Gold Coast Health Plan℠
A Public Entity

Gold Coast Health Plan Pharmacy Services Newsletter

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CMO Message — by Al Reeves, M.D.

This is the first opportunity that I have had to communicate updates on pharmacy issues in the Pharmacy Newsletter. January 2014 is a momentous month with the advent of the full institution of the Affordable Care Act (ACA). The Plan has worked hard to make the transition of our new members seamless and looks forward to providing care to those who previously did not have access and for those transitioning from the low income health program (LIHP).

Gold Coast Health Plan (GCHP) continues to strive to provide medically necessary pharmacy benefits in the most cost effective manner. The Plan applauds our providers in prescribing 86.4% generic medications. The appropriate use of generic medications greatly improves the Plan's ability to provide a cost effective pharmacy benefit.

GCHP recently added a new Pharmacy Director, Anne Freese, Pharm. D. Anne comes to us with a rich background in corporate pharmacy benefits. Her knowledge regarding the provision of the pharmacy benefit adds a great deal to our ability to assure that GCHP members receive the best possible service from the pharmacy benefit. Anne has been instrumental in the production of this publication and has made several new additions to the newsletter that we think will be beneficial to you. The FDA Alerts section includes the following: New Drugs to the Market, Drug Safety Labeling Changes, Current Drug Shortages and Safety Alerts.

I look forward to working with all of you during this historic time in health care reform.

Reminder: Continuum of Care and Grandfathering for New Members

GCHP offers a continuum of care provision for new members transitioning to GCHP from another health plan. This includes ACE for Adults enrollees who moved to GCHP as part of the LIHP transition. These members may continue medications they previously had been taking for up to 60 days, even if the medication is non-formulary or has a restriction in the GCHP Pharmacy Plan. The 60 days allows the member's physician time to review the medication in an effort to find a covered formulary medication that can be prescribed to the member. If there is no alternative medication available, the provider will need to request for that medication to be continued through GCHP's Pharmacy Benefit Manager (PBM) Script Care, LTD. Script Care may be reached via phone at 888-531-0889.

California Children's Services (CCS) Initiative

What is California Children's Services?

CCS is a statewide program that treats children with certain physical limitations and chronic health conditions or diseases. CCS can authorize and pay for specific medical services and equipment provided by CCS-approved specialists. The California Department of Health Care Services (DHCS) manages the CCS program. Larger counties operate their own CCS programs, while smaller counties share the operation of their program with state CCS regional offices in Sacramento, San Francisco and Los Angeles. The program is funded with state, county and federal tax monies, along with some fees paid by parents.

Who qualifies for CCS?

The program is open to anyone who:

- is under 21 years old;
- has or may have a medical condition that is covered by CCS;
- is a resident of California; and
- has a family income of less than $40,000 as reported on the adjusted gross income on the state tax form or whose out-of-pocket medical expenses for a child who qualifies are expected to be more than 20 percent of family income; or the child was previously covered under the Healthy Families Program.

Family income is not a factor for children who:

- need diagnostic services to confirm a CCS eligible medical condition; or
- were adopted with a known CCS eligible medical condition; or
- are applying only for services through the Medical Therapy Program; or
- have Medi-Cal full scope, no share of cost; or
- were previously covered under the Healthy Families Program.

What medical conditions does CCS cover?

Only certain conditions are covered by CCS. In general, CCS covers medical conditions that are physically disabling or require medical, surgical or rehabilitative services. There also may be certain criteria that determine if your child's medical condition is eligible. Listed below are categories of medical conditions that may be covered and some examples of each:

- Conditions involving the heart (congenital heart disease)
- Neoplasms (cancers, tumors)
- Disorders of the blood (hemophilia, sickle cell anemia)
- Endocrine, nutritional, and metabolic diseases (thyroid problems, PKU, diabetes)
- Disorders of the genito-urinary system (serious chronic kidney problems)
- Disorders of the gastrointestinal system (chronic inflammatory disease, diseases of the liver)
- Serious birth defects (cleft lip/palate, spina bifida)
- Disorders of the sense organs (hearing loss, glaucoma, cataracts)
- Disorders of the nervous system (cerebral palsy, uncontrolled seizures)
- Disorders of the musculoskeletal system and connective tissues (rheumatoid arthritis, muscular dystrