Gold Coast Health Plan℠
A Public Entity

Gold Coast Health Plan Pharmacy Services Newsletter

Issue VII. Quarter 2, 2014

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CMO Message

by Al Reeves, M.D.

The Pharmacy and Therapeutics (P&T) Committee had a full agenda at its Feb 20th meeting. Gold Coast Health Plan (GCHP) is now actively reviewing denials and approvals of requests for medications which require prior authorization, have quantity limits or are not on the formulary. This data is now reported to the P&T Committee. Anne Freese, GCHP's director of pharmacy, has been reviewing the guidelines for each medication needing prior authorization, as well as medications that have quantity limits. These were presented to the Committee for review and for appropriate changes. The Committee managed to get through some of this process but will continue work on this project at our next meeting, in May.

Another large project underway is complying with the requirement that the Plan review all new medications approved by the FDA. Since that had not been done recently, the Committee reviewed all new medications approved by the FDA in 2013. As a result, a number of new medications have been added to the formulary. Most of these new medications are specialty medications, will have a prior authorization requirement and may also be restricted to a provider in a specific specialty.

One of the new medications added to the formulary is Sovaldi; a once-a-day prescription medicine that is used with other antiviral medicines to treat chronic hepatitis C. This medication is very expensive ($1,000 per tablet) and has now become the Plan's most costly medication; a course of treatment is $84,000 to $168,000. This drug is extremely effective with a sustained virologic response of 90% – 100%, in some studies. GCHP feels that it is important to make this treatment available to our members; however, we also want to make sure that the medication is being used appropriately. Its prescribing is limited to gastroenterologists or infections disease specialists and the Plan is case managing all of our members who have been prescribed the medication in order to insure that it is used properly.

As always, if you have any questions, please do not hesitate to reach out to me or Anne.

Reminder: New Address

This notice is to inform you that Gold Coast Health Plan (GCHP) relocated its headquarters to Camarillo, Calif., on April 7, 2014. As one of Gold Coast Health Plan's trusted external partners, we are providing you with this change of address notification. The new mailing address for Gold Coast Health Plan is:

Gold Coast Health Plan
711 E. Daily Drive
Suite 106
Camarillo, CA 93010-6082

Please update your records to replace any previous address with the new Gold Coast Health Plan mailing address.

HEDIS® Focus: Annual Monitoring for Patients on Persistent Medications (MPM)

The HEDIS® measurement of Annual Monitoring for Patients on Persistent Medications (MPM) focuses on the monitoring of certain lab values for select classes of medications:

- Angiotensin Converting Enzyme (ACE) Inhibitors or Angiotensin Receptor Blockers (ARB)
- Digoxin
- Diuretics
- Anticonvulsants

The table below indicates the labs required to meet the necessary monitoring:

Drug Class	Lab Monitoring for Compliance
ACE Inhibitors or ARBs Digoxin Diuretics	At least one of the following: • Lab panel • Serum potassium and serum creatinine • Serum potassium and serum BUN
Anticonvulsants	• Serum concentration for the prescribed drug

Potassium, Creatinine and BUN Monitoring

For the drug classes of ACE inhibitors/ARBs, digoxin, and diuretics, the levels of potassium, creatinine, and BUN may have profound effects on the therapeutic doses for which a patient may

need. Routine monitoring is recommended at initiation and annually for these drugs classes. The table below shows the normal levels of each of these laboratory parameters and brief information regarding the effect of abnormal values for each of these drugs classes:

Laboratory Parameter	Normal Value	Effects on Drug Treatment
Potassium	3.5 to 5 mEq/L	Digoxin: low levels of potassium increase the toxicity of digoxin and patients may experience toxicity at therapeutic doses of digoxin ACE inhibitor/ARB: may cause retention of potassium Diuretics: depletes potassium at unpredictable levels
Creatinine	0.6 to 1.2 mg/dL	Digoxin: increased creatinine levels signify a decrease in kidney function which may result in toxicity at therapeutic doses of digoxin ACE inhibitor/ARB/diuretics: increase creatinine levels
BUN	8 to 18 mg/dL	Digoxin: increased BUN signifies a decrease in kidney function which may result in toxicity at therapeutic doses of digoxin ACE inhibitor/ARB/diuretics: increase BUN levels

Anticonvulsant Drug Monitoring

The monitoring of therapeutic drugs involves measuring serum drug concentrations. This information is used to individualize dosages so that drug concentrations can be maintained within a target range. For a few anticonvulsants, concentration measurements are a valuable surrogate of drug exposure, particularly if there is no simple or sensitive measure of effect.

