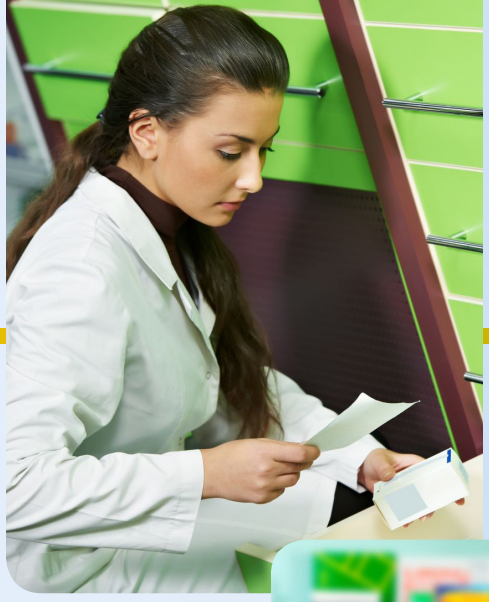

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

MARCH 2017

Q2 2017

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PN Q2 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

On June 1, Gold Coast Health Plan will be undergoing a major change when it starts working with a new pharmacy benefit manager (PBM).

Since the Plan's inception in 2011, the PBM has been Script Care, Ltd. Beginning June 1, OptumRx (ORx) will be taking over as PBM. We anticipate that this change will be a positive one for the Plan, its providers and its members. When it comes to drug usage reviews and quality programs, OptumRx has robust offerings.

We are working diligently with OptumRx to make this change as seamless as possible for the Plan's providers and members. The formulary will be the same and the pharmacy network will be almost the same. For the few local pharmacies that are not currently contracted with OptumRx, the PBM is working to get them under contract.

Detailed information will be mailed and emailed to providers the week of April 17. Please watch for these communications as they will contain important contact numbers and processes that will need to be followed.

I also want to take this opportunity to make you aware that the U.S. Food and Drug Administration (FDA) has issued a large number of new black box warnings on opiate medications and benzodiazepines. In previous newsletters, I have discussed the importance of the safe prescribing of opiate and benzodiazepine medications. On page 6, there is a link to the FDA's website. In the interest of best practices and the safety of our members, I encourage all of our providers to visit the FDA's website and review the new warnings that have been issued on these medications.

Regards,

C. Albert Reeves M.D.

C. Albert Reeves, MD

Allergies & Seasonal Rhinitis

As we enter spring, allergy season will be quickly arriving. With the strong winter rain California received and warm weather fast approaching, the allergy season is likely to be intense and last longer than usual this year.

To aid your practice, below are the products available on the Gold Coast Health Plan (GCHP) formulary that you may use to help treat seasonal allergy symptoms:

Systemic Antihistamines:

Covered Agent	Restrictions
Diphenhydramine 25 mg capsules	104 capsules per 31 days
Loratadine (generic tablets)	31 capsules per 31 days
Desloratadine (generic tablets)	31 tablets per 31 days
fexofenadine (generic tablets)	62 tablets per 31 days
Hydroxyzine capsules	
Cetirizine (generic tablets)	31 tablets per 31 days; must try and fail loratadine

Ophthalmic Antihistamines:

Covered Agent	Restrictions
Azelastine 0.05 %	
LASTACRAFT 0.25 %	
Epinastine 0.05%	
Olopatadine 0.1 %	

Leukotriene Receptor Modifier:

Covered Agent	Restrictions
montelukast	
zafirlukast	Requires a prior authorization stating that long-term controller medications (inhaler corticosteroids and long-acting beta agonists) have been tried and failed.

Nasal Corticosteroids:

Covered Agent	Restrictions
Fluticasone 50 mcg	1 bottle per month
Flunisolide 0.025%	3 bottles per 31 days
NASONEX	Must trial and fail fluticasone or flunisolide
BECONASE AQ	Must trial and fail fluticasone or flunisolide
NASACORT AQ	Must trial and fail fluticasone or flunisolide
OMNARIS	Must trial and fail fluticasone or flunisolide
VERAMYST	Must trial and fail fluticasone or flunisolide
RHINOCORT AQUA	

Other Agents:

Covered Agent	Restrictions
XOLAIR	Requires a prior authorization stating the diagnosis, lab values of IgE, and prior trial and failure of an inhaled corticosteroid and a long-acting beta agonist.
Ipratropium nasal spray	
Azelastine 0.1% and 0.15% nasal spray	2 bottles per 31 days
Olopatadine	Must trial and fail 1) fluticasone or flunisolide OR 2) an oral antihistamine or azelastine
Cromolyn sodium 5.2 mcg/act nasal spray	

New Safety Warnings Related to Opioids and Benzodiapezines

The FDA has issues new black box warnings on all opioids, opioid-containing products and benzodiazepines related to some or all of the following issues:

- Addiction, Abuse and Misuse
- Life-Threatening Respiratory Depression
- Accidental Ingestion
- Neonatal Opioid Withdrawal Syndrome
- Cytochrome P450 Isoenzyme Interactions
- Risks from Concomitant Use with Benzodiazepines (opioids) or other CNS Depressants
- Death Related to Ultra-Rapid Metabolism of Codeine to Morphine
- Concomitant Use of Demerol with Monoamine Oxidase inhibitors (MAOI)
- Risk of Dosing Errors
- Risks with Neuroaxial Administration
- Interaction with Alcohol
- Cardiovascular Thrombotic Events

Click here to visit the FDA's website and read the full text of each new black box warning for all opioids, opioid-containing products and benzodiazepines.

Pharmacy Department Update

GCHP has selected a new Pharmacy Benefits Manager (PBM), OptumRx (ORx). ORx will replace Script Care on June 1. GCHP and ORx have been working diligently over the past several months to achieve a smooth transition and minimize any member and provider disruption.

As a provider for GCHP, you will receive additional information regarding the change. Please be on the lookout for information in the Provider Operations Bulletin (POB) and in Provider Updates.

Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

- GCHP Formulary
- List of Participating Pharmacies
- Provider Resources

Formulary Changes

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

Additions

Drug	Formulary Status/Change
BASAGLAR *(insulin glargine) 100 unit/ML*	Add with PA as preferred agent for new starts.
SOLIQUA 100/33 *(insulin glargine and lixisenatide injection)*	Add with PA as preferred agent for new starts.

Removals

Drug	Formulary Status/Change
FOCALIN XR 25 mg and 35 mg capsules	Brand removed; generic now available.
AMPYRA ER 10 mg tablets	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
CASPOFUNGIN ACETATE	*caspofungin acetate*	IV Infusion	CASPOFUNGIN ACETATE for injection is an echinocandin antifungal indicated in adults and pediatric patients (3 months of age and older) for: • Empirical therapy for presumed fungal infections in febrile, neutropenic patients. • Treatment of candidemia and the following Candida infections: intra-abdominal abscesses, peritonitis and pleural space infections. • Treatment of esophageal candidiasis. • Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (e.g., amphotericin B, lipid formulations of amphotericin B, itraconazole).
COLPREP KIT	*(sodium sulfate, potassium sulfate, and magnesium sulfate)*	Powder for Oral Solution	COLPREP KIT is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults.
EUCRISA	*crisaborole*	Topical Ointment	EUCRISA is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild-to-moderate atopic dermatitis in patients 2 years of age and older.
ISOPTO ATROPINE	*atropine sulfate ophthalmic solution*	Ophthalmic Solution	ISOPTO ATROPINE 1% is a muscarinic antagonist indicated for: • Mydriasis • Cycloplegia • Penalization of the healthy eye in the treatment of amblyopia.
RUBRACA	*rucaparib*	Oral Tablets	RUBRACA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies.
SPINRAZA	*nusinersen*	Intrathecal Injection	SPINRAZA is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SYNJARDY XR	*empagliflozin and metformin hydrochloride extended release*	Oral Tablets	SYNJARDY XR 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 when treatment with both empagliflozin and metformin is appropriate. Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
TIGECYCLINE	*tigecycline*	IV Injection	TIGECYCLINE for injection is a tetracycline class antibacterial indicated in patients 18 years of age and older for: • Complicated skin and skin structure infections. • Complicated intra-abdominal infections. • Community-acquired bacterial pneumonia. Limitations of use: TIGECYCLINE for injection is not indicated for treatment of diabetic foot infection or hospital-acquired pneumonia, including ventilator-associated pneumonia.
TIROSINT-SOL	*levothyroxine sodium*	Oral Solution	TIROSINT-SOL is L-thyroxine (T4) indicated for: • Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. • Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Limitations of use: • Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients. • Not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ARYMO ER	*morphine sulfate*	Extended Release Oral Tablets	ARYMO ER 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. Limitations of use: • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve ARYMO ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • ARYMO ER is not indicated as an as-needed (prn) analgesic.
ESBRIET	*pirfenidone*	Capsules and Film-Coated Tablets for Oral Use	ESBRIET is a pyridone indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
VANTRELA ER	*hydrocodone bitartrate*	Extended Release Oral Tablets	VANTRELA ER 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. Limitations of use: • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve VANTRELA ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • VANTRELA ER is not indicated as an as-needed (prn) analgesic.
RHOFADE	*oxymetazoline hydrochloride*	Topical Cream	RHOFADE is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.
TRULANCE	*plecanatide*	Oral Tablets	TRULANCE is a guanylate cyclase-C agonist indicated in adults for treatment of chronic idiopathic constipation (CIC).

