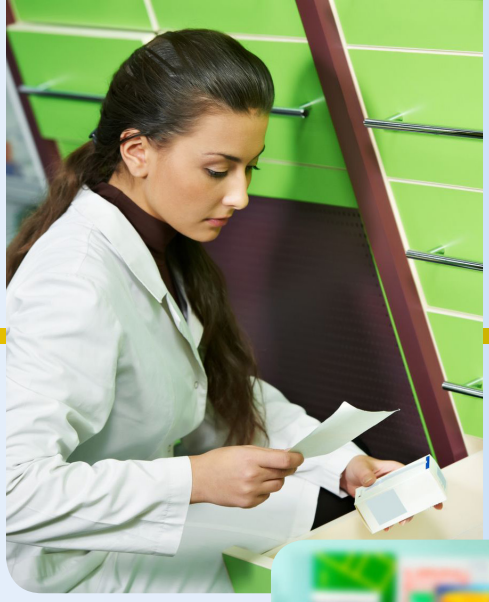

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

JANUARY 2015

Q1

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CMO Message

C. Albert Reeves, MD

Winter has arrived and so has the flu season. As we move into the early part of 2015, I can't stress strongly enough to Gold Coast Health Plan (GCHP) members and providers the necessity of receiving the flu immunization. Flu immunization is a benefit that is available for all members of the Plan when or if it is indicated for them and prescribed by their provider. GCHP providers should be aware that the Centers for Disease Control and Prevention (CDC) recently released information that the flu vaccine prepared this season is not totally effective against the H3N2 virus strain that has been isolated in 50% of cases this year. Tamiflu is available when a GCHP provider feels it is appropriate for an ill patient or as chemoprophylaxis for certain exposed or vulnerable patients.

I wanted to share the following story with you. Recently, I received a message from a provider informing me that based on feedback from a patient there were issues regarding the availability of a certain medication they had been prescribed. The medication in question was available on the GCHP formulary as a generic, but not as the brand drug. Unfortunately, the generic became temporarily unavailable and will not be restocked until sometime after the 2nd quarter of 2015. As soon as GCHP became aware of this issue, the brand was included on the formulary. GCHP wants our members to receive their needed medications and while the Plan wants to be as cost effective as possible, we do not want unnecessary barriers to members and providers. This is a perfect example of how communication between providers and the Plan result in a mutually beneficial outcome for the provider, the Plan and the member. If you become aware of an issue such as this or for any other concern for that matter, please contact me or Anne Freese, the director of pharmacy, so that we can investigate and correct a problem. Here's wishing you all the best in the New Year.

Influenza and Tamiflu

Influenza Update

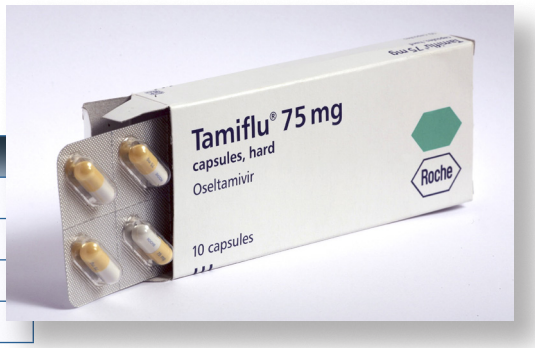
On December 3, 2014, the CDC issued a health advisory: CDC Health Advisory Regarding the Potential for Circulation of Drifted Influenza A (H3N2) Viruses. Click here to access the CDC Health Advisory.

On December 4, 2014, the CDC reported via a telebreifing that influenza A H3N2 has been detected most frequently and in all states. In seasons when H3 viruses are predominant, the tendency is for those to be the some of the worst flu years, with more hospitalizations and deaths from the flu. About half the H3N2 viruses analyzed by the CDC are different than the H3N2 virus included in this year's flu vaccine.

The CDC emphasized the availability of antiviral medications to help treat the flu. The antiviral medications, oseltamivir and zanamivir, can make the disease milder and shorter. Even if not given within the first 48 hours, antiviral medications can still be helpful for some patients when given later in the course of the illness.

Click here to access the full transcript of the CDC's Telebriefing.

Gold Coast Health Plan covers Tamiflu WITHOUT a prior authorization. There are quantity limits on Tamiflu as noted below:



Product	Limit
Tamiflu 30 mg capsules	20 capsules/31 days
Tamiflu 45 mg capsules	10 capsules/31 days
Tamiflu 75 mg capsules	10 capsules/31 days
Tamiflu 12 mg/ml Susp.	120 ml/31 days

Click here for some helpful information regarding influzena prevention for your practice from Genentech.

Office preparation steps

These tips can help you protect your practice this flu season.

1. Refresh diagnostic skills.
Promote influenza awareness in your practice to ensure that your staff recognizes the signs of flu. Rapid recognition is essential in managing influenza with antiviral therapy.[2,3] Often, the onset of influenza is sudden: fever, muscle aches, chills, and extreme tiredness are common symptoms and help differentiate influenza from other common respiratory viral infections, such as a cold.[4]

2. Make time for telephone triage.
Develop a practice protocol for telephone triage that will enable your office to:
- Prioritize visits for patients by severity of illness
- Identify patients who are candidates for antiviral therapy
- Assess if patients are taking over-the-counter medications for symptomatic relief

3. Plan for prompt initiation of treatment.
Establish over the phone if a patient may be an appropriate candidate for antiviral treatment. Since early initiation is essential for treating influenza with antivirals, it is important to see the patient as soon as possible.[2,3]

Indications

Tamiflu is indicated for the treatment of acute, uncomplicated illness due to influenza infection in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. Tamiflu is also indicated for the prophylaxis of influenza in patients 1 year and older

- Efficacy of Tamiflu in patients who begin treatment after 48 hours of symptoms has not been established
- Tamiflu is not a substitute for early and annual influenza vaccination
- There is no evidence for efficacy of Tamiflu in any illness caused by agents other than influenza viruses types A and B
- Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Tamiflu

Important Safety Information

Serious Skin/Hypersensitivity Reactions

- Tamiflu is contraindicated in patients who have had severe allergic reactions such as anaphylaxis or serious skin reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome, and erythema multiforme to any component of Tamiflu
- In postmarketing experience, cases of anaphylaxis and serious skin reactions, including toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme, have been reported with Tamiflu. Tamiflu should be stopped and appropriate treatment instituted if an allergic-like reaction occurs or is suspected

Neuropsychiatric Events

- Influenza can be associated with a variety of neurologic and behavioral symptoms, which can include events such as hallucinations, delirium and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease
- Closely monitor patients with influenza for signs of abnormal behavior. If neuropsychiatric symptoms occur, evaluate the risks and benefits of continuing treatment for each patient

Bacterial Infections

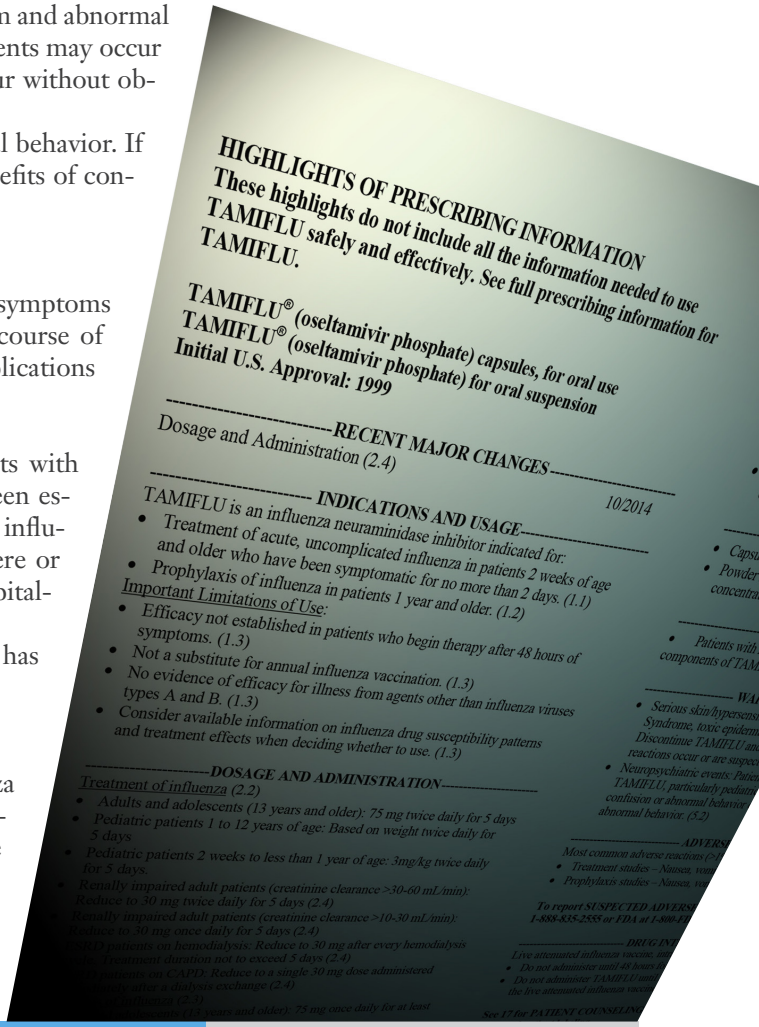
- Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. Tamiflu has not been shown to prevent such complications

Limitations of Populations Studied

- Efficacy of Tamiflu in the treatment of influenza in patients with chronic cardiac disease and/or respiratory disease has not been established. No information is available regarding treatment of influenza in patients with any medical condition sufficiently severe or unstable to be considered at imminent risk of requiring hospitalization
- Efficacy of Tamiflu for treatment or prophylaxis of influenza has not been established in immunocompromised patients

Concurrent Use with Live Attenuated Influenza Vaccine

- The concurrent use of Tamiflu with live attenuated influenza vaccine (LAIV) intranasal has not been evaluated. However, because of the potential for interference between these products, LAIV should not be administered within 2 weeks before or 48 hours after administration of Tamiflu, unless medically indicated


HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TAMIFLU safely and effectively. See full prescribing information for TAMIFLU.

TAMIFLU® (oseltamivir phosphate) capsules, for oral use
TAMIFLU® (oseltamivir phosphate) for oral suspension
Initial U.S. Approval: 1999

RECENT MAJOR CHANGES
Dosage and Administration (2.4) 10/2014

INDICATIONS AND USAGE
TAMIFLU is an influenza neuraminidase inhibitor indicated for:
- Treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. (1.1)
- Prophylaxis of influenza in patients 1 year and older. (1.2)

Important Limitations of Use:
- Efficacy not established in patients who begin therapy after 48 hours of symptoms. (1.3)
- Not a substitute for annual influenza vaccination. (1.3)
- No evidence of efficacy for illness from agents other than influenza viruses types A and B. (1.3)
- Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use. (1.3)

DOSAGE AND ADMINISTRATION
Treatment of Influenza (2.2)
- Adults and adolescents (13 years and older): 75 mg twice daily for 5 days
- Pediatric patients 1 to 12 years of age: Based on weight twice daily for 5 days
- Pediatric patients 2 weeks to less than 1 year of age: 3mg/kg twice daily for 5 days.
- Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg twice daily for 5 days (2.4)
- Renally impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once daily for 5 days (2.4)
- ESRD patients on hemodialysis: Reduce to 30 mg after every hemodialysis treatment; duration not to exceed 5 days (2.4)
- Patients on CAPD: Reduce to a single 30 mg dose administered [illegible] (2.4)
- [illegible] (2.3)
- Prophylaxis (13 years and older): 75 mg once daily for at least

Most Common Adverse Reactions

- Adverse events that occurred more frequently in patients treated with Tamiflu than in patients taking placebo (frequency ≥ 2%) across clinical trials were nausea, vomiting, abdominal pain, ear disorder, and diarrhea
- The safety profile observed in pediatric patients 2 weeks to less than 1 year of age was consistent with the established safety profile of subjects aged 1 year and above, with vomiting, diarrhea and diaper rash being the most frequently reported adverse reactions

For additional important safety information, please see Tamiflu full prescribing information at www.tamiflu.com.

