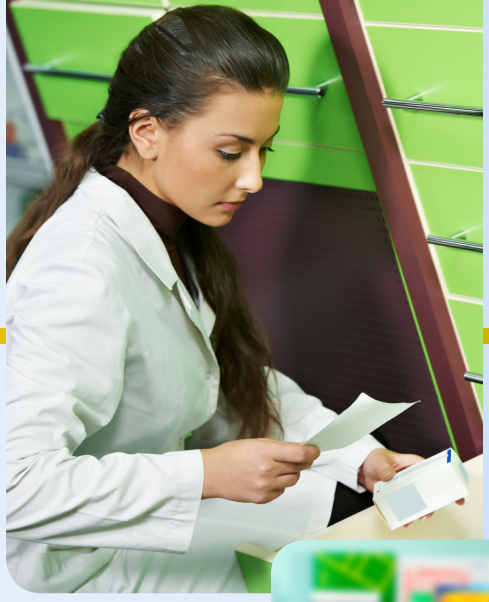

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

SEPTEMBER 2015

Q4

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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.

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CMO Message

C. Albert Reeves, MD

It shouldn't come as a surprise that diabetes is a prevalent disease for members of Gold Coast Health Plan (GCHP) and for costs to the Plan. In terms of pharmacy costs, diabetes is the most expensive disease. In the first six months of 2015, GCHP spent $11.1 million on providing medications and supplies for its diabetic members. During that period, GCHP had 9,181 identified diabetic members. Nearly half of those had three or more co-morbidities.

Health care costs for a person with diabetes are three times more than a person without it. GCHP wants its members to have the important drugs to treat this devastating disease. However, GCHP's goal is that its members never need diabetes medication.

November is American Diabetes Month and during fall 2015, GCHP is looking forward to the launch of its Diabetes Disease Management Program. The population-focused program will help those with diabetes improve the management of their disease. Members with pre-diabetes will receive help on how to avoid becoming a full-fledged diabetic who has to rely on multiple medications.

GCHP will be sending information to diabetic members about the program, along with an invitation to join and attend diabetes classes. The Plan will also be sending information about the program to providers with the hope that they will encourage members to participate.

We look forward to working with members and providers to decrease diabetic pharmacy costs, improve the health of the Plan's diabetic members and implement prevention measures.

As always, if you have any questions, please do not hesitate to contact me or GCHP's Director of Pharmacy, Anne Freese.

Regards,

C. Albert Reeves, M.D.

C. Albert Reeves, MD

Diabetes Medications: Quick Reference Table

The GCHP Medical Advisory Committee previously reviewed guidelines for the treatment of diabetes. The committee is made up of physicians including practicing physicians, specialists, and plan physicians. The committee adopted the American Diabetes Association Standard of Medical Care in Diabetes – 2015, which was updated in January. Click here to access the guidelines on GCHP's website.

In order to be consistent with the guidelines and the recommendations on medication use, the GCHP Pharmacy and Therapeutics Committee reviewed and updated the formulary status and step therapies associated with all diabetes medications. Some of the existing step therapy protocols were relaxed in order to facilitate access to these medications.

The table below lists the classes and specific diabetes medications, their formulary status and any relevant notes. The Plan includes most of the available agents on the formulary to ensure that members are receiving the most appropriate medication in the most expedient manner.

Class	Drug*	Formulary Status
Diabetic Testing Supplies	All TruTrak, TruMetic, TruTest products	Meters – available free through a free meter program Test Strips – limited to 100/31 days Lancets – limited to 200/31 days
Insulins	AFREZZA	PA
	Lily Insulin Products (i.e. HUMULIN, HUMALOG)	Pen Devices† – PA High Dose Humalog – PA
	LANTUS	Pen Devices† – PA
	Novo Insulin Products (i.e. NOVOLIN, NOVOLOG)	Pen Devices† – PA
	APIDRA	PA
	LEVEMIR	PA
	TOUJEO	PA
Biguanides	*metformin*	All generic products are covered without restriction
Alpha-glucosidase inhibitor	*acarbose*	Covered without restriction
Amylin Analog	GLYSET	Not covered

Class	Drug*	Formulary Status
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	JANUVIA (*sitagliptin*)	Step: metformin
	NESINA (*alogliptin*)	Step: metformin
	ONGLYZA (*saxagliptin*)	Step: metformin
	TRADJENTA (*linagliptin*)	Step: metformin
Glucagon-like Peptide 1 (GLP-1) Receptor Agonist	BYETTA (*exenatide*)	Step: metformin
	BYDUREON (*exenatide*)	Step: metformin
	TANZEUM (*albiglutide*)	Step: metformin
	TRULICITY (*dulaglutide*)	Step: metformin
	VICTOZA (*liraglutide*)	Step: metformin
Meglitinides	*nateglinide*	Covered without restriction
	repaglinide	Covered without restriction
Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitors	INVOKANA (canagliflozin)	Step: metformin
	FARXIGA (dapagliflozin)	Step: metformin
	JARDIANCE (empagliflozin)	Step: metformin
Sulfonylureas	*chlorpropamide, glimepiride, glipizide, glyburide, tolazamide, tolbutamide*	All generic products covered without restriction
Thiazolidine-diones (TZDs)	*pioglitazone*	Step: metformin
	rosiglitazone	Not covered

* In general, combination products are treated in the same fashion as the single agent originator product.

† Insulin pen devices require documentation of visual impairment, physical inability to use a syringe, severe needle phobia or documented compliance issues with vials/syringes and better adherence with the device.

