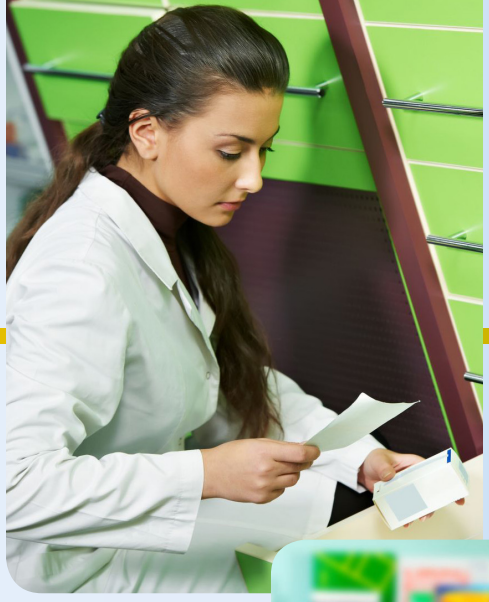

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

JANUARY 2017

Q1 2017

Table of Contents

PN Q1 2017

The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Pharmacy Director Anne Freese, at afreese@goldchp.org or 1-805-437-5652.

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CMO Message

C. Albert Reeves, MD

Winter is upon us once again and so are the upper respiratory infections and influenza that come with it. Because overuse of antibiotics leads to antibiotic resistance, I want to remind you of the recommendations for treating upper respiratory infections. As you know, antibiotics will not be effective for a viral illness and are not indicated for many diagnosed upper respiratory infections. The Centers for Disease Control and Prevention (CDC) has recommendations, which were published in March, for appropriate antibiotic prescribing for adults and children.

I also want to make you aware of two relatively new updates for flu prevention and treatment. First, it is no longer recommended that the nasal spray vaccine, Flumist, be used for influenza immunization because it was found to be less effective than the shot in preventing the flu. Second, oseltamivir capsules (Tamiflu) have recently become available as a generic medication. The brand name medication, "Tamiflu Capsules," is no longer available on GCHP's formulary. The generic product, oseltamivir, is the drug required for use by members of the Plan. The Tamiflu Oral Suspension will still be available.

As always, feel free to contact me or Anne Freese, Gold Coast Health Plan's (GCHP) pharmacy director, with any questions. Best wishes for a wonderful 2017!

Regards,

C. Albert Reeves, M.D.

C. Albert Reeves, MD

Opioid Formulary Changes

Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

- GCHP Formulary
- List of Participating Pharmacies
- Provider Resources

The following are important changes for the use of opioids for GCHP members beginning January 1:

1. OXYCONTIN and methadone 40 mg will no longer be formulary products. Any member who is currently using these medications will be allowed to continue using them until they are no longer prescribed. Any new member who receives a prescription for one of these products must have a prior authorization requested and will only be approved when ALL formulary agents have been tried and failed or are considered contraindicated.
2. A prior authorization must be requested for any member that will be using alprazolam and any opioid medication together due to the increased risk of overdose when these medications are used together. The prior authorization must detail that this risk has been considered and the benefit of the combination therapy greatly outweighs the overdose risk.

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

Drug	Formulary Status/Change
Daklinza *(daclatasvir)*	Add step therapy to existing PA where Zepatier and Epclusa are required to be tried/failed and or are considered inappropriate or contraindicated.
Harvoni *(ledipasvir/sofosbuvir)*	Add step therapy to existing PA where Zepatier and Epclusa are required to be tried/failed and or are considered inappropriate or contraindicated.
Technivie *(Ombitasvir/Paritaprevir/Ritonavir)*	Add step therapy to existing PA where Zepatier and Epclusa are required to be tried/failed and or are considered inappropriate or contraindicated.
Viekira Pak *(ombitasvir/paritaprevir/ritonavir/dasabuvir)*	Add step therapy to existing PA where Zepatier and Epclusa are required to be tried/failed and or are considered inappropriate or contraindicated.
Sovaldi *(sofosbuvir)*	Add step therapy to existing PA where Zepatier and Epclusa are required to be tried/failed and or are considered inappropriate or contraindicated.

Formulary Changes

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

Additions

Drug	Formulary Status/Change
BELVIQ XR *(lorcaserin)*	Add with a PA.
INFLECTRA *(infliximab-dyyb)*	Add with a PA.
INVOKAMET XR *(cangliflozin, metformin)*	Add with a PA with step therapy of metformin.
NUCYNTA *(tapentadol)* 50 mg tablets	Add with a one-time limit of 30 tablets only, then PA for additional fills.
NUCYNTA *(tapentadol)* 75 mg and 100 mg tablets	Add with a PA.
NUCYNTA ER *(tapentadol extended release)*	Add with a PA.
ZARXIO *(filgrastim-sndz)*	Add with a PA.
ZINBRYTA *(daclizumab)*	Add with a step therapy of BOTH high-dose interferon beta-1a and glatiramer.
ZURAMPIC *(lesinurad)*	Add with a PA.

Removals

Drug	Formulary Status/Change
BENICAR *(olmesartan)* all strengths	Brand removed; generic now available.
BENICAR HCT *(olmesartan/hydrochlorothiazide)* all strengths	Brand removed; generic now available.
AZOR *(Amlodipine/olmesartan)* all strengths	Brand removed; generic now available.
NAMENDA XR *(memantine extended release)* all strengths	Brand removed; generic now available.
TRILIPIX *(fenofibric acid delayed release)* all strengths	Brand removed; generic now available.
TAMIFLU Capsules *(Oseltamivir)* all strengths	Brand removed; 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
YOSPRALA	*aspirin and omeprazole*	Oral Delayed-Release Tablet	YOSPRALA is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI), indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin-associated gastric ulcers.
KYLEENA	*levonorgestrel*	Intrauterine Device	KYLEENA is a progestin-containing intrauterine system (IUS) indicated for the prevention of pregnancy for up to five years.
EXONDYS 51	*eteplirsen*	Intravenous Injection	EXONDYS 51 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with EXONDYS 51. A clinical benefit of EXONDYS 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.
INVOKAMET XR	*canagliflozin and metformin hydrochloride extended-release*	Oral Extended-Release Tablet	INVOKAMET XR is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate. Limitation of use: Not for treatment of type 1 diabetes or diabetic ketoacidosis.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
EPANED	*enalapril maleate*	Oral Solution	EPANED is an angiotensin-converting enzyme inhibitor indicated for the treatment of: • Hypertension in adults and children older than one month to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Symptomatic heart failure. • Asymptomatic left ventricular dysfunction to decrease the rate of development of overt heart failure and reduce hospitalization for heart failure.
AMJEVITA	*adalimumab-atto*	Subcutaneous Injection	AMJEVITA is a Tumor Necrosis Factor (TNF)-blocker. AMJEVITA is used to reduce the signs and symptoms of: • Moderate-to-severe rheumatoid arthritis (RA) in adults. AMJEVITA can be used alone, with methotrexate, or with certain other medicines. • Moderate-to-severe polyarticular juvenile idiopathic arthritis (JIA) in children 4 years of age and older. AMJEVITA can be used alone, with methotrexate, or with certain other medicines. • Psoriatic arthritis (PsA) in adults. AMJEVITA can be used alone or with certain other medicines. • Ankylosing spondylitis (AS) in adults. • Moderate-to-severe Crohn's disease (CD) in adults when other treatments have not worked well enough. • Moderate-to-severe ulcerative colitis (UC) in adults to get it under control (induce remission) and keep it under control (sustain remission) when certain other medicines have not worked well enough. It is not known if AMJEVITA is effective in people who stopped responding to or could not tolerate TNF-blocker medicines. • Moderate-to-severe chronic (lasting a long time) plaque psoriasis (Ps) in adults who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
RUBY-FILL	*rubidium Rb 82 generator*	Intravenous Injection	RUBY-FILL is a closed system used to produce rubidium Rb 82 chloride injection for intravenous use. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
CARNEXIV	*carbamazepine*	Intravenous Injection	CARNEXIV is indicated as replacement therapy for oral carbamazepine formulations, when oral administration is temporarily not feasible, in adults with the following seizure types: • Partial seizures with complex symptomatology • Generalized tonic-clonic seizures • Mixed seizure patterns which include the above, or other partial or generalized seizures
VARIBAR PUDDING	*barium sulfate*	Oral Paste	VARIBAR PUDDING is a radiographic contrast agent indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.
TECENTRIQ	*atezolizumab*	Intravenous Injection	TECENTRIQ is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: • Have disease progression during or following platinum-containing chemotherapy. • Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. For the treatment of metastatic non-small cell lung cancer in patients who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving TECENTRIQ.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
VERMOX CHEWABLE	*mebendazole chewable tablets*	Chewable Tablet	VERMOX CHEWABLE is an anthelmintic indicated for the treatment of patients one year of age and older with gastrointestinal infections caused by: • Ascaris lumbricoides (roundworm). • Trichuris trichiura (whipworm).
EVZIO	*naloxone hydrochloride injection*	Auto-Injector for intramuscular or subcutaneous use	EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients. EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. EVZIO is not a substitute for emergency medical care.
LARTRUVO	*olaratumab*	Intravenous Injection	LARTRUVO is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery. This indication is under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.
ZINPLAVA	*bezlotoxumab*	Intravenous Injection	ZINPLAVA is a human monoclonal antibody that binds to Clostridium difficile toxin B, indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence. Limitation of use: ZINPLAVA is not indicated for the treatment of CDI. ZINPLAVA is not an antibacterial drug. ZINPLAVA should only be used in conjunction with antibacterial drug treatment of CDI.
SELZENTRY	*maraviroc*	Oral Solution	SELZENTRY is a CCR5 co-receptor antagonist indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing at least 10 kg. Limitations of use: • Not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
BONJESTA	*doxylamine succinate and pyridoxine hydrochloride*	Oral Extended-Release Tablet	BONJESTA is a fixed-dose combination drug product of 20 mg doxylamine succinate, an antihistamine, and 20 mg pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.
VEMLIDY	*tenofovir alafenamide*	Oral Tablet	VEMLIDY is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor and is indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.
INTRAROSA	*prasterone*	Vaginal Insert	INTRAROSA is a steroid indicated for the treatment of moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.
XULTOPHY	*insulin degludec and liraglutide injection*	Subcutaneous Injection	XULTOPHY 100/3.6 is a combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily).
SOLIQUA	*insulin glargine and lixisenatide injection*	Subcutaneous Injection	SOLIQUA 100/33 is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Limitations of use: • Has not been studied in patients with a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. • Not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist. • Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Not recommended for use in patients with gastroparesis. • Has not been studied in combination with prandial insulin.

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
AVELOX *(moxifloxacin)* CIPRO *(ciprofloxacin hydrochloride)* FACTIVE *(gemifloxacin mesylate)* LEVAQUIN *(levofloxacin)* MOXIFLOXACIN injection NOROXIN *(norfloxacin)*	Boxed Warning	WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS Fluoroquinolones, including AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN®, have been associated with disabling and potentially-irreversible serious adverse reactions that have occurred together including: • Tendinitis and tendon rupture • Peripheral neuropathy • Central nervous system effects Discontinue AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN® immediately and avoid the use of fluoroquinolones, including AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN®, in patients who experience any of these serious adverse reactions. Fluoroquinolones, including AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN®, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN® in patients with known history of myasthenia gravis. Because fluoroquinolones, including AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN®, have been associated with serious adverse reactions, reserve AVELOX®, CIPRO®, FACTIVE®, LEVAQUIN®, MOXIFLOXACIN®, and NOROXIN® for use in patients who have no alternative treatment options for the following indications: • Acute exacerbation of chronic bronchitis • Acute uncomplicated cystitis • Acute sinusitis

Drug	Type of Change	Change
SYNJARDY *(empagliflozin and metformin hydrochloride)*	Boxed Warning	LACTIC ACIDOSIS • Post marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio, and metformin plasma levels generally >5 mcg/mL. • Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. • Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the full prescribing information. If metformin-associated lactic acidosis is suspected, immediately discontinue SYNJARDY and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.
EVOTAZ *(atazanavir/ cobicistat)*	Contraindication	Drugs that are contraindicated with EVOTAZ: • Anticonvulsants Drug Class added to table containing the following drugs: carbamazepine, phenobarbital and phenytoin with the following clinical comment: Potential for decreased atazanavir plasma concentrations, which may result in loss of therapeutic effect and development of resistance.
HICON (for the preparation of sodium iodide I 131 solution or sodium iodide I 131 capsules)	Contraindication	HICON is contraindicated in: • Patients with vomiting and diarrhea • Pregnancy • Lactation • Patients receiving concurrent anti-thyroid therapy
Isoniazid	Contraindication	Isoniazid is contraindicated in patients who: • Develop severe hypersensitivity reactions, including drug-induced hepatitis. • Have had previous isoniazid-associated hepatic injury. • Have severe adverse reactions to isoniazid such as drug fever, chills, arthritis. • Have acute liver disease of any etiology.
LAMPRENE *(clofazimine)*	Contraindication	LAMPRENE is contraindicated in patients with known hypersensitivity to clofazimine or any of the excipients of LAMPRENE.
MIRVASO *(brimonidine)*	Contraindication	MIRVASO topical gel is contraindicated in patients who have experienced a hypersensitivity reaction to any component. Reactions have included angioedema, urticarial, and contact dermatitis.
PHOXILLUM and PRISMASOL Renal Replacement Solution	Contraindication	PHOXILLUM and PRISMASOL replacement solutions are contraindicated in patients with known hypersensitivities to these products.

Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Chloroquine 250 mg and 500 mg tablets	Rising	All products are on shortage due to delays in obtaining raw materials. Expected release date is early-January.
DAYTRANA transdermal patch	Noven	All products are on shortage due to shipping delays. Noven has all Daytrana presentations on intermittent back order and the company is releasing supplies as they become available.
Amoxicillin and Clavulanate 1000 mg/62.5 mg Extended-Release Tablets	Dr. Reddy's, Sandoz	Dr. Reddy's states they are having raw ingredient issues. Sandoz did not provide a reason for the shortage. Expected release date not known.

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
Direct-Acting Antivirals for the treatment of Hepatitis C	The FDA is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death. As a result, a Boxed Warning will be added to drug labels to screen and monitor for HBV in all patients receiving DAA treatment.

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