You are encouraged to report side effects to Genentech by calling 1-888-835-2555 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

References:

1. Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Updated September 4, 2014. Accessed October 2, 2014.
2. Centers for Disease Control and Prevention. Influenza symptoms and the Role of Laboratory Diagnostics. http://www.cdc.gov/flu/professionals/diagnosis/labrolesprocedures.htm. Updated December 9, 2011. Accessed October 2, 2014.
3. Centers for Disease Control and Prevention. Rapid Diagnostic Testing for Influenza: Information for Health Care Professionals. http://www.cdc.gov/flu/professionals/diagnosis/rapidclin.htm. Updated August 27, 2013. Accessed October 2, 2014.
4. National Institute of Allergy and Infectious Diseases. Is It a Cold or the Flu? http://www.niaid.nih.gov/topics/Flu/Documents/sick.pdf. Updated August 2014. Accessed October 2, 2014.
5. Whitley RJ, Hayden FG, Reisinger KS, et al. Oral oseltamivir treatment of influenza in children. *Pediatr Infect Dis J*. 2001;20:127-133.

Emergency Overrides

What overrides does GCHP allow?
Gold Coast Health Plan authorizes emergency 10 day supply overrides for members who need to have a prescription filled urgently.

What qualifies for an emergency override?
Some situations that would qualify for an override are any level of care changes, such as hospital discharges, moving into or out of an acute care facility, LTC, or other care environments.

How are emergency overrides obtained?
The pharmacy simply needs to call the pharmacy benefits manager, Script Care, to request the override and state the reason for the override. Script Care can be reached at 888-531-0998.

Who can request the override?
The override can be requested by the prescribing provider, the prescribing provider's agent, or the pharmacy.

Are there any limits to drugs that are eligible for the override requests?
No, there are no limits, but some high cost drugs or drugs with specialty dispensing/authorization criteria, such as Sovaldi or IVIG, will require plan approval before authorization will be given.

Formulary Changes

The following changes to the Gold Coast Health Plan formulary will be effective 1/1/2015:

Additions

Drug	Formulary Status/Change
Rasuvo (methotrexate) Auto-Injector	Added with a prior authorization
Invokamet (canagliflozin/metformin)	Added with a step therapy
Jublia (efinaconazole) Topical	Added with a prior authorization
Zydelig (idelalisib)	Added with a prior authorization
Striverdi Respimat (olodaterol)	Added
Jardiance (empagliflozin)	Added with a step therapy
Belsomra (suvexorant)	Added with a step therapy
Plegridy (peginterferon beta-1a)	Added with a prior authorization
Cerdelga (eligustat)	Added with a prior authorization
Voltaren Gel	Added with a prior authorization and a quantity limit
Testosterone topical (generic)	Added with a prior authorization

Criteria Changes

Drug	Formulary Status/Change
Foradil	Removed the prior authorization; Added a step therapy – must try/fail Striverdi Respimat
Serevent	Removed the prior authorization; Added a step therapy – must try/fail Striverdi Respimat
Androderm (testosterone)	Added criteria where generic testosterone must be tried/failed
Axiron (testosterone)	Added criteria where generic testosterone must be tried/failed
Glucagon	Changed prior authorization to allow first fill without an authorization

Removals

Drug	Formulary Status/Change
Lumigan	Removed from the formulary, generic now available
Targretin	Removed from the formulary, generic now available
Vigamox	Removed from the formulary, generic now available
Protopic	Removed from the formulary, generic now available
Cubicin	Removed from the formulary, generic now available
Patanase	Removed from the formulary, generic now available
Ritalin LA	Removed from the formulary, generic now available
Stromectol	Removed from the formulary, generic now available
Rapamune	Removed from the formulary, generic now available
Remodulin	Removed from the formulary, generic now available