The following anticonvulsants are included in the HEDIS monitoring: phenobarbital, carbamazepine, phenytoin, divalproex sodium, and valproic acid. Additionally, routine monitoring is also recommended for lamotrigine and topiramate. The table below shows the recommended serum target ranges for each of these drugs.

Drug	Total Range
Phenytoin	10 to 20 mg/L
Carbamazepine	5 to 12 mg/L
Sodium Valproate	50 to 100 mg/L
Lamotrigine	1.5 to 3 mg/L
Topiramate	2.0 to 5.0 ug/mL
Phenobarbital	15 to 30 ug/mL for infants and children less than 5 15 to 40 ug/mL for adults

Formulary Changes

The following changes to the GCHP Formulary were made, effective 4/1/2014:

Drug	Formulary Status/Change
Qvar 40 mg, 80 mg	On formulary without restriction
Amitiza 8 mcg, 24 mcg	Added an additional step 1 agent of docusate when used for the indication of opioid induced constipation
Duloxetine	Added an additional step 1 agent of two SSRI or SNRI OR 1 non-SSRI/ SNRI agents when used for the treatment of general anxiety disorder
Delzicol	Added with a prior authorization
Procysbi	Added with a prior authorization
Brisdelle	Added with a prior authorization
Otrexup	Added with a prior authorization
Noxafil	Added with a step therapy where fluconazole must be tried and failed prior to approval
Invokana	Added with a step therapy where metformin and a sulfonylurea must be tried and failed prior to approval
Mirvaso	Added with a prior authorization
Duavee	Added with a step therapy where both Evista and alendronate must be tried and failed prior to approval
Adempas	Added with a prior authorization
Opsumit	Added with a prior authorization
Zohydro ER	Added with a prior authorization
Imbruvica	Added with a prior authorization
Sovaldi	Added with a prior authorization
Kynamro	Added with a prior authorization
Raviciti	Added with a prior authorization
Polmalyst	Added with a prior authorization
Stivarga	Added with a prior authorization
Tecfidera	Added with a prior authorization
Tafinlar	Added with a prior authorization
Mekinist	Added with a prior authorization
Gilotrif	Added with a prior authorization
Valchlor	Added with a prior authorization

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
Impavido	Miltefosine	Oral capsule	Impavido is an antileishmanial drug indicated for adults and adolescents ≥ 12 years of age weighing ≥ 30 kg for the treatment of visceral leishmaniasis due to Leishmania donovani, cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis, and mucosal leishmaniasis due to Leishmania braziliensis.
Neuraceq	Florbetaben F-18	Injection	Neuraceq is a radioactive diagnostic agent for PET scan
Tivorbex	Indomethacin	Oral capsule	Tivorbex is an NSAID indicated for the treatment of mild to moderate acute pain in adults.
Myalept	Metreleptin	SQ injection	Myalept is a leptin analog indicated as adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.
Northera	Droxidopa	Oral capsule	Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatis hypotension caused by primary autonomic failure, dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.
Vimizim	Elosulfase alfa	IV infusion	Vimizim is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquino A syndrome).
Hetlioz	Tasimelteon	Oral capsule	Hetlioz is a melatonin receptor agonist indicated for the treatment of Non-24-Hour Sleep Wake Disorder (Non-24)

FDA Safety Labeling Changes

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

Drug	Type of Change	Change
Stavzor (valprioc acid)	Modified black box warning	• Hepatotoxicity: new sections were added for the general population, patients under 2 years of age, and patients with mitochondrial disease
Xarelto	Modified black box warning	• Optimal timing between the administration of Xarelto and neuraxial procedures is not known
Diflucan	Modified contraindication	Coadministration of other drugs known to prolong the CT interval and which are metabolized via the enzyme CYP3A4 such as erythromycin... are contraindicated in patients receiving fluconazole
Evamist	Modified contraindications	• Known anaphylactic reaction or angioedema • Known protein C, protein S, or antithrombin deficiency, or other thrombophilic disorders
Promacta	Updated black box warning	• In patients with chronic hepatitis c, Promacta in combination with interferon and ribavirin may increase the risk of hepatic decompensation
Nizoral	Updated black box warning	• Addition of contraindicated medication... methadone, disopyramide, dronedarone, ranolazine
Bravelle	Updated contraindications	• Pregnancy... may cause fetal harm when administered to a pregnant woman... is contraindicated in woman who are pregnant. If this drug is used during pregnancy, or if the woman becomes pregnant while taking this drug, the woman should be apprised of the potential hazard to the fetus.
Juvisync	Updated contraindications	• Added... cobicistat-containing products
Menopur	Updated contraindications	• Pregnancy... may cause fetal harm when administered to a pregnant woman... is contraindicated in woman who are pregnant. If this drug is used during pregnancy, or if the woman becomes pregnant while taking this drug, the woman should be apprised of the potential hazard to the fetus.
Mevacor	Updated contraindications	• Added... cobicistat-containing products
Samsca	Updated contraindications	• Added hypersensitivity section
Vytorin	Updated contraindications	• Added... cobicistat-containing products
Simvastatin	Updated contraindications	• Added... cobicistat-containing products

Cozaar/Hyzaar	Updated black box warnings	• Added warning regarding fetal toxicity
Victrelis	Updated contraindications	• Added... alfusozin, doxazosin, silodosin, and tamsulosin

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	Affect Manufacturers	Summary
Fluorometholone Ophthalamic Ointment	Allergan	Shortage is not resolved
Ciprofloxacin IR products	Carlsbad Technology	All generic product by Carlsbad Technology has been discontinued; currently available from Dr. Reddy's, Teva, UDL, Actavis, and West-Ward
Leuprolide 14 Day Kit	Teva	Shortage due to manufacturing delays; product is available from Caraco or Sandoz
Methylphenidate 20 mg IR	Sandoz	Sandoz has methylphenidate on backorder, no other supply issues at this time
Pantoprazole	Aurobindo, Mylan, Torrent, Wockhard	Aurobindo expects product mid-April
Tamoxifen	Actavis, Mylan, Teva	Actavis expects product mid-to-late April; Teva expects product late-May
Mirtazapine	Mylan, Teva, Actavis	Mylan expects release in late-April or early-May; Teva expects product in early-June 2014
Cenestin/Enjuvia	Teva	0.625 and Cenestin 0.9 and 1.25 are backordered without an estimated date
Tetracycline	Teva	All products unavailable; Heritage products launched in 10/2013
Isoniazid	Versapharm	Versapharm discontinued all products; available from Sandoz, Mylan, and Teva
Liptruzet	Merck	All products recalled
Thiothixene	Mylan	1 mg product is backorder until mid-April and 10 mg is on backorder until mid-June
Methazolamide	Sandoz	All Sandoz products are backorder; product is available from Perrigo

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	Communication Summary
Revatio	The U.S. Food and Drug Administration (FDA) is clarifying its previous recommendation related to prescribing Revatio (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient
Doribax	The U.S. Food and Drug Administration (FDA) has concluded that Doribax (doripenem), an antibacterial drug that has been used to treat patients who develop pneumonia while on ventilators, carries an increased risk of death and lower clinical cure rates compared to use of imipenem and cilastatin for injection (marketed in the U.S. under the name Primaxin). Based on our analysis of data from a three-year clinical trial that was prematurely stopped in 2011 due to these safety concerns, we have approved changes to the Doribax drug label that describe these risks.
Onglyza (saxagliptin) and Kombiglyze XR (saxagliptin/metformin)	The U.S. Food and Drug Administration (FDA) has requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of the type 2 diabetes drug and heart failure. Our request resulted from a study[3,4] published in the New England Journal of Medicine (NEJM), which reported an increased rate of hospitalization for heart failure, when the heart does not pump blood well enough, with use of saxagliptin (marketed as Onglyza and Kombiglyze XR) compared to an inactive treatment.[1] The study did not find increased rates of death or other major cardiovascular risks, including heart attack or stroke, in patients who received saxagliptin. The manufacturer is expected to submit the trial data to FDA by early March 2014, after which we will conduct a thorough analysis and report our findings publicly.
FDA-approved testosterone products	The U.S. Food and Drug Administration (FDA) is investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. We have been monitoring this risk and decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy. We are providing this alert while we continue to evaluate the information from these studies and other available data, and will communicate our final conclusions and recommendations when the evaluation is complete.

OTC sodium phosphate drugs	The U.S. Food and Drug Administration (FDA) is warning that using more than one dose in 24 hours of over-the-counter (OTC) sodium phosphate drugs to treat constipation can cause rare but serious harm to the kidneys and heart, and even death. OTC sodium phosphate drug products include oral solutions taken by mouth and enemas used rectally. Consumers and health care professionals should always read the Drug Facts label for OTC sodium phosphate drugs and use these products as recommended on the label, and not exceed the labeled dose. Caregivers should not give the oral products to children 5 years and younger without first discussing with a health care professional. Health care professionals should use caution when recommending an oral dose of these products for children 5 years and younger. The rectal form of these products should never be given to children younger than 2 years.