br>ethanolate)       | Contraindication | PREZCOBIX is contraindicated in patients receiving the following co-administered drugs:<br>Drugs That Are Contraindicated with Prezcoibx reformatted to a bulleted line listing; please refer to label for complete information.   |



## 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  |
|--|------------------------|--|
| SHINGRIX<br>(recombinant zoster vaccine)                 | GlaxoSmithKline        | <ul style="list-style-type: none"> <li>GlaxoSmithKline has Shingrix on shortage due to high demand for the product.</li> </ul> <p>GlaxoSmithKline has Shingrix kits in 1 count and 10 count on intermittent back order with regular releases.</p>  |
| Thiothixene capsules<br>1 mg, 2mg, 10mg and 5mg          | Mylan                  | <ul style="list-style-type: none"> <li>Mylan did not provide a reason for the shortage.</li> <li>Mylan is the sole supplier of thiothixene.</li> </ul> <p>Mylan has thiothixene 1 mg, 2 mg, 5 mg, and 10 mg capsules in 100 count bottles on back order and the company estimates a release date of mid-June 2018.</p> <p>Mylan Institutional has thiothixene 2 mg, 5 mg, and 10 mg capsules in 100 count unit-dose blister packs on back order and the company estimates a release date of early-July 2018.</p> |
| Isosorbide Dinitrate<br>Extended-Release<br>Tablets 40mg | Sun Pharma             | <ul style="list-style-type: none"> <li>Sun Pharma is not currently manufacturing isosorbide dinitrate 40 mg extended-release tablets.</li> <li>There are no presentations available.</li> </ul> <p>Sun Pharma has isosorbide dinitrate 40 mg extended-release tablets on long-term back order and the company cannot estimate a release date.</p>  |

## 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  |
|---------------------------|---|
| LAMICTAL<br>(lamotrigine) | The FDA is warning that the medicine lamotrigine (Lamictal) for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body's infection-fighting immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, we are requiring a new warning about this risk be added to the prescribing information in the lamotrigine drug labels. |



Page left intentionally blank.

Page left intentionally blank.

Page left intentionally blank.



**Gold Coast  
Health Plan**<sup>SM</sup>  
A Public Entity

**Q2** 2018

## **Pharmacy Newsletter**

**AUGUST 2018**

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](http://www.goldcoasthealthplan.org)