FDA Alerts

FDA New Drug Approvals

The information included in this section will be 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 website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
KEYTRUDA	pembrolizumab	IV solution	KEYTRUDA is a human programmed death receptor-1 blocking antibody indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.
CONTRAVE	naltrexone/ bupropion	Tablet	CONTRAVE is indicated as an adjunct to a reduced-caloric diet and increased physical activity for chronic weight management in adults with a BMI of greater than 30 or greater than 27 with a co-mobidity (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia).
MOVANTIK	naloxegol	Tablet	MOVANTIK is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain.
TRULICITY	dulaglutide	Injectable	TRULICITY is a glucagon-like peptide (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
OTEZLA	apremilast	Tablet	OTEZLA is a phosphodiesterase-4 (PDE-4) inhibitor and is indicated for the treatment of adult patients with active psoriatic arthritis and patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
AKYNZEO	netupitant/ palonosetron	Capsules	AKYNZEO is a fixed combination of netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and palonosetron, a serotonin-3 ($5\text{-}HT_3$) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
HARVONI	ledipasvir/ sofosbuvir	Tablet	HARVONI is a combination fo ledipasvir, a hepatitis C virus (HCV) HS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.
ESBRIET	pirfenidone	Capsule	ESBRIET is a pyridine indicated for the treatment for idiopathic pulmonary fibrosis (IPF).
OFEV	nintedanib	Capsule	OFEV is a kinase inhibitor indicated for the treatment of idiopathy pulmonary fibrosis (IPF).
XIGDUO XR	dapagliflozin/ metformin	ER Tablet	XIGDUO XR is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

FDA Safety Labeling Changes

The information included in this section will be all safety labeling changes that are new or updated boxed warnings or contraindications. Click here to access this information from the FDA website.

Drug	Type of Change	Change
Eliquis (apixaban)	New Boxed Warning	• Premature discontinuation of Eliquis increases the risk of thrombotic events: Premature discontinuation of any oral anticoagulant, including Eliquis, increases the risk of thrombotic events. If anticoagulation with Eliquis is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant...
Estring (estradiol vaginal ring)	Updated Boxed Warning and New Contraindication	• Updated Boxed Warning to reflect current recommended estrogen-class labeling • Added the following 2 contraindications ‣ Known anaphylactic reaction or angioedema or hypersensitivity to Estring ‣ Known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders

Drug	Type of Change	Change
Zohydro ER (hydrocodone)	New Boxed Warning	• Neonatal Opioid Withdrawal Syndrome ‣ Prolonged use of Zohydro ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available... ‣ ...The concomitant use of Zohydro ER with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may results in an increase in hydrocodone plasma concentration. Monitor patients receiving Zohydro ER and any CYP3A4 inhibitor or inducer
Lumizyme	Updated Boxed Warnings and Contraindications	• Extensive changes to Boxed Warnings and Contra-indications. See the PI for more details
Pegasys	Updated Boxed Warnings and Contraindications	• All “Use with Ribavirin” sections removed from Boxed Warnings • Additional Contraindications ‣ When used in combination with other HCV antiviral drugs, all contra-indications also apply to Pegasys combination therapy ‣ Ribavirin is contraindicated in pregnant women and men whose female partners are pregnant
Revlimid	New Boxed Warning	• Significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with multiple myeloma receiving Revlimid with dexamethasone
Lidocaine Viscous	New Boxed Warning	• Post-marketing cases of seizures, cardiopulmonary arrest, and death in patients under the age of 3 years have been reported with use of Xylocaine 2% Viscous Solution when it was not administered in strict adherence to the dosing and administrative recommendations. In the setting of teething pain, Xylocaine Viscous Solution should generally not be used. For other countries, the use of the product in patients less than 3 years of age should be limited to those situations where safer alternatives are not available or have been tried and failed. To decrease the risk of serious adverse events with the use of Xylocaine 2% Viscous Solution, instruct caregivers to strictly adhere to the prescribed dose and frequency of administration and store the prescription bottle safely out of risk of children
Arthrotec (diclofenac/ misoprostol)	Added Contraindications	• Add contraindication for patients with active gastrointestinal bleeding
Halcion (triazolam)	Updated Contraindications	• Halcion is contraindicated with medications that significantly impair the oxidative metabolism mediated by cytochrome P450 3A4 (CYP3A4) including ketoconazole, itraconazole, and several HIV protease inhibitors