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
TEPADINA	*thiotepa*	injection, for intravenous, intracavitary, or intravesical use	TEPADINA (thiotepa) is an alkylating drug indicated: • To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia. • For treatment of adenocarcinoma of the breast or ovary. • For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities. • For treatment of superficial papillary carcinoma of the urinary bladder.
ARMONAIR RESPICLICK	*fluticasone propionate*	Oral Inhalation Powder	ARMONAIR RESPICLICK is a corticosteroid indicated for: • Maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Important limitation of use: • Not indicated for the relief of acute bronchospasm.
CORPHEDRA	*ephedrine sulfate injection, USP*	IV Injection	CORPHEDRA is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
PARSABIV	*etelcalcetide*	IV Injection	PARSABIV is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. Limitations of use: PARSABIV has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.
EMFLAZA	*deflazacort*	Oral Tablets and Oral Solution	EMFLAZA is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.
SILIQ	*brodalumab*	Subcutaneous Injection	SILIQ is a human interleukin-17 receptor A (IL-17RA) antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
GANCICLOVIR	*ganciclovir*	IV Injection	GANCICLOVIR injection is a nucleoside analogue CMV DNA polymerase inhibitor indicated for the: • Treatment of CMV retinitis in immunocompromised adult patients, including patients with acquired immunodeficiency syndrome (AIDS). • Prevention of CMV disease in adult transplant recipients at risk for CMV disease.
QTERN	*dapagliflozin and saxagliptin*	Oral Tablets	QTERN is a dipeptidyl peptidase-4 (DPP-4) inhibitor combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) who have inadequate control with dapagliflozin or who are already treated with dapagliflozin and saxagliptin. Limitations of use: • Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Should only be used in patients who tolerate 10 mg dapagliflozin.
XERMELO	*telotristat ethyl*	Oral Tablets	XERMELO is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.
EPHEDRINE SULFATE	*Ephedrine sulfate*	IV Injection	EPHEDRINE SULFATE injection is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
NOCTIVA	*desmopressin acetate*	Nasal Spray	NOCTIVA is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Limitation of use: Not studied in patients younger than 50 years of age.

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
ADASUVE *(loxapine)*	Boxed Warning	WARNING: BRONCHOSPASM and INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS Bronchospasm • ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress. • ADASUVE is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the ADASUVE REMS. • Administer ADASUVE only in an enrolled health care facility that has immediate access on site to supplies and personnel trained to manage acute bronchospasm, and ready access to emergency response services. Facilities must have a short-acting bronchodilator, including a nebulizer and inhalation solution, for the immediate treatment of bronchospasm. Increased Mortality in Elderly Patients with Dementia-Related Psychosis Psychosis • Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ADASUVE is not approved for the treatment of patients with dementia-related psychosis.
COMBIVIR *(lamivudine; zidovudine)*	Boxed Warning	WARNING: HEMATOLOGIC TOXICITY, MYOPATHY, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY WITH STEATOSIS, and EXACERBATIONS OF HEPATITIS B.
CYTOTEC *(misoprostol)*	Boxed Warning	CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE BIRTH DEFECTS, ABORTION, PREMATURE BIRTH OR UTERINE RUPTURE. THE RISK OF UTERINE RUPTURE INCREASES WITH ADVANCING GESTATIONAL AGES AND WITH PRIOR UTERINE SURGERY, INCLUDING CESAREAN DELIVERY.