Formulary Changes

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

Additions

Drug	Formulary Status/Change
Natpara	Added to the formulary with prior authorization
Farydak	Added to the formulary with prior authorization
Cresemba	Added to the formulary with prior authorization
Cholbam	Added to the formulary with prior authorization
Humalog Kwikpen	Added to the formulary with prior authorization

Removals

Drug	Formulary Status/Change
Lotronex tablets	Removed from the formulary, generic now available
Zyvox tablets	Removed from the formulary, generic now available
Atelvia tablets	Removed from the formulary, generic now available
Moxeza opth solution	Removed from the formulary, generic now available
Vagifem tablets	Removed from the formulary, generic now available
Zyvox for oral suspension	Removed from the formulary, generic now available
Factive tablets	Removed from the formulary, generic now available
Acanya gel	Removed from the formulary, generic now available
Zetia tablets	Removed from the formulary, generic now available
Pristiq tablets	Removed from the formulary, generic now available
Axert tablets	Removed from the formulary, generic now available
Travatan Z	Removed from the formulary, generic now available
Pataday	Removed from the formulary, generic now available
Prandimet	Removed from the formulary, generic now available
Prilosec OTC	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.

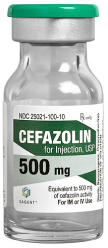
Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
GLUCAGON	*glucagon hydrochloride*	Powder; intramuscular, intravenous	• As a diagnostic aid during radiologic examinations to temporarily inhibit movement of the GI tract in adults. • Treatment of severe hypoglycemia in pediatric and adult patients. The American Diabetes Association (ADA) recommends that glucagon be prescribed for all diabetic patients at significant risk of severe hypoglycemia; caregivers or family members of these patients should be trained on how to administer glucagon.
HYCOFENIX	*guaifenesin; hydrocodone bitartrate; pseudoephedrine hydrochloride*	Solution; oral	Indicated for the symptomatic relief of cough, nasal congestion, and to loosen mucus associated with the common cold.
FLOWTUSS	*guaifenesin; hydrocodone bitartrate*	Solution; oral	Indicated for the symptomatic relief of cough and to loosen mucus associated with the common cold.
INVEGA TRINZA	*paliperidone palmitate*	Suspension, extended release; intramuscular	A 3-month injection is an atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA (1-month paliperidone palmitate extended-release injectable suspension) for at least four months.
STIOLTO RESPIMAT	*olodaterol hydrochloride; tiotropium bromide*	Spray, metered; inhalation	Indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).
HUMALOG KWIKPEN	*Insulin lispro recombinant*	Solution: subcutaneous	Rapid-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.
VIBERZI	*eluxadoline*	Tablet; oral	A mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).
METAXALONE	*metaxalone*	Tablet; oral	Indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.

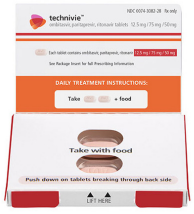
Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ALBENZA	*albendazole*	Tablet, chewable; oral	Indicated for: • Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium. • Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.
LINEZOLID	*linezolid sodium chloride*	Injectable	Linezolid is an oxazolidinone-class antibacterial indicated in adults and children for the treatment of the following infections caused by susceptible gram-positive bacteria: Nosocomial pneumonia; community-acquired pneumonia; Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; Vancomycin-resistant Enterococcus faecium infections.
KENGREAL	*cangrelor*	Powder, for injection solution, lyophilized powder	KENGREAL is a platelet inhibitor indicated as an adjunct to percutaneous coronary intervention (PCI) for reducing the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients in who have not been treated with a P2Y platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.
CODEINE PHOSPHATE; CHLORPHENIRAMINE MALEATE	*codeine phosphate; chlorpheniramine maleate*	Tablet, extended release; oral	A combination of codeine phosphate, an antitussive, and chlorpheniramine maleate a histamine-1 receptor antagonist indicated for cough and symptoms associated with upper respiratory allergies or a common cold.
ORKAMBI	*lumacaftor/ ivacaftor*	Tablet; oral	A combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.
ENTRESTO	*sacubitril; valsartan*	Tablet; oral	A combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
REXULTI	*brexpiprazole*	Tablet; oral	Indicated for the adjunctive treatment of major depressive disorder (MDD) and treatment of schizophrenia.
ENVARSUS XR	*tacrolimus*	Tablet, extended release; oral	A calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in kidney transplant patients converted from Tacrolimus immediate-release formulations in combination with other immunosuppressants.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
IRESSA	*gefitinib*	Tablet; oral	A tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by an FDA-approved test.
PRALUENT	*alirocumab*	Injectable; injection	A PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol (LDL-C).
EPIDUO FORTE	*adapalene; benzoyl peroxide*	Gel; topical	A combination of adapalene, a retinoid, and benzoyl Peroxide; indicated for the topical treatment of acne vulgaris.
ODOMZO	*sonidegib*	Capsule; oral	A hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.
DAKLINZA	*daclatasvir*	Tablet; oral	A hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection. Limitations of use: Sustained virologic response (SVR) rates are reduced in patients with cirrhosis.
TECHNIVIE	*ombitasavir; paritaprevir; ritonavir*	Tablet; oral	A fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. Limitations of use: TECHNIVIE is not recommended for use in patients with moderate hepatic impairment (Child-Pugh B).
FINACEA	*azelaic acid*	Emulsion, aerosol foam	Indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea.
SPRITAM	*levetiracetam*	Tablet; oral	Indicated for adjunctive therapy in the treatment of: • Partial onset seizures in patients with epilepsy 4 years of age and older weighing more than 20 kg. • Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy. • Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
CEFAZOLIN	*Cefazolin*	Solution; injection	Cefazolin is indicated in the treatment of the following serious infections due to susceptible organisms: • Biliary tract infections • Bone and joint infections • Endocarditis • Genital infections (i.e., prostatitis, epididymitis) • Perioperative prophylaxis • Respiratory tract infections • Septicemia • Skin and skin structure infections • Urinary tract infections
ADDYI	*Flibanserin*	Tablet; oral	ADDYI is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition, • Problems within the relationship • The effects of a medication or other drug substance
POTASSIUM CHLORIDE FOR ORAL SOLUTION	*Potassium Chloride*	Solution; oral	Potassium Chloride is a potassium salt indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
PROMACTA	*eltrombopag*	Suspension; oral, powder	PROMACTA is a thrombopoietin receptor agonist indicated for the treatment of: • Thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. (1.1) • Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. (1.2) • Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. (1.3) Limitations of use: • PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. • PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. (1.4)

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 cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
XURIDEN	*uridine triacetate*	Granule; oral	Hereditary orotic aciduria; treatment of hereditary orotic aciduria.
SYNJARDY	*empagliflozin; metformin hydrochloride*	Tablet; oral	SYNJARDY is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. Limitation of use: • Not for the treatment of type 1 diabetes.
REPATHA	*Evolocumab*	Injectable; injection	REPATHA is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated as an adjunct to diet and: • Maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). • Other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. Limitation of use: • The effect of REPATHA on cardiovascular morbidity and mortality has not been determined.





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
ERIVEDGE (vismodegib)	Boxed Warning (edited)	• ERIVEDGE can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. • ERIVEDGE is embryo toxic, fetotoxic, and teratogenic in animals.
LAMICTAL (lamotrigine) Tablets, Chewable Dispersible Tablets, and Orally Disintegrating Tablets	Boxed Warning (edited)	• LAMICTAL can cause serious rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.3% to 0.8% in pediatric patients (aged 2 to 17 years) and 0.08% to 0.3% in adults receiving LAMICTAL. One rash-related death was reported in a prospectively followed cohort of 1,983 pediatric patients (aged 2 to 16 years) with epilepsy taking LAMICTAL as adjunctive therapy. In worldwide post marketing experience, rare cases of toxic epidermal necrolysis and/or rash-related death have been reported in adult and pediatric patients, but their numbers are too few to permit a precise estimate of the rate.
SIRTURO (bedaquiline)	Boxed Warning (edited)	• QT prolongation can occur with SIRTURO. Use with drugs that prolong the QT interval may cause additive QT prolongation. Monitor ECGs. Discontinue SIRTURO if significant ventricular arrhythmia or if QTcF interval prolongation of greater than 500 ms develops [see Warnings and Precautions (5.2)].
PREZISTA (darunavir) suspension and tablets	Updated contraindications	• Added medications to Table 6: dronedarone, colchicine, and ranolazine. Modified the information for pimozide.
PROVERA (medroxyprogesterone acetate)	Updated contraindications	• Added: Known anaphylactic reaction or angioedema to PROVERA.

Drug	Type of Change	Change
ENJUVIA (synthetic conjugated estrogens, B) Tablets	Boxed Warning (edited), Contraindications	Estrogen-Alone Therapy Endometrial Cancer • There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding. Cardiovascular Disorders and Probable Dementia • Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia. • The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo. • The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. • In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens. • Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. Estrogen Plus Progestin Therapy • Cardiovascular Disorders and Probable Dementia • Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia.
HYCAMTIN (topotecan hydrochloride) injection	Boxed Warning (edited)	BONE MARROW SUPPRESSION • HYCAMTIN can cause severe myelosuppression. Administer only to patients with baseline neutrophil counts of greater than or equal to 1,500 cells/mm3 and platelet counts greater than or equal to 100,000 cells/mm3. Monitor blood cell counts.
CAPOTEN (captopril) Tablets	Contraindications	• Do not co-administer aliskiren with Capoten in patients with diabetes
JEVTANA (cabazitaxel) Injection	Contraindications	• Severe hepatic impairment (Total Bilirubin > 3 x ULN).

Drug	Type of Change	Change
Rocephin (ceftriaxone sodium) for Injection	Contraindications	Hypersensitivity • Rocephin is contraindicated in patients with known hypersensitivity to ceftriaxone, any of its excipients or to any other cephalosporin. Patients with previous hypersensitivity reactions to penicillin and other beta lactam antibacterial agents may be at greater risk of hypersensitivity to ceftriaxone. Neonates • Premature neonates: Rocephin is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age).Hyperbilirubinemic neonates: Hyperbilirubinemic neonates should not be treated with Rocephin. Ceftriaxone can displace bilirubin from its binding to serum albumin, leading to a risk of bilirubin encephalopathy in these patients. Neonates Requiring Calcium Containing IV Solutions • Rocephin is contraindicated in neonates (= 28 days) if they require (or are expected to require) treatment with calcium-containing IV solutions, including continuous calcium containing infusions such as parenteral nutrition because of the risk of precipitation of ceftriaxone-calcium. • Cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving Rocephin and calcium containing fluids. • In some of these cases, the same intravenous infusion line was used for both Rocephin and calcium-containing fluids and in some a precipitate was observed in the intravenous infusion line. There have been no similar reports in patients other than neonates. Lidocaine • Intravenous administration of ceftriaxone solutions containing lidocaine is contraindicated. When lidocaine solution is used as a solvent with ceftriaxone for intramuscular injection, exclude all contraindications to lidocaine. Refer to the prescribing information of lidocaine.
DROXIA (hydroxyurea)	Boxed Warning (Edited)	WARNING: MYELOSUPPRESSION AND MALIGNANCIES • Myelosuppression: Droxia may cause severe myelosuppression. Monitor blood counts at baseline and throughout treatment. Interrupt treatment and reduce dose as necessary. • Malignancies: Hydroxyurea is carcinogenic. Advise sun protection and monitor patients for malignancies.

Drug	Type of Change	Change
DYSPORT (abobotulinumtoxinA)	Boxed Warning (Edited)	WARNING: DISTANT SPREAD OF TOXIN EFFECT • Postmarketing reports indicate that the effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.
Ortho Tri-Cyclen Lo (norgestimate/ethinyl estradiol) Tablets	Boxed Warning (Edited)	WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS • Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.
Lantus (insulin glargine [rDNA origin] injection) solution	Contraindications	• During episodes of hypoglycemia.
Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) Fixed Dose Combination Tablets	Contraindications	• Updated with information related to the anticonvulsant medications carbamazepine, phenobarbital, and phenytoin.
Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Copackaged for Oral Use	Contraindications	• Drugs that are moderate or strong inducers.

Drug Shortages

The information included in 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
Acamprosate Calcium Tablets	Glenmark, Mylan Pharmaceuticals	No product available from Glenmark or Mylan; manufacturers cannot provide a reason for the shortage; no estimate for release of additional product.
Acetaminophen and Codeine Phosphate 300 mg/30 mg Tablets	Aurobindo, Mallinckrodt, Teva, Janssen	Aurobindo and Teva could not provide a reason for the shortage. Mallinckrodt states the shortage is due to a variety of market conditions. Aurobindo has acetaminophen and codeine 300 mg/30 mg tablets on back order and the company estimates a release date of early-July 2015 for the 1000-count size and cannot estimate a release date for the 100-count size. Mallinckrodt is releasing monthly allocations of acetaminophen and codeine 300 mg/30 mg tablets. Teva has acetaminophen and codeine 300 mg/30 mg tablets in 1000-count on back order and the company estimates a release date in early-July 2015. Janssen has Tylenol with Codeine #3 tablets in 100- and 1000-count on back order and the company cannot estimate a release date.
Acetylcysteine inhalation Solution	American Regent, Fresenius Kabi	American Regent has 200 mg/ml, 4 ml vials available, 100 mg/ml, 4ml and 10 ml vials with expiration date of October 2015. Fresenius Kabi has 200 mg/ml, 4 ml and 10 ml vials available with an expiration date of less than 5 months. Hospira has 100 mg/ml, 30 ml vials and 200 mg/ml, 30 ml vials available. American Regent state shortage is due to manufacturing delays. Fresenius Kabi state shortage is due to increased demand.
Atenolol Tablets	Avkare, Ingenus , Mylan Pharmaceuticals, Pack, Ranbaxy, Sandoz, Almatica	Almatica has new NDC numbers for Tenormin tablets. Avkare and Mylan could not provide a reason for the shortage. Pack Pharmaceuticals discontinued atenolol tablets in October 2014, Ranbaxy states shortage is due to manufacturing delays. Mylan discontinued atenolol 100 mg, 30-count bottles. Avkare has product available in the 90-, 500- and 1000-count bottles,45- and 180-count bottles and 100 mg 90-count bottles are on back order with no estimated release date. Mylan has product available in the 100- and 1000-count bottles. Sandoz has product available in the 100- and 1000-count bottles except for 100 mg, 1000-count bottles which have an estimated release date of early-June 2015 and 25 mg, 1000-count bottles with no estimated release date. Ranbaxy has atenolol on back order with no estimated release date.

Drug Product	Affected Manufacturers	Summary
Amoxicillin 875 mg Tablets	Dr. Reddy's, Ranbaxy, Sandoz, West-Ward	Dr. Reddy's discontinued amoxicillin 875 mg tablets in June 2014. Ranbaxy has an FDA import ban on amoxicillin tablets. Sandoz cannot provide a reason for the shortage. West-Ward has amoxicillin on shortage due to increased demand. Sandoz has amoxicillin 875 mg tablets on back order and the company cannot estimate a release date. Ranbaxy has amoxicillin 875 mg tablets on long-term back order and the company cannot estimate a release date. West-Ward has amoxicillin 875 mg tablets on back order and the company cannot estimate a release date.
Aprepitant Capsules	Merck	Merck is the sole supplier of EMEND (*aprepitant*) capsules. Merck states the reason for this shortage is increased demand. Merck has all EMEND capsules on intermittent back order through July and August 2015. This shortage is expected to resolve by September 2015. EMEND injection is not affected by this shortage.
Aripiprazole Oral Disintegrating Tablets	Otsuka America Pharmaceuticals, Inc.	Otsuka has discontinued Abilify Discmelt oral disintegrating tablets. The company has also discontinued the oral solution and injection. There are no other suppliers of aripiprazole oral disintegrating tablets. Abilify oral tablets and generic aripiprazole oral tablets are not affected. Otsuka has discontinued Abilify Discmelt 10 mg oral disintegrating tablets. The 15 mg tablets are still available, but supply is expected to be depleted by November 2015.
Atropine Sulfate Ophthalmic Solution	Akorn, Sandoz, Valeant	Alcon has Isopto Atropine only available through wholesalers and not available for direct order. 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. Akorn has Atropine Sulfate 1% Ophthalmic Solution 2 ml, 5 ml and 15 ml single-count bottles available. Sandoz could not provide a reason for the shortage. Sandoz has atropine 5 mL and 15 mL bottles on back order and the company cannot estimate a release date. Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015.
Azathioprine Tablets	Roxanne, Zydus	Roxanne discontinued product in mid-January due to problems obtaining active ingredient. Zydus cannot provide a reason for the shortage. Mylan has 50 mg tablets available in the 50- and 100-count bottles; Valeant (formerly Salix) has 75 mg and 100 mg tablets available in the 100-count bottles. Zydus has product available on allocation.

Drug Product	Affected Manufacturers	Summary
Benzonatate Capsules	Amneal, Ascend, Caraco, Major	Amneal and Ascend cannot provide a reason for the shortage. Caraco discontinued product in mid-2015. Vertical has Zonatuss 150 mg capsules available in the 100-count bottles. Amneal estimates a release date of late-May 2015. Ascend has 200 mg, 100- and 500-count bottles in limited supply, no estimated release date for the 100 mg capsules, 100- and 500-count bottles. Major has 100 mg capsules on back order with no estimated release date.
Boceprevir Capsules	Merck Sharp & Dohme Corp.	Merck Sharp & Dohme has made a business decision to discontinue Victrelis capsules in the U.S. by December 2015. Merck Sharp & Dohme is the sole supplier of boceprevir capsules. Merck Sharp & Dohme Victrelis 200 mg capsules are available with an expiration date of December 2015. The company is discontinuing the product by December 2015.
Buprenorphine Sublingual Tablets	Teva	Teva could not provide a reason for the shortage.
Caffeine Citrate Oral Solution	Caraco, Fresenius Kabi, Sagent	Teva has buprenorphine 2 mg and 8 mg sublingual tablets temporarily unavailable and the company cannot estimate a release date.
Carbidopa and Levodopa Extended-Release Tablets	Accord Healthcare, Caraco	Caraco discontinued caffeine citrate oral solution in mid-2015. Fresenius states the reason for the shortage is manufacturing delays. Sagent states the reason for the shortage is manufacturing delays. Fresenius Kabi has caffeine citrate oral solution on back order and the company cannot estimate a release date. Sagent has caffeine citrate oral solution on allocation.
Cefpodoxime Tablets	Aurobindo, Ranbaxy, Sandoz	Aurobindo could not provide a reason for the shortage but has cefpodoxime 50 mg/5 mL 50 mL and 100 mg/5 mL 50 mL and 100 mL oral suspension available but with short expiration dates. The 100 mg tablets are also only available with short expiration dating. The 50 mg/5 mL 100 mL oral suspension is on back order and the company estimates a release date of September 2015. The 200 mg tablets are on back order and the company estimates a release date of mid-June 2015. Ranbaxy has an import ban on all solid medications including cefpodoxime and has all cefpodoxime presentations on long term back order and the company cannot estimate a release date. Sandoz cannot provide a reason for the shortage and has cefpodoxime 50 mg/5 mL oral suspension in 50 mL and 100 mL bottles on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Chlorothiazide Oral Suspension (DIURIL)	Valeant	Valeant cannot provide a reason for the shortage but recently acquired Diuril oral suspension from Salix. Valeant has Diuril on back order and the company cannot estimate a release date.
Chloroquine Tablets	Ranbaxy, West-Ward	Ranbaxy has chloroquine tablets on shortage due to third party supply issues. West-Ward cannot provide a reason for the shortage. Ranbaxy has chloroquine tablets on long-term back order and the company cannot estimate a release date. West-Ward has chloroquine tablets available with short expiration dating (July 2015). The company cannot estimate a release date for additional supplies.
Chorionic Gonadotropin (Human) Injection	Novarel, Ferring, Pregnyl, Merck, Fresenius Kabi	Merck states their product is on allocation to prevent use in the gray market. Insufficient supplies for usual ordering. Fresenius Kabi has chorionic gonadotropin injection on back order and the company estimates a release date in mid-July 2015. Ferring is releasing Novarel injection regularly to direct order customers. Merck has Pregnyl injection on allocation. Place orders through your wholesaler.
Ciprofloxacin Immediate-Release Tablets	Actavis (formerly Watson), Marlex, Ranbaxy, West-Ward	Ranbaxy has an FDA import ban on several of their products manufactured in India. Marlex is unable to provide a reason for their shortage. Actavis has ciprofloxacin 250 mg tablets on back order and the company cannot estimate a release date. Marlex has ciprofloxacin immediate-release tablets on back order and the company cannot estimate a release date. Ranbaxy has ciprofloxacin immediate-release tablets on back order and the company cannot estimate a release date. West-Ward has ciprofloxacin 500 mg immediate-release tablets in 100 counts (NDC 00143-2037-01) available with short expiration dating (February and March 2016).
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 cannot estimate a release date.
Disopyramide Phosphate Controlled-release Capsules	Pfizer	Pfizer has Norpace CR on shortage due to manufacturing delays. Pfizer has Norpace CR 100 mg capsules in 100-count and 500-count and 150 mg in 100-count on back order and the company cannot estimate a release date.
Dibucaine Ointment	Perrigo, Fougera	Perrigo and Fougera cannot provide a reason for the shortage. Perrigo has temporarily discontinued dibucaine ointment and the company cannot estimate a resupply date. Fougera has dibucaine ointment on long-term back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Divalproex Sodium Delayed Release Tablets	Aurobindo, Dr. Reddy's, Lupin, Mylan Pharmaceuticals, Teva, Upsher-Smith, Zydus	Aurobindo, Dr. Reddy's and Lupin have discontinued product, Upsher-Smith has transitioned product to new NDC numbers, and Zydus has product on allocation due to increased demand. Mylan has 125 mg and 250 mg available in 100-count bottles, Teva has 125 mg available in 100-count bottles and 250 mg and 500 mg available in 500-count bottles. Zydus has all product on allocation and Teva has 250 mg, 100-count bottles on back order with an estimated release date in mid-July 2015 and 500 mg, 100-count bottles on back order with an estimated release date of late-June 2015.
Ethambutol Tablets	Akorn, Lupin, Teva, X-Gen	Akorn acquired VersaPharm, Inc. in 2014. Akorn could not provide a reason for the shortage. X-Gen could not provide a reason for the shortage. Akorn has ethambutol 400 mg tablets in 60-count and 90-count, 100-count unit-dose, and 1000-count sizes on back order and the company cannot estimate a release date. Lupin has ethambutol 100 mg tablets on back order and the company estimates a release date of late-July 2015. Teva has had ethambutol 400 mg tablets temporarily unavailable since December 2013.
Ezetimibe and Atorvastatin Tablets	Merck	In January 2014, Merck recalled all Liptruzet lots from wholesalers due to packaging defects in the outer laminate foil pouches. Merck has all Liptruzet presentations on back order and the company cannot estimate a release date.
Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution	Akorn	Akorn discontinued Paredrine ophthalmic solution in 1999. There are no commercially available hydroxyamphetamine hydrobromide ophthalmic products.
Hydroxychloroquine Sulfate Tablets	Ranbaxy, Sandoz	Ranbaxy has hydroxychloroquine on shortage due to a regulatory issue. Sandoz states the hydroxychloroquine shortage is due to increased demand. Ranbaxy has product on long-term back order and the company cannot estimate a release date. Sandoz has hydroxychloroquine 200 mg in 500-count on intermittent back order and the company is releasing product as it becomes available.
Leflunomide Tablets	Heritage, Sanofi-Aventis	Heritage states the shortage is due to a delay in obtaining active ingredient. Sanofi-Aventis could not provide a reason for the shortage. Heritage has leflunomide 10 mg and 20 mg tablets on tight allocation. Sanofi-Aventis has Arava 20 mg tablets on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Liotrix Tablets	Forest Laboratories	Thyrolar tablets from Forest Laboratories are on back order due to manufacturing changes. Forest has all Thyrolar presentations on a long term back order and the company cannot estimate a release date.
Methotrexate Injection	Accord Healthcare, Mylan Institutional, Sandoz	Mylan cannot provide a reason for the shortage and has all methotrexate presentations on back order and the company cannot estimate a release date. Sandoz discontinued methotrexate 2 ml and 10 ml vials. Accord has methotrexate 10 ml vials on back order and the company estimates a release date in late-June 2015.
Memantine Hydrochloride	Actavis (formerly Forest)	Actavis (formerly Forest) states the reason for the shortage of Namenda XR capsules is manufacturing delay. Actavis launched generic memantine immediate release tablets in July 2015. There are several other manufacturers of generic memantine immediate release tablets and supplies are available. Actavis has Namenda XR 14 mg and 28 mg 100-count unit-dose presentations, 14 mg 90-count presentations, and titration packs on back order and the company estimates a release date of 4th quarter 2015.
Mercaptopurine Tablets	Mylan, Teva	Teva discontinued mercaptopurine generic and Purinethol in mid-2015. Mylan has mercaptopurine 50 mg tablets in 25-count bottles on back order and the company estimates a release date of late-July 2015.
Methylphenidate Hydrochloride Chewable Tablets	Shionogi Pharma	Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues. Gavis launched methylphenidate chewable tablets in April 2015. Shionogi Pharma has all Methylin chewable tablets on back order and the company cannot estimate a release date.
Methylphenidate Hydrochloride Extended Release Oral	Actavis, Kremers Urban, Teva	Actavis states the shortage of methylphenidate is due to increased demand. Actavis estimates a shortage of methylphenidate ER tablets will begin in December 2014 and last through 2nd quarter 2015. Kremers Urban has Methylphenidate CD on allocation due to increased demand. Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules. Actavis has methylphenidate LA extended release 30 mg capsules on back order and the company cannot estimate a release date. Kremers Urban has all methylphenidate CD presentations available on allocation. Teva has all methylphenidate LA extended release capsules on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Nebivolol Tablets	Actavis	Actavis could not provide a reason for the shortage. Actavis has Bystolic 20 mg tablets in 30- and 90-count sizes temporarily unavailable and the company cannot estimate when product will return.
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 473 mL bottle on back order and the company estimates a release date in September 2015. Nymalize oral solution in unit-dose cups are on back order and the company estimates a release date in October 2015.
Ofloxacin Otic Solution	Apotex, Sandoz, Valeant	Apotex discontinued ofloxacin otic solution in early 2015. Sandoz cannot provide a reason for the shortage. Valeant cannot provide a reason for the shortage. Sandoz has ofloxacin otic solution in 5 mL and 10 mL bottles temporarily unavailable and the company cannot estimate a resupply date. Valeant has ofloxacin otic 5 mL and 10 mL vials on back order and the company cannot estimate a release date.
Pantoprazole Tablets	Actavis, Aurobindo, Kermers-Urban, Mylan Pharmaceuticals, Prasco, Wockhardt,	Aurobindo, Kermers-Urban and Mylan have limited product available, Aurobindo, Actavis and Mylan cannot provide a reason for the shortage, Actavis discontinued pantoprazole 20 mg tablets in October 2014. Kermers-Urban state shortage is due to increased demand, FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole. Actavis has 40 mg tablets on back order and no estimated release date. Aurbindo has 40 mg tablets on back order with an estimated release date in late-May 2015. Kremers-Urban is allocating pantoprazole 20 mg tablets weekly, Mylan has pantoprazole 20 mg and 40 mg on back order with an estimated release date in mid-May 2015, Wockhardt has pantoprazole on back order with no estimated release date.
Phenazopyridine Hydrochloride	Avkare, Marlex	Amneal Pharmaceuticals, Avkare, SDA Laboratories discontinued phenazopyridine tablets. Marlex could not provide a reason for the shortage. Marlex has phenazopyridine 100 mg tablets on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Phenylephrine 2.5% and 10% Ophthalmic Solution	Akorn, Alcon, Hub, Paragon BioTeck	Akorn received FDA approval of phenylephrine ophthalmic solution in January 2015 and has product available. Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014. Alcon discontinued Mydfrin 2.5% ophthalmic solution in 2014. Hub discontinued phenylephrine 2.5% and 10% ophthalmic solution in 2013. Phenylephrine 2.5% and 10% from Paragon BioTeck was the first FDA-approved phenylephrine ophthalmic product. Paragon BioTeck supplies phenylephrine ophthalmic solution 2.5% and 10% and this is distributed by Bausch & Lomb (a division of Valeant).
Posaconazole Oral Suspension (NOXAFIL)	Merck	Merck states that shortage is due to manufacturing delays. Noxafil delayed-release tablets and intravenous injections are not affected by this. Merck is the only supplier of posaconazole oral suspension. Merck has Noxafil oral suspension on back order and the company cannot estimate a release date. There is emergency supply available for patients who cannot tolerate the delayed-release tablets. Emergency supply should be requested through wholesalers. Wholesalers can call Merck at 1-800-637-2579 and product will be drop-shipped if approved for the patient.
Propranolol Hydrochloride Tablets	Actavis, Heritage, Mylan Instutional, Teva	Actavis cannot provide a reason for the shortage. Heritage states the reason for the shortage is a raw materials issue. Mylan Institutional discontinued propranolol unit-dose tablets. The 10 mg tablets were discontinued in March 2013, the 20 mg tablets were discontinued in May 2014, and the 40 mg tablets were discontinued in January 2015. Teva could not provide a reason for the shortage. Actavis has propranolol 80 mg tablets in 500-count on back order and the company cannot estimate a release date. Heritage has all propranolol presentations on back order and the company estimates a release date of mid-August 2015. Teva has propranolol 10 mg in 100-count and 1000-count, 20 mg in 1000-count, and 60 mg in 100-count on back order and the company estimates a release date of late-August 2015.
Resperipine Oral tablets	Sandoz	Sandoz said the shortage is due to a delay in obtaining raw materials. There is no other manufacturer of reserpine tablets. Sandoz has all reserpine tablet presentations temporarily unavailable and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Sumatriptan Succinate Injection	Sagent, Teva, Pfizer	Sagent states the reason for the shortage is increased demand. Sagent has sumatriptan 6 mg/0.5 mL prefilled syringes on back order and the company estimates a release date of June 2015. Sagent has sumatriptan 6 mg/0.5 mL prefilled syringes on back order and the company estimates a release date of June 2015. Teva has temporarily suspended the production of sumatriptan injection and the company estimates product will be re-introduced in March 2017. Pfizer has had Alsuma on shortage since September 2013 due to manufacturing issues but the company estimates a release date in September 2016.
Synthetic Conjugated Estrogen	Teva	Teva discontinued Cenestin in late-August 2014. Premarin is not affected by this shortage. Teva has Enjuvia 0.625 mg and 1.25 mg tablets temporarily unavailable and the company cannot estimate a release date.
Tacrolimus Capsules	Mylan	Mylan could not provide a reason for the shortage but discontinued 500-count presentations in early 2015. Mylan has tacrolimus 1 mg capsules in 100-count bottles on back order and the company estimates a release date in late-June 2015.
Tamsulosin Hydrochloride Capsules (FLOMAX)	Aurobindo, Citron Pharma, Zydus, Boehringer Ingelheim	Boehringer Ingelheim could not give a reason for the shortage and has Flomax 0.4 mg capsules in 100-count on back order and the company estimates a release date of mid-August 2015. Aurobindo is not marketing the 100-count size but has tamsulosin 0.4 mg capsules on intermittent back order and the company is releasing product as it becomes available. Zydus states the reason for the shortage is increased demand; Zydus has tamsulosin 0.4 mg capsules in 100- and 1000-count on allocation to current customers. Citron Pharma has tamsulosin 0.4 mg capsules in 100-count and 500-count available on allocation to current customers.
Testosterone Cypionate Intramuscular Injection	Actavis, Paddock, Sun Pharma	Actavis discontinued testosterone cypionate injection in 2015. Paddock has testosterone on shortage due to increased demand and shipping delays from their contract manufacturer. Sun Pharmaceuticals could not provide a reason for the shortage. Paddock has testosterone cypionate 200 mg/mL 1 mL vials available in limited supply. Sun Pharma has testosterone cypionate 200 mg/mL 1 mL vials on back order and the company estimates a release date in early-August 2015.

FDA Drug Safety Communications

The information included in this section is drug alerts that were released in the last 3 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
POTIGA (ezogabine)	Based on reviews of additional safety reports from patients treated with the anti-seizure drug POTIGA (ezogabine), the U.S. Food and Drug Administration (FDA) has determined that the potential risks of vision loss due to pigment changes in the retina and of skin discoloration can be adequately managed by following the current recommendations in the POTIGA labeling. To further explore any potential long-term consequences of these pigment changes, the FDA has required the POTIGA manufacturer, GlaxoSmithKline, to conduct a long-term observational study. The review of additional safety reports does not indicate that the pigment changes in the retina observed in some patients affect vision. Skin discoloration associated with the use of POTIGA appears to be a cosmetic effect and does not appear to be associated with more serious adverse effects. Therefore, the FDA has determined that a modification of the Risk Evaluation and Mitigation Strategy (REMS) is not needed at this time to ensure that the benefits of POTIGA outweigh the risks of retinal and skin pigment changes. The FDA expects that the required long-term observational study will provide further information on whether pigment changes in the retina caused by POTIGA can lead to vision loss or other long-term side effects. In addition, the study should provide more information on the relationship between pigment changes in the retina and skin discoloration.
Daytrana patch (methylphenidate transdermal system)	The U.S. Food and Drug Administration (FDA) is warning that permanent loss of skin color may occur with use of the Daytrana patch (methylphenidate transdermal system) for Attention Deficit Hyperactivity Disorder (ADHD). The FDA added a new warning to the drug label to describe this skin condition, which is known as chemical leukoderma.
CODEINE cough and cold medicines.	The U.S. Food and Drug Administration (FDA) is investigating the possible risks of using codeine-containing medicines to treat coughs and colds in children under 18 years because of the potential for serious side effects, including slowed or difficult breathing. The FDA is evaluating all available information and will also consult with external experts by convening an advisory committee to discuss these safety issues. The agency will communicate its final conclusions when the review is complete.
NSAIDS (non-aspirin nonsteroidal anti-inflammatory drugs)	The U.S. Food and Drug Administration (FDA) is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on the FDA's comprehensive review of new safety information, the agency is requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. The FDA will also request updates to the OTC non-aspirin NSAID Drug Facts labels.

Drug	Communications Summary
PROGLYCEM (diazoxide)	The U.S. Food and Drug Administration (FDA) is warning that a serious lung condition called pulmonary hypertension, which is high pressure in the blood vessels leading to the lungs, has been reported in infants and newborns treated with Proglycem (diazoxide) for low blood sugar. In all cases, the pulmonary hypertension resolved or improved after Proglycem was stopped. We are continuing to investigate this safety issue and will determine whether changes are needed in the Proglycem prescribing information.
GADOLINIUM-BASED CONTRAST AGENTS FOR MAGNETIC RESONANCE IMAGING (MRI)	The U.S. Food and Drug Administration (FDA) is investigating the risk of brain deposits following repeated use of gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (MRI). MRIs help detect abnormalities of body organs, blood vessels, and other tissues. Recent publications in the medical literature have reported that deposits of GBCAs (see Table 1) remain in the brains of some patients who undergo four or more contrast MRI scans, long after the last administration. It is unknown whether these gadolinium deposits are harmful or can lead to adverse health effects.
BRINTELLIX (vortioxetine) and BRILINTA (ticagrelor)	The U.S. Food and Drug Administration is warning health care professionals and patients that reports of confusion between the antidepressant Brintellix and anti-blood clotting medication Brilinta have resulted in the wrong medication being prescribed or dispensed. The FDA has determined that the main reason for the confusion between these two medications is the similarity of their brand (proprietary) names. None of the reports indicates that a patient ingested the wrong medication; however, reports of prescribing and dispensing errors continue. As a result, the FDA is alerting the public about this safety issue.
GILENYA (fingolimod)	The U.S. Food and Drug Administration is warning that a case of definite progressive multifocal leukoencephalopathy (PML) and a case of probable PML have been reported in patients taking Gilenya (fingolimod) for multiple sclerosis (MS). These are the first cases of PML reported in patients taking Gilenya who had not been previously treated with an immunosuppressant drug for MS or any other medical condition. As a result, information about these recent cases is being added to the drug label.
PICATO (ingenol mebutate) gel	The U.S. Food and Drug Administration (FDA) is warning about reports of severe allergic reactions and herpes zoster (shingles) associated with the use of Picato gel (ingenol mebutate). Picato is used to treat actinic keratosis, a scaly, crusty lesion on the skin that may be red or yellow in color.
DPP-4 inhibitors for type 2 diabetes	The U.S. Food and Drug Administration (FDA) is warning that the type 2 diabetes medicines sitagliptin, saxagliptin, linagliptin, and alogliptin may cause joint pain that can be severe and disabling. The FDA has added a new Warning and Precaution about this risk to the labels of all medicines in this drug class, called dipeptidyl peptidase-4 (DPP-4) inhibitors.
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. The FDA is continuing to evaluate the risk of bone fractures with other drugs in the SGLT2 inhibitor class, including dapagliflozin (Farxiga, Xigduo XR) and empagliflozin (Jardiance, Glyxambi, Synjardy), to determine if additional label changes or studies are needed.

NOTES:

Gold Coast Health Plan℠
A Public Entity

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Pharmacy Newsletter

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