Drug	Type of Change	Change
Cymbalta	Updated Boxed Warnings	• Antidepressants increase 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 age 24; there was a reduction in risk with antidepressant use in patients aged 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 behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber
Dilatrate SR (isosorbide dinitrate), Monoket (isosorbide mononitrate), Nitro-DUR (nitroglycerine), nitroglycerine 5% in dextrose	Updated Contraindications	• Do not use in patients who are taking certain drugs for erectile dysfunction (phosphodiesterase inhibitors) such as sildenafil, tadalafil, or vardenafil. Concomitant use can cause severe hypotension, syncope, or myocardial ischemia • Do not use in patients who are taking soluble guanylate cyclase stimulator riociguat. Concomitant use can cause hypotension
Dutoprol (metoprolol succinate extended release/ HCTZ)	Added Contraindications	• Dutoprol is contraindicated in: ‣ Cardiogenic shock or decompensated heart failure ‣ Sinus bradycardia, sick sinus syndrome, and greater than first-degree block unless a permanent pacemaker is in place ‣ Anuria ‣ Hypersensitivity to metoprolol succinate or hydrochlorothiazide or to other sulfonamide-derived drugs
Xiaflex (collagenase clostridium histolyticum)	Added Contraindications	• Xiaflex is contraindicated in: ‣ The treatment of peyronie's plaque that involve the penile urethra due to potential risk to this structure ‣ Patients with a history of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic application or application method

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 from the ASHP Resource Center website.

Drug Product	Affected Manufacturers	Summary
Namenda XR	Forest	Namenda XR 7 mg, 14 mg, and 21 mg products are available only in limited supply; Namenda XR 28 mg is available
Methylphenidate ER (18 mg, 27 mg, 36 mg, 54 mg)	Actavis	Product is available as "Concerta" from Janssen-Ortho-McNeil

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 website.

Drug	Communications Summary
Xolair (omalizumab)	The FDA review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair (omalizumab) than in those who were not treated with Xolair. As a result, the FDA has added information about these potential risks to the drug label. Patients taking Xolair should continue to take their medication as prescribed and discuss any questions or concerns with their health care professionals.
Long-Term Antiplatelet therapy	The FDA is evaluating preliminary data from a clinical trial showing that treatment for 30 months with dual antiplatelet blood-thinning therapy decreased the risks of heart attacks and clot formation in stents, but there was an increased overall risk of death compared to 12 months of treatment. The clinical trial compared 30 months versus 12 months of treatment with dual antiplatelet therapy consisting of aspirin plus either clopidogrel or prasugrel, following implantation of drug-eluding coronary stents. The FDA believes the benefits og clopidogrel and prasugrel therapy continue to outweigh their potential risks when used for approved uses. Patients should not stop taking these drugs because doing so may result in an increased risk of heart attacks, blot clots, strokes, and other major cardiovascular problems. Health care professionals should not change the way they prescribe these drugs at this time.
Tecfidera (dimethyl fumarate)	The FDA is warning that a patient with multiple sclerosis (MS) who was being treated with Tecfidera (dimethyl fumarate), developed a rare and serious brain infection called PML, and later died. As a result, information describing this case of PML, or progressive multifocal leukoencephalopathy, is being added to the Tecfidera drug label. Patients taking Tecfidera should contact their health care professionals right away if they experience symptoms that concern them, such as new or worsening weakness; trouble using their arms or legs; or changes to thinking, eyesight, strength or balance. Health care professionals should stop Tecfidera if PML is suspected.
Geodon (ziprasidone)	The FDA is warning that the antipsychotic drug ziprasidone (marketed under the brand name, Geodon, and its generics) is associated with a rare but serious skin reaction that can progress to affect other parts of the body. A new warning has been added to the Geodon drug label to describe the serious condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Patients who have a fever with a rash and/or swollen lymph glands should seek urgent medical care. Health care professionals should immediately stop treatment with ziprasidone if DRESS is suspected.