Drug	Type of Change	Change
DAKLINZA *(daclatasvir dihydrochloride)*; EPCLUSA *(sofosbuvir; velpatasvir)*; HARVONI *(ledipasvir; sofosbuvir)*; OLYSIO *(simeprevir sodium)*; SOVALDI *(sofosbuvir)*; TECHNIVIE *(ombitasvir; paritaprevir; ritonavir)* VIEKIRA PAK (COPACKAGED), VIEKIRA XR; ZEPATIER *(elbasvir; grazoprevir)*	Boxed Warning	WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate management for HBV infection as clinically indicated.
FLUOXETINE HYDROCHLORIDE	Boxed Warning	WARNING: SUICIDAL THOUGHTS AND BEHAVIORS • Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over the age of 24; there was a reduction in risk with antidepressant use in patients ages 65 and older. • In patients of all ages who are started on antidepressant therapy, monitor closely for worsening and for emergence of suicidal thoughts and behavior. Advise families and caregivers of the need for close observation and communication with the prescriber. • Fluoxetine is not approved for use in children less than 7 years of age.

Drug	Type of Change	Change
JANUMET (metformin hydrochloride; sitagliptin phosphate), JANUMET XR (metformin hydrochloride; sitagliptin phosphate); JENTADUETO (linagliptin; metformin hydrochloride); KAZANO (alogliptin benzoate; metformin hydrochloride); KOMBIGLYZE XR (metformin hydrochloride; saxagliptin hydrochloride); SYNJARDY (empagliflozin; metformin hydrochloride)	Boxed Warning	WARNING: LACTIC ACIDOSIS Postmarketing 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 (greater than 5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally greater than 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 and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.
LATUDA *(lurasidone hydrochloride)*	Boxed Warning	WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS **Increased Mortality in Elderly Patients with Dementia-Related Psychosis** Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LATUDA is not approved for use in patients with dementia-related psychosis. **Suicidal Thoughts and Behaviors** Antidepressants increased the risk of suicidal thoughts and behaviors in patients ages 24 years and younger in short-term studies. Monitor closely for clinical worsening and for emergence of suicidal thoughts and behaviors. LATUDA is not approved for use in pediatric patients with depression.
LINZESS *(linaclotide)*	Boxed Warning	WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS • LINZESS is contraindicated in patients less than 6 years of age; in nonclinical studies in neonatal mice, administration of a single, clinically-relevant adult oral dose of linaclotide caused deaths due to dehydration. • Avoid use of LINZESS in patients 6 years to less than 18 years of age.

Drug	Type of Change	Change
RETROVIR *(zidovudine)*	Boxed Warning	WARNING: RISK OF HEMATOLOGICAL TOXICITY, MYOPATHY, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY WITH STEATOSIS
SOLIRIS (eculizumab)	Boxed Warning	WARNING: SERIOUS MENINGOCOCCAL INFECTIONS Life-threatening and fatal meningococcal infections have occurred in patients treated with SOLIRIS. Meningococcal infection may become rapidly life threatening or fatal if not recognized and treated early. • Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies. • Immunize patients with meningococcal vaccines least two weeks prior to administering the first dose of SOLIRIS, unless the risks of delaying SOLIRIS therapy outweigh the risk of developing a meningococcal infection. • Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.
TRIZIVIR *(abacavir sulfate; lamivudine; zidovudine)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS, HEMATOLOGIC TOXICITY, MYOPATHY, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY WITH STEATOSIS, and EXACERBATIONS OF HEPATITIS B.
TRULICITY *(dulaglutide)*	Boxed Warning	WARNING: RISK OF THYROID C-CELL TUMORS • In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. It is unknown whether TRULICITY causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined. • TRULICITY is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of TRULICITY and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with TRULICITY.

Drug	Type of Change	Change
XIGDUO XR *(dapagliflozin propanediol; metformin hydrochloride)*	Boxed Warning	Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, 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 lactic acidosis is suspected, discontinue XIGDUO XR and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.
ZOLOFT *(sertraline hydrochloride)*	Boxed Warning	WARNING: SUICIDAL THOUGHTS AND BEHAVIORS Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.
ADDERALL *(amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate)*, ADDERALL XR *(amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate)*	Contraindication	Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Known hypersensitivity or idiosyncrasy to amphetamine. Patients with a history of drug abuse. In patients known to be hypersensitive to amphetamine, or other components of Adderall®. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products. Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.

Drug	Type of Change	Change
ADEMPAS *(riociguat)*	Contraindication	**Phosphodiesterase Inhibitors** Do not administer within 24 hours of sildenafil. Do not administer 24 hours before or 48 hours after tadalafil. **Pulmonary Hypertension Associated with Idiopathic Interstitial Pneumonias (PH-IIP)** Adempas is contraindicated in patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).
ADZENYS XR-ODT *(amphetamine)*	Contraindication	Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.
DEMADEX *(torsemide)*	Contraindication	• DEMADEX is contraindicated in patients with known hypersensitivity to DEMADEX or to povidone. • DEMADEX is contraindicated in patients with hepatic coma.
DESOXYN *(methamphetamine hydrochloride)*	Contraindication	In patients known to be hypersensitive to amphetamine, or other components of DESOXYN. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products. Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.
DEXEDRINE *(dextroamphetamine sulfate)*	Contraindication	Known hypersensitivity or idiosyncrasy to amphetamine. In patients known to be hypersensitive to amphetamine, or other components of DEXEDRINE. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products. Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.
DYANAVEL XR *(amphetamine)*	Contraindication	Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.
E-Z-HD *(barium sulfate)*	Contraindication	High risk of GI perforation such as those with a recent prior GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to pelvis.

Drug	Type of Change	Change
FETZIMA *(levomilnacipran hydrochloride)*	Contraindication	Hypersensitivity to levomilnacipran, milnacipran HCl or to any excipient in the formulation. The use of MAOIs intended to treat psychiatric disorders with FETZIMA or within seven days of stopping treatment with FETZIMA is contraindicated because of an increased risk of serotonin syndrome. The use of FETZIMA within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Starting FETZIMA in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.
FLUOXETINE HYDROCHLORIDE	Contraindication	**Monoamine Oxidase Inhibitors (MAOIs)** The use of MAOIs intended to treat psychiatric disorders with FLUOXETINE or within five weeks of stopping treatment with FLUOXETINE is contraindicated because of an increased risk of serotonin syndrome. The use of FLUOXETINE within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Starting FLUOXETINE in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome. **Other Contraindications** The use of FLUOXETINE is contraindicated with the following: • Pimozide • Thioridazine Pimozide and thioridazine prolong the QT interval. FLUOXETINE can increase the levels of pimozide and thioridazine through inhibition of CYP2D6. Fluoxetine can also prolong the QT interval.
GRANIX *(tbo-filgrastim)*	Contraindication	GRANIX is contraindicated in patients with a history of serious allergic reactions to filgrastim or pegfilgrastim products.
JADELLE *(levonorgestrel)*	Contraindication	JADELLE is contraindicated in patients who have: • Current thrombophlebitis or thromboembolic disorders. • Undiagnosed abnormal uterine bleeding. • Known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past.

Drug	Type of Change	Change
PROLIA *(denosumab)*	Contraindication	Multiple Vertebral Fractures (MVF) Following Discontinuation of PROLIA Treatment Following discontinuation of PROLIA treatment, fracture risk increases, including the risk of multiple vertebral fractures. Cessation of PROLIA treatment results in markers of bone resorption increasing above pretreatment values then returning to pretreatment values 24 months after the last dose of PROLIA. In addition, bone mineral density returns to pretreatment values within 18 months after the last injection. New vertebral fractures occurred as early as seven months (on average 19 months) after the last dose of PROLIA. Prior vertebral fracture was a predictor of multiple vertebral fractures after PROLIA discontinuation. Evaluate an individual's benefit/risk before initiating treatment with PROLIA. If PROLIA treatment is discontinued, consider transitioning to an alternative antiresorptive therapy.
QUILLICHEW ER *(methylphenidate hydrochloride)*	Contraindication	**Hypersensitivity to Methylphenidate or other Components of QUILLICHEW ER** QUILLICHEW ER is contraindicated in patients known to be hypersensitive to methylphenidate, or other components of QUILLICHEW ER. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other methylphenidate products. **Monoamine Oxidase Inhibitors** QUILLICHEW ER is contraindicated during concomitant treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days following discontinuation of treatment with a monoamine oxidase inhibitor (MAOI), because of the risk of hypertensive crisis.
REVLIMID *(lenalidomide)*	Contraindication	Pregnancy If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to a fetus.
RISPERDAL *(risperidone)*, RISPERDAL CONSTA *(risperidone)*	Contraindication	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/ INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.

Drug	Type of Change	Change
VYVANSE *(lisdexamfetamine dimesylate)*	Contraindication	VYVANSE administration is contraindicated in patients with the following conditions: • Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis.
ZEPATIER *(elbasvir; grazoprevir)*	Contraindication	• ZEPATIER is contraindicated with inhibitors of organic anion transporting polypeptides 1B1/3 (OATP1B1/3) that are known or expected to significantly increase grazoprevir plasma concentrations, strong inducers of cytochrome P450 3A (CYP3A), and efavirenz.
ZOLOFT *(sertraline hydrochloride)*	Contraindication	ZOLOFT is contraindicated in patients: • With known hypersensitivity to sertraline (e.g., anaphylaxis, angioedema). In addition to the contraindications for all ZOLOFT formulations listed above, ZOLOFT oral solution is contraindicated in patients: • Taking disulfiram. ZOLOFT oral solution contains alcohol, and concomitant use of ZOLOFT and disulfiram may result in a disulfiram-alcohol reaction.

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
Liotrix Tablets	Actavis	Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes. Actavis (formerly Forest) has all Thyrolar presentations on long-term back order and the company cannot estimate a release date.
Mupirocin Calcium 2% Nasal Ointment	GlaxoSmithKline	GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes on long-term back order and the company cannot estimate a release date.
Penicillin G Benzathine	Pfizer	Pfizer states the shortage is due to a delay in the manufacturing process. Pfizer has Bicillin L-A 600,000 unit/1 mL syringes, 1,200,000 unit/2 mL syringes, and 2,400,000 unit/4 mL syringes on allocation.
Disopyramide Phosphate Controlled-release Capsules	Pfizer	Pfizer has disopyramide controlled-release capsules on shortage due to manufacturing delays. Pfizer has Norpace CR available but with short-expiration dating. The 100 mg capsules in 100 count and 500 count and 150 mg capsules in 500 count have an expiration date of May 2017. The 150 mg capsules in 100 count have an expiration date of June 2017. Once this supply is depleted the company cannot estimate a release date.

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
Chlorhexidine gluconate skin antiseptic	The FDA is warning that rare, but serious, allergic reactions have been reported with the widely-used skin antiseptic products containing chlorhexidine gluconate. Although rare, the number of reports of serious allergic reactions to these products has increased over the last several years. As a result, the FDA is requesting the manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate to add a warning about this risk to the Drug Facts labels. Prescription chlorhexidine gluconate mouthwashes and oral chips used for gum disease already contain a warning about the possibility of serious allergic reactions in their labels.

Drug	Communications Summary
Chantix *(varenicline)* and Zyban *(bupropion)*	Based on an FDA review of a large clinical trial that the FDA required the drug companies to conduct, the FDA has determined the risk of serious side effects on mood, behavior, or thinking with the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. However, most people who had these side effects did not have serious consequences such as hospitalization. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines. As a result of the FDA's review of the large clinical trial, the FDA is removing the Boxed Warning, the FDA's most prominent warning, for serious mental health side effects from the Chantix drug label. The language describing the serious mental health side effects seen in patients quitting smoking will also be removed from the Boxed Warning in the Zyban label. The FDA is also updating the existing warning section in both labels that describes the side effects on mood, behavior, or thinking to include the results from the clinical trial. This decision is consistent with the recommendations of external experts at a September 2016 FDA Advisory Committee meeting. The patient Medication Guide that explains the risks associated with the use of the medicines will continue to be provided with every patient prescription; however, the risk evaluation and mitigation strategy (REMS) that formally required the Medication Guide will be removed. The FDA's review of the clinical trial results also confirmed that Chantix, Zyban, and nicotine replacement patches were all more effective for helping people quit smoking than was an inactive treatment called a placebo. These medicines were found to better help people quit smoking regardless of whether or not they had a history of mental illness. The health benefits of quitting smoking are substantial, including decreasing the chances of developing lung disease, heart disease, and some cancers. There are also benefits that are nearly immediate or occur after a short time as a nonsmoker, such as improvements in circulation, breathing, and the senses of taste and smell. Millions of Americans have serious health problems caused by smoking that can be reduced by quitting. Smoking has been found to harm many organs in the body and diminishes a person's overall health. Chantix and Zyban are prescription medicines that are FDA-approved to help adults quit smoking.

Drug	Communications Summary
Pioglitazone	As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and the FDA has now approved label updates to describe the additional studies it reviewed. The FDA alerted the public about the possible risk of bladder cancer in September 2010 and June 2011 based on interim results from a 10-year epidemiologic study. The FDA changed the labels of pioglitazone-containing medicines in August 2011 to include warnings about this risk, and required the manufacturer to modify and continue the 10-year study. Pioglitazone is approved to improve blood sugar control, along with diet and exercise, in adults with type 2 diabetes. Pioglitazone works by increasing the body's sensitivity to insulin, a natural hormone that helps control blood sugar levels. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

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