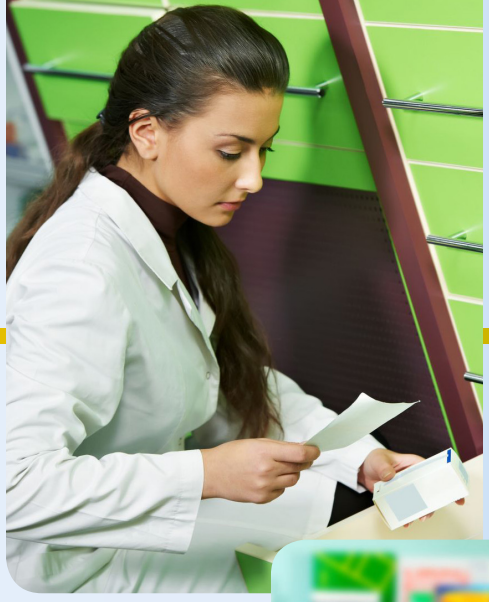

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

DECEMBER 2015

Q1 2016

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PN Q1 2016

The Pharmacy Newsletter is published quarterly as a service for the provider community of Gold Coast Health Plan.

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:
C. Albert Reeves, MD

Editor:
Steven Lalich

Copy Editor:
Susana Enriquez

CMO Message

C. Albert Reeves, MD

Vaccines are the most effective tool we have to prevent infectious diseases.

Health economist Jenifer Ehreth estimates that annually, vaccines prevent nearly 6 million deaths worldwide. In the U.S., there has been a 99% decrease in incidence for the nine diseases for which vaccines have been recommended for decades, accompanied by a similar decline in mortality and disease sequelae.

All recommended vaccines are available to members of Gold Coast Health Plan (GCHP). The Plan has adopted the immunization recommendations of the Advisory Committee for Immunization Practices (ACIP) for its members (children and adults).

Despite the fact that GCHP promotes vaccination and that these vaccines are provided free to members, the Plan's rates of immunization are not close to complete. In 2014, GCHP's rate of immunization for 2 year olds went down in the Healthcare Effectiveness Data and Information Set (HEDIS®) survey. As a result, the Plan is embarking on an improvement project with one of its provider clinics to develop strategies to increase immunizations.

In 2014, ACIP added a second pneumonia vaccine to the immunization recommendation for older adults. It is now recommended that adults over 65 years old receive a Prevnar (PCV13) vaccination in addition to the Pneumovax (PPSV23), which has been recommended for years.

GCHP has now made several adult vaccines available to its members on the pharmacy benefit. That means that members can either get the vaccination at the pharmacy or receive the vaccine with a prescription and have it administered at their physician's office. The pharmacy will record the vaccination in the California Immunization Registry (CAIR) so that it is documented as having been given.

The vaccines that are now available at the pharmacy are Zostavax, Havrix (hep A), Twinix (hep A/B), and Engerix (hep B). In 2016, the Plan will be adding influenza, Pneumovax (PPSV23) and Prevnar (PCV13).

We are hoping that by making these vaccines more readily available through the pharmacy benefit, it will help to make all of the Plan's members immune to these preventable diseases. We strongly urge all of GCHP's providers to make sure that our members - your patients - are fully immunized with all recommended vaccines.

If you have any questions, please feel free to contact me or the Plan's Director of Pharmacy, Anne Freese.

Regards,

C. Albert Reeves, M.D.

C. Albert Reeves, MD

Disease State Topic: Immunization Availability

Previously, GCHP limited the provision of immunizations to physician's offices. However, GCHP became aware that several clinics or clinic systems did not store Zostavax. As a result, the pharmacy benefit was adjusted to allow members to pick-up the immunization at the pharmacy to take to their doctor's office and also to be able to receive the immunization at the pharmacy. This has allowed more of GCHP's members to access this extremely important prevention measure that, for some, was previously very difficult to get.

To that end, GCHP has decided to allow other vaccines to be available through the pharmacy benefit. As with Zostavax, pharmacists will be able to continue providing the vaccines to members to take to their physician's office, but they may now also administer the vaccines.

Pharmacists are authorized to administer vaccines to their patients through a statewide protocol after completion of a training program endorsed by the CDC or the Accreditation Council for Pharmacy Education (ACPE). The program requires pharmacists to: follow ACIP's recommendations; comply with all state and federal recordkeeping and reporting requirements; provide documentation to the patient's primary care provider; and enter information into the appropriate immunization registry designated by the immunization branch of the state Department of Public Health - CAIR.

The immunizaitions that are available through the pharmacy benefit effective today are Zostavax, Havrix, Twinrix, and Engerix.

The additional immunizations that will be available through the pharmacy benefit effective January 1 are:

- Influenza, including the standard- and high-dose trivalent and the quadrivalent vaccines.
- Pneumonia, both Pneumovax and Prevnar.

Immunization Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

- ACIP Vaccine Recommendations
- Birth – 18 Years and "Catch-Up" Immunization Schedules
- Adult Immunization Schedules

Pharmacy Department Update

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 or via regular mail by writing to GCHP at the following address:

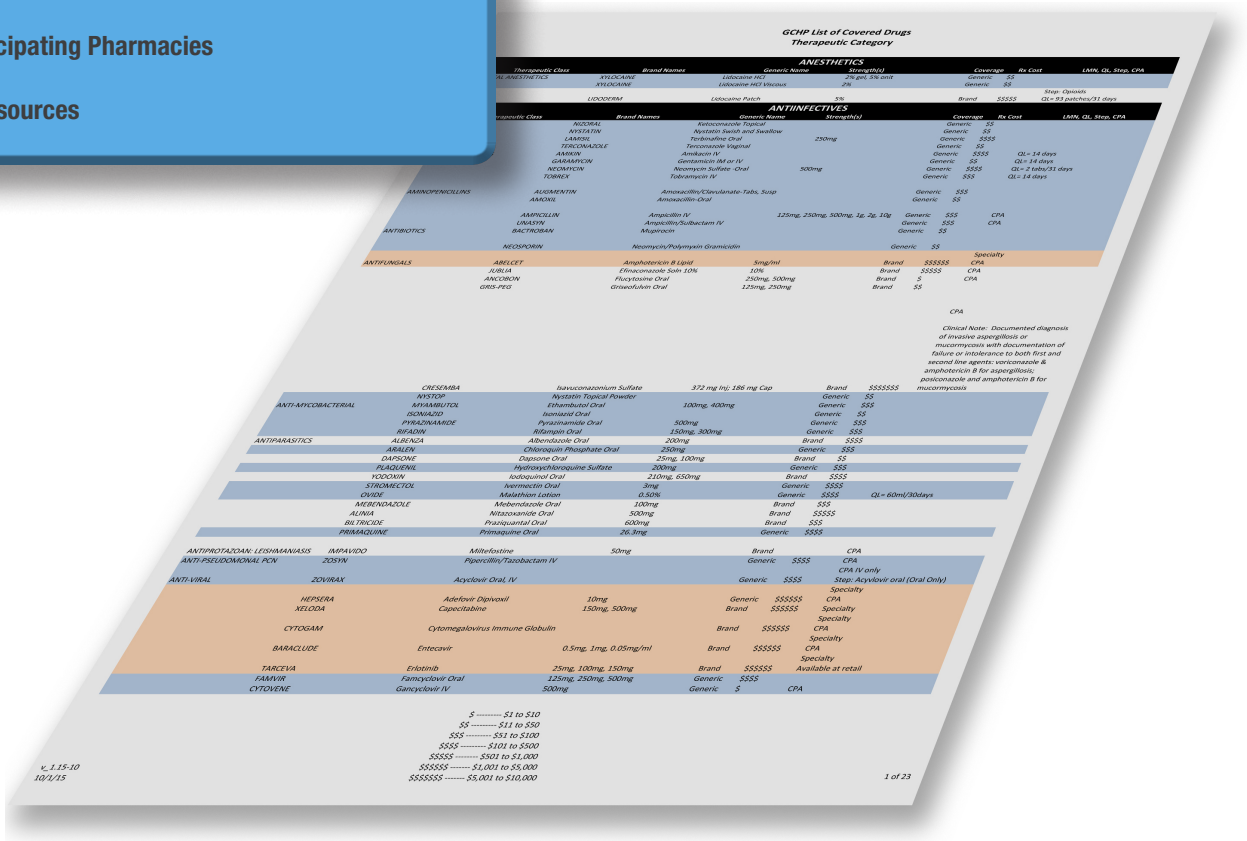
GCHP Pharmacy Director
711 E. Daily Dr. Suite 106
Camarillo, CA 93010

All requests will be reviewed, researched, and, if feasible, brought to the Pharmacy and Therapeutics Committee for discussion and potential voting.

Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

- GCHP Formulary
- List of Participating Pharmacies
- Provider Resources


GCHP List of Covered Drugs
Therapeutic Category

ANESTHETICS

Therapeutic Class	Brand Names	Generic Name	Strength(s)	Coverage	Rx Cost	LMN, QL, Step, CPA
TOPICAL ANESTHETICS	XYLOCAINE	Lidocaine HCl	2% gel, 5% oint	Generic	$$	
	XYLOCAINE	Lidocaine HCl Viscous	2%	Generic	$$	
						Step: Opioids
	LIDODERM	Lidocaine Patch	5%	Brand	$$$$$	QL= 93 patches/31 days

ANTIINFECTIVES

Therapeutic Class	Brand Names	Generic Name	Strength(s)	Coverage	Rx Cost	LMN, QL, Step, CPA
	NIZORAL	Ketoconazole Topical		Generic	$$	
	NYSTATIN	Nystatin Swish and Swallow		Generic	$$	
	LAMISIL	Terbinafine Oral	250mg	Generic	$$$$	
	TERCONAZOLE	Terconazole Vaginal		Generic	$$	
	AMIKIN	Amikacin IV		Generic	$$$$	QL= 14 days
	GARAMYCIN	Gentamicin IM or IV		Generic	$$	QL= 14 days
	NEOMYCIN	Neomycin Sulfate Oral	500mg	Generic	$$$$	QL= 2 tabs/31 days
	TOBREX	Tobramycin IV		Generic	$$$	QL= 14 days
AMINOPENICILLINS	AUGMENTIN	Amoxicillin/Clavulanate-Tabs, Susp		Generic	$$$	
	AMOXIL	Amoxicillin Oral		Generic	$$	
	AMPICILLIN	Ampicillin IV	125mg, 250mg, 500mg, 1g, 2g, 10g	Generic	$$$	CPA
	UNASYN	Ampicillin/Sulbactam IV		Generic	$$$	CPA
ANTIBIOTICS	BACTROBAN	Mupirocin		Generic	$$	
	NEOSPORIN	Neomycin/Polymyxin Gramicidin		Generic	$$	
						Specialty
ANTIFUNGALS	ABELCET	Amphotericin B Lipid	5mg/ml	Brand	$$$$$$	CPA
	JUBLIA	Efinaconazole Soln 10%	10%	Brand	$$$$$	CPA
	ANCOBON	Flucytosine Oral	250mg, 500mg	Brand	$	CPA
	GRIS-PEG	Griseofulvin Oral	125mg, 250mg	Brand	$$	
						CPA

Clinical Note: Documented diagnosis of invasive aspergillosis or mucormycosis with documentation of failure or intolerance to both first and second line agents: voriconazole & amphotericin B for aspergillosis; posiconazole and amphotericin B for mucormycosis

	CRESEMBA	Isavuconazonium Sulfate	372 mg Inj; 186 mg Cap	Brand	$$$$$$$	
	NYSTOP	Nystatin Topical Powder		Generic	$$	
ANTI-MYCOBACTERIAL	MYAMBUTOL	Ethambutol Oral	100mg, 400mg	Generic	$$$	
	ISOMIAZID	Isoniazid Oral		Generic	$$	
	PYRAZINAMIDE	Pyrazinamide Oral	500mg	Generic	$$$	
	RIFADIN	Rifampin Oral	150mg, 300mg	Generic	$$$	
ANTIPARASITICS	ALBENZA	Albendazole Oral	200mg	Brand	$$$$	
	ARALEN	Chloroquin Phosphate Oral	250mg	Generic	$$$	
	DAPSONE	Dapsone Oral	25mg, 100mg	Brand	$$	
	PLAQUENIL	Hydroxychloroquine Sulfate	200mg	Generic	$$$	
	YODOXIN	Iodoquinol Oral	210mg, 650mg	Brand	$$$$	
	STROMECTOL	Ivermectin Oral	3mg	Generic	$$$$	
	OVIDE	Malathion Lotion	0.50%	Generic	$$$$	QL= 60ml/30days
	MEBENDAZOLE	Mebendazole Oral	100mg	Brand	$$$	
	ALINIA	Nitazoxanide Oral	500mg	Brand	$$$$$	
	BILTRICIDE	Praziquantal Oral	600mg	Brand	$$$	
	PRIMAQUINE	Primaquine Oral	26.3mg	Generic	$$$$	
ANTIPROTAZOAN- LEISHMANIASIS	IMPAVIDO	Miltefosine	50mg	Brand		CPA
ANTI-PSEUDOMONAL PCN	ZOSYN	Piperacillin/Tazobactam IV		Generic	$$$$	CPA
						CPA IV only
ANTI-VIRAL	ZOVIRAX	Acyclovir Oral, IV		Generic	$$$$	Step: Acyclovir oral (Oral Only)
						Specialty
	HEPSERA	Adefovir Dipivoxil	10mg	Generic	$$$$$$	CPA
	XELODA	Capecitabine	150mg, 500mg	Brand	$$$$$$	Specialty
						Specialty
	CYTOGAM	Cytomegalovirus Immune Globulin		Brand	$$$$$$$	CPA
						Specialty
	BARACLUDE	Entecavir	0.5mg, 1mg, 0.05mg/ml	Brand	$$$$$$	CPA
						Specialty
	TARCEVA	Erlotinib	25mg, 100mg, 150mg	Brand	$$$$$$	Available at retail
	FAMVIR	Famciclovir Oral	125mg, 250mg, 500mg	Generic	$$$$	
	CYTOVENE	Ganciclovir IV	500mg	Generic	$	CPA

$ --------- $1 to $10
$$ --------- $11 to $50
$$$ --------- $51 to $100
$$$$ --------- $101 to $500
$$$$$ --------- $501 to $1,000
$$$$$$ --------- $1,001 to $5,000
$$$$$$$ --------- $5,001 to $10,000

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10/1/15

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Formulary Changes

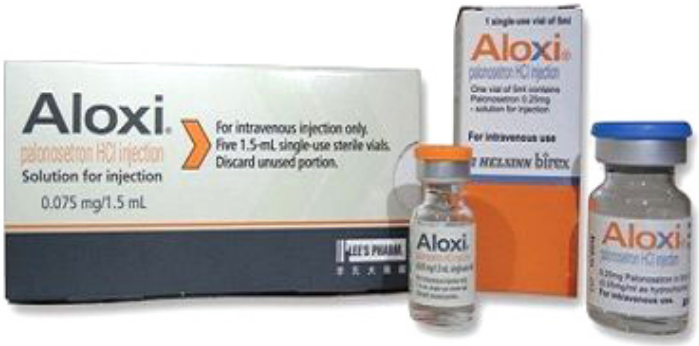
The following changes to the GCHP formulary will be effective January 1:

Additions

Drug	Formulary Status/Change
SYNJARDY *(empagliflozin; metformin hydrochloride)*	Added to the formulary with a step therapy
ORKAMBI *(ivacaftor; lumacaftor)*	Added to the formulary with prior authorization
ENTRESTO *(sacubitril; valsartan)*	Added to the formulary with prior authorization
ODOMZO *(sonidegib phosphate)*	Added to the formulary with prior authorization
DAKLINZA *(daclatasvir dihydrochloride)*	Added to the formulary with prior authorization
TECHNIVIE *(ombitasvir; paritaprevir; ritonavir)*	Added to the formulary with prior authorization
MEPHYTON 5 mg tablets	Added to the formulary with prior authorization
Aluminum hydroxide, magnesium hydroxide, and simethicone	Added to the formulary
Calcium carbonate	Added to the formulary
Calcium gluconate	Added to the formulary
Vitamin A, D, C	Added to the formulary
Vitamin A, D, C with iron	Added to the formulary
Vitamin A, D, C with sodium fluoride	Added to the formulary
Sodium chloride 5% ophthalmic solution	Added to the formulary
CHEMET	Added to the formulary with prior authorization
Phenylephrine hydrochloride	Added to the formulary
Pseudoephedrine hydrochloride 30 mg	Added to the formulary
Oral electrolyte maintenance solutions (e.g., Pedialyte)	Added to the formulary
RIDAURA capsule	Added to the formulary with prior authorization
Pneumococcal vaccine	Added to the formulary
Influenza vaccine	Added to the formulary
XARELTO *(rivaroxaban)*	Added to the formulary with a step therapy

Removals

Drug	Formulary Status/Change
XENAZINE tablets	Removed from the formulary, generic now available
EXELON transdermal system	Removed from the formulary, generic now available
EPIDUO topical gel	Removed from the formulary, generic now available
ALOXI injection	Removed from the formulary, generic now available
SPORANOX oral solution	Removed from the formulary, generic now available



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
VARUBI	*rolapitant*	Tablet; oral	VARUBI is a substance P/neurokinin 1 (NK1) receptor antagonist indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic.
DURLAZA	*aspirin*	Capsule, extended release; oral	DURLAZA is a nonsteroidal anti-inflammatory drug indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack. Limitation of use: Use immediate-release aspirin, not DURLAZA, in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).
XURIDEN	*uridine triacetate*	Granule; oral	XURIDEN is a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria.
SPIRIVA RESPIMAT	*tiotropium bromide*	Spray; inhalation	SPIRIVA RESPIMAT is an anticholinergic indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with Chronic Obstructive Pulmonary Disease (COPD) and for reducing COPD exacerbations. Limitation of use: Not indicated for relief of acute bronchospasm.
VRAYLAR	*cariprazine*	Capsule; oral	VRAYLAR is an atypical antipsychotic indicated for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder.
TOLAK	*fluorouracil*	Cream, augmented; topical	TOLAK (fluorouracil) Cream, 4%, is a nucleoside metabolic inhibitor indicated for the topical treatment of actinic keratosis lesions of the face, ears, and scalp.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
LONSURF	*Trifluridine; Tipiracil*	Tablet; oral	LONSURF is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
RYZODEG 70/30	*insulin degludec; insulin aspart*	Tablet; oral	RYZODEG 70/30 is an insulin analog indicated to improve glycemic control in adults with diabetes mellitus.
TRESIBA	*insulin degludec*	Tablet, chewable; oral	TRESIBA is a long-acting human insulin analog indicated to improve 9 glycemic control in adults with diabetes mellitus.
MORPHABOND	*morphine sulfate*	Injectable	MORPHABOND is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
ARISTADA	*aripiprazole lauroxil*	Powder, for injection solution, lyophilized powder	ARISTADA is an atypical antipsychotic indicated for the treatment of Schizophrenia.
ENSTILAR	*calcipotriene; betamethasone dipropionate*	Tablet, extended release; oral	Enstilar Foam is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.
PRAXBIND	*idarucizumab*	Injectable; injection	PRAXBIND is a humanized monoclonal antibody fragment (Fab) indicated in patients treated with Pradaxa® when reversal of the anticoagulant effects of dabigatran is needed: • For emergency surgery/urgent procedures. • In life-threatening or uncontrolled bleeding.
DYANAVEL XR	*Amphetamine*	Suspension, extended release; oral	DYANAVEL XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
VELTASSA	*Patiromer*	Powder; oral	Veltassa is a potassium binder indicated for the treatment of hyperkalemia. Limitation of use: Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.
DEXMEDETOMIDINE HYDROCHLORIDE	*dexmedetomidine hydrochloride*	Injectable; injection	Dexmedetomidine Hydrochloride Injection is a central alpha-2 adrenergic agonist indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.

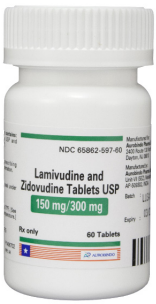
Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
VIVLODEX	*Meloxcam*	Capsule; oral	VIVLODEX is a non-steroidal anti-inflammatory drug indicated for management of osteoarthritis (OA) pain.
ONIVYDE	*irinotecan liposome*	Vial; single use	ONIVYDE is a topoisomerase inhibitor indicated, in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.
STRENSIQ	*asfotase alfa*	Solution; injection	Limitation of use: ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.
BELBUCA	*buprenorphine*	Film; Buccal	BELBUCA buccal film contains buprenorphine, a partial opioid agonist. BELBUCA is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
YONDELIS	*trabectedin*	Injectable; injection	YONDELIS is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.
ACETAMINOPHEN	*acetaminophen*	Injectable; injection	Acetaminophen injection is indicated for the management of mid-to-moderate pain, management of moderate-to-severe pain with adjunctive opioid analgesics, reduction of fever.
SEEBRI NEOHALER	*glycopyrrolate*	Powder; inhalation	SEEBRI NEOHALER is an anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD).
UTIBRON NEOHALER	*indacaterol; glycopyrrolate*	Powder; inhalation	UTIBRON NEOHALER is a combination of indacaterol, a long-acting beta2adrenergic agonist (LABA), and glycopyrrolate, an anticholinergic, indicated for the long-term, maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD). Limitations of use: Not indicated for the relief of acute bronchospasm or for the treatment of asthma.

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
Brilinta (ticagrelor) 90 mg Tablets	Boxed Warning	WARNING: (A) BLEEDING RISK, (B) ASPIRIN DOSE AND BRILINTA EFFECTIVENESS A. BLEEDING RISK • Brilinta, like other antiplatelet agents, can cause significant, sometimes fatal bleeding. • Do not use Brilinta in patients with active pathological bleeding or a history of intracranial hemorrhage. • Do not start Brilinta in patients undergoing urgent coronary artery bypass graft surgery (CABG). • If possible, manage bleeding without discontinuing Brilinta. Stopping Brilinta increases the risk of subsequent cardiovascular events. B. ASPIRIN DOSE AND BRILINTA EFFECTIVENESS • Maintenance doses of aspirin above 100 mg reduce the effectiveness of Brilinta and should be avoided.
All clozapine containing products: • Clozaril (clozapine HCl) tablets • Fazaclo (clozapine) orally disintegrating tablets • Versacloz (clozapine) Oral Suspension	Boxed Warning and Contraindications	WARNING: SEVERE NEUTROPENIA; ORTHOSTATIC HYPOTENSION, BRADYCARDIA, AND SYNCOPE; SEIZURE; MYOCARDITIS AND CARDIOMYOPATHY; INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS Severe Neutropenia • Clozapine treatment has caused severe neutropenia, defined as an absolute neutrophil count (ANC) less than 500/μL. Severe neutropenia can lead to serious infection and death. Prior to initiating treatment with clozapine a baseline ANC must be at least 1500/ μL for the general population; and must be at least 1000/μL for patients with documented Benign Ethnic Neutropenia (BEN). During treatment, patients must have regular ANC monitoring. Advise patients to immediately report symptoms consistent with severe neutropenia or infection (e.g., fever, weakness, lethargy, or sore throat). Because of the risk of severe neutropenia, Clozapine is available only through a restricted program under a Risk Evaluation Mitigation Strategy (REMS) called the Clozapine REMS Program. CONTRAINDICATIONS: Hypersensitivity • Clozapine is contraindicated in patients with a history of serious hypersensitivity to clozapine (e.g., photosensitivity, vasculitis, erythema multiforme, or Stevens-Johnson Syndrome) or any other component of the product.

Drug	Type of Change	Change
Combivir *(lamivudine and zidovudine)* Tablets	Boxed Warning (updated) and Contraindications	WARNING: HEMATOLOGIC TOXICITY, MYOPATHY, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, and EXACERBATIONS OF HEPATITIS B Hematologic Toxicity • Zidovudine, a component of Combivir (lamivudine and zidovudine) tablets, has been associated with hematologic toxicity including neutropenia and severe anemia, particularly in patients with advanced Human Immunodeficiency Virus (HIV-1) disease. Myopathy • Prolonged use of zidovudine has been associated with symptomatic myopathy. Lactic Acidosis and Severe Hepatomegaly with Steatosis • Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues and other antiretrovirals. Discontinue Combivir if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicities occur. Exacerbations of Hepatitis B • Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with hepatitis B virus (HBV) and HIV-1 and have discontinued lamivudine, which is one component of Combivir. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Combivir and are co-infected with HIV-1 and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.



Drug	Type of Change	Change
All abacavir containing products: • Epzicom *(abacavir and lamivudine)* Tablets • Triumeq *(abacavir/ dolutegravir/lamivudine)* • Trizivir *(abacavir, lamivudine, and zidovudine)* Tablets • Ziagen *(abacavir sulfate)* Tablets and Oral Solution	Boxed Warning (updated)	Hypersensitivity Reactions • Serious and sometimes fatal hypersensitivity reactions, with multiple organ involvement, have occurred with abacavir, a component of Epzicom (abacavir and lamivudine). Patients who carry the HLA-B*5701 allele are at a higher risk of a hypersensitivity reaction to abacavir; although, hypersensitivity reactions have occurred in patients who do not carry the HLA-B*5701 allele. Epzicom is contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLA-B*5701-positive patients. All patients should be screened for the HLA-B*5701 allele prior to initiating therapy with Epzicom or reinitiation of therapy with Epzicom, unless patients have a previously documented HLA-B*5701 allele assessment. Discontinue Epzicom immediately if a hypersensitivity reaction is suspected, regardless of HLA-B*5701 status and even when other diagnoses are possible. Following a hypersensitivity reaction to Epzicom, NEVER restart Epzicom or any other abacavir-containing product because more severe symptoms, including death, can occur within hours. Similar severe reactions have also occurred rarely following the reintroduction of abacavir-containing products in patients who have no history of abacavir hypersensitivity. Lactic Acidosis and Severe Hepatomegaly with Steatosis • Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues and other antiretrovirals. Discontinue Epzicom if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicities occur. Exacerbations of Hepatitis B • Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with hepatitis B virus (HBV) and human immunodeficiency virus (HIV-1) and have discontinued lamivudine, which is a component of Epzicom. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Epzicom and are co-infected with HIV-1 and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Drug	Type of Change	Change
PDE5 Inhibitors - Increased Risk of Hypotension with Concomitant Use of Guanylate Cyclase Stimulators. Including: • Cialis *(tadalafil)* Tablets • Levitra *(vardenafil hydrochloride)* Tablets • Staxyn *(vardenafil hydrochloride)* Orally Disintegrating Tablets • Stendra *(avanafil)* Tablets • Viagra *(sildenafil citrate)* Tablets	Contraindications	Guanylate Cyclase (GC) Stimulators • Do not use Cialis (tadalafil) Tablets, Levitra (vardenafil hydrochloride) Tablets, Staxyn (vardenafil hydrochloride) Orally Disintegrating Tablets, Stendra (avanafil) Tablets, Viagra (sildenafil citrate) Tablets in patients who are using a GC stimulator, such as riociguat. PDE5 inhibitors, including Cialis (tadalafil) Tablets, Levitra (vardenafil hydrochloride) Tablets, Staxyn (vardenafil hydrochloride) Orally Disintegrating Tablets, Stendra (avanafil) Tablets, Viagra (sildenafil citrate) Tablets may potentiate the hypotensive effects of GC stimulators.
Myalept (metreleptin) for Injection	Contraindications	Hypersensitivity Known hypersensitivity reactions have included anaphylaxis.

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
Acetylcysteine Oral and Inhalation Solution	American Regent, Fresenius Kabi	American Regent has a consistent supply of acetylcysteine oral and inhalation solution. Fresenius Kabi states the reason for the shortage is increased demand. American Regent has acetylcysteine solution 100 mg/mL 10 mL vials available with an expiration date of Oct. 31, 2015. Acetylcysteine 200 mg/mL solution 4 mL vials are available in limited supply. Check with your wholesaler for availability. Fresenius Kabi has acetylcysteine solution 200 mg/mL 4 mL vials on back order and the company cannot estimate a release date. Acetylcysteine 100 mg/mL 4 mL, 10 mL, and 30 mL vials are available with short expiration dating (< 5 months for the 4 mL vials, < 2 months for the 10 mL vials, and < 7 months for the 30 mL vials).

Drug Product	Affected Manufacturers	Summary
Ampicillin	AuroMedics, Fresenius Kabi, Hospira, Sagent, Sandoz, WG Critical Care, West-Ward	AuroMedics Pharma launched new product mid-June 2012. Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay. Sagent has ampicillin sulbactam vials on allocation due to increased demand for the product. WG Critical Care states the shortage is due to increased demand. WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014. West-Ward acquired several Baxter products in early 2011. AuroMedics has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on intermittent back order and the company is releasing product as it becomes available. Fresenius Kabi has ampicillin sulbactam 3 gram vials on intermittent back order and the company is releasing product as it becomes available. Fresenius Kabi has ampicillin sulbactam 1.5 gram and 15 gram vials on back order and the company estimates a release date of 4th quarter 2015. Hospira has all ampicillin sulbactam presentations on back order and the company estimates a release date of late-1st quarter 2016. Sagent has ampicillin sulbactam 1.5 gram vials and 3 gram vials on allocation. Ampicillin sulbactam 15 gram vials are on back order and the company estimates a release date of December 2015. Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date. West-Ward has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on allocation. WG Critical Care has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company cannot estimate a release date. Check with your wholesaler for availability.
Aprepitant Capsules	Merck	Merck is the sole supplier of Emend (aprepitant) capsules. Merck states the reason for this shortage is increased demand. Merck has Emend 40 mg capsules in unit dose packages of 5 on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Atropine Sulfate Ophthalmic Solution	Akorn, Sandoz, Valeant	Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015. All other atropine sulfate ophthalmic solution products are unapproved products. Sandoz could not provide a reason for the shortage. Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015. Sandoz has atropine 5 mL and 15 mL bottles on back order and the company cannot estimate a release date.
Caffeine Citrate Oral Solution	Caraco, Fresenius Kabi	Caraco discontinued caffeine citrate oral solution in mid-2015. Fresenius states the reason for the shortage is manufacturing delays. Fresenius Kabi has caffeine citrate oral solution on back order and the company estimates a release date of early-November 2015.
Chlorothiazide Oral Suspension	Valeant	Valeant cannot provide a reason for the shortage. Valeant recently acquired Diuril oral suspension from Salix. Valeant has Diuril oral suspension on back order and the company estimates a release date of early-November 2015.
Dexamethasone 0.1% Ophthalmic Drops	Valeant	Valeant could not provide a reason for the shortage. Valeant has dexamethasone 0.1% ophthalmic solution on back order and the company estimates a release date of mid- to late-November 2015.
Dexamethasone and Neomycin sulfate and Polymyxin B sulfate ophthalmic ointment	Perrigo, Sandoz, Valeant	Perrigo has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on shortage due to manufacturing issues. Sandoz has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on shortage due to increased demand. Valeant has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on shortage due to manufacturing delay. Perrigo has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on back order and the company estimates a release date of early-November 2015. Sandoz has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on back order and the company cannot estimate a release date. Check your wholesaler for availability. Valeant has dexamethasone/neomycin sulfate/polymyxin B sulfate ophthalmic ointment on back order and the company estimates a release date of December 2015.

Drug Product	Affected Manufacturers	Summary
Disopyramide Phosphate Controlled-release Capsules	Pfizer	Pfizer has Norpace CR on shortage due to manufacturing delays. Pfizer has all Norpace CR presentations on back order and the company estimates a release date of early-November 2015. Short-dated product is available for allocated drop-shipments for the 100 mg 100 count, 150 mg 100 count, and 150 mg 500 count presentations. These presentations have an expiration date of June 2016.
Hydroxyamphetamine	Akorn	Akorn has Paremyd on shortage due to manufacturing delays. Akorn has Paremyd ophthalmic solution on back order and the company cannot estimate a release date.
Leuprolide	Caraco, Teva	Caraco states the reason for the shortage is increased demand. Teva states the shortage is due to manufacturing delays. Caraco has leuprolide acetate injection on back order and the company estimates a release date in late-December 2015 to early-January 2016. Teva has leuprolide acetate injection on back order and the company estimates a release date in first quarter of 2018.
Methylphenidate Transdermal	Noven	Noven has Daytrana patches on shortage due to problems with adhesive backing and also increased demand. Noven has Daytrana 20 mg patches on back order and the company estimates a release date of late-December 2015. Daytrana 30 mg patches are on back order and the company estimates a release date of late-November 2015.
Mupirocin Calcium 2% Cream	Prasco, GlaxoSmithKline	GlaxoSmithKline could not provide a reason for the shortage. GlaxoSmithKline has mupirocin calcium 2% cream in 15 and 30 gram sizes on back order and the company cannot estimate a release date. Prasco could not provide a reason for the shortage. Prasco has mupirocin calcium 2% cream in 15 and 30 gram sizes on back order and the company cannot estimate a release date.
Mupirocin Calcium 2% Nasal Ointment	GlaxoSmithKline	GlaxoSmithKline could not provide a reason for the shortage. Mupirocin ointment 22 gram tubes are not affected by this shortage. GlaxoSmithKline has Bactroban Nasal 2% Ointment 1 gram tubes on back order and the company cannot estimate a release date.
Nebivolol Tablets	Actavis	Actavis could not provide a reason for the shortage. Actavis has Bystolic 20 mg tablets in 30- and 90-count sizes on back order and the company estimates a release date of late-October 2015.

Drug Product	Affected Manufacturers	Summary
Nimodipine Oral Solution	Arbor	Arbor has Nymalize oral solution on temporary back order due to shortage of an active ingredient. Arbor has Nymalize oral solution in unit-dose cups on back order and the company cannot estimate a release date.
Pramipexole Dihydrochloride Tablets	Aurobindo, Glenmark, Mylan, Sandoz	Aurobindo, Mylan, and Sandoz cannot provide a reason for the shortage. Aurobindo has all pramipexole 1000-count presentations on back order and the company cannot estimate a release date. Glenmark has pramipexole 0.25 mg, 0.5 mg, and 1.5 mg tablets on back order with an estimated release date of mid-October 2015. Mylan has temporarily discontinued all pramipexole presentations and the company cannot estimate when product will return. Sandoz has all pramipexole presentations on back order and the company cannot estimate a release date.
Reserpine	Sandoz	Sandoz said the shortage is due to a delay in obtaining raw materials. Sandoz has all reserpine tablet presentations temporarily unavailable and the company cannot estimate a release date.
Tamsulosin Hydrochloride Capsules	Boehringer Ingelheim, Mylan	Boehringer Ingelheim could not provide a reason for the shortage. Boehringer-Ingelheim has Flomax 0.4 mg capsules in 100 count on back order and the company estimates a release date of early-November 2015. Mylan has tamsulosin 0.4 mg capsules in 90 count and 1000 count on back order and the company estimates a release date of early-November 2015 for the 90 count and mid-November 2015 for the 1000 count. Tamsulosin 0.4 mg capsules in 25-count unit-dose are on back order and the company cannot estimate a release date.
Tropicamide 1% Ophthalmic Solution	Sandoz, Valeant	Sandoz cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution. Valeant cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution. Sandoz has tropicamide 1% ophthalmic solution 15 mL bottles on back order and the company estimates a release date of February 2016. Valeant has tropicamide 1% ophthalmic solution 2 mL and 15 mL bottles on back order and the company estimates a release date of November 2015.

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 from the FDA's website.

Drug	Communications Summary
Canagliflozin (Invokana, Invokamet)	The U.S. Food and Drug Administration (FDA) has strengthened the warning for the type 2 diabetes medicine canagliflozin (Invokana, Invokamet) related to the increased risk of bone fractures and added new information about decreased bone mineral density. Bone mineral density relates to the strength of a person's bones. To address these safety concerns, the FDA added a new Warning and Precaution and revised the Adverse Reactions section of the Invokana and Invokamet drug labels.
Clozapine	The U.S. Food and Drug Administration (FDA) is making changes to the requirements for monitoring, prescribing, dispensing, and receiving the schizophrenia medicine clozapine to address continuing safety concerns and current knowledge about a serious blood condition called severe neutropenia. Severe neutropenia is a dangerously low number of neutrophils, white blood cells that help fight infections. Severe neutropenia can be life-threatening.
Tramadol	The U.S. Food and Drug Administration (FDA) is investigating the use of the pain medicine Tramadol in children ages 17 years and younger because of the rare, but serious, risk of slowed or difficult breathing. This risk may be increased in children treated with Tramadol for pain after surgery to remove their tonsils and/or adenoids. The FDA is evaluating all available information and will communicate its final conclusions and recommendations to the public when its review is complete.
AVYCAZ (ceftazidime and avibactam)	The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the intravenous antibacterial drug Avycaz (ceftazidime and avibactam) due to confusion about the drug strength displayed on the vial and carton labels. Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (i.e., 2 gram/0.5 gram); however, the product is dosed based on the sum of the active ingredients (i.e., 2.5 gram). To prevent medication errors, the FDA has revised the labels to indicate that each vial contains Avycaz 2.5 gram, equivalent to ceftazidime 2 gram and avibactam 0.5 gram.
KAYEXALATE (sodium polystyrene sulfonate)	The U.S. Food and Drug Administration (FDA) is requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth – drug interactions that could affect how well the other medications work.
VIEKIRA PAK and TECHNIVIE	The U.S. Food and Drug Administration (FDA) is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, the FDA is requiring the manufacturer to add new information about this safety risk to the drug labels.
Entacapone	A Food and Drug Administration (FDA) safety review has found no clear evidence of an increased risk of heart attacks, stroke, or other cardiovascular events associated with the use of entacapone for the treatment of Parkinson's disease. As a result, the FDA's recommendations for using Comtan (entacapone) and Stalevo (a combination of entacapone, carbidopa, and levodopa) will remain the same on the drug labels. Patients should discuss any questions they have with their health care professionals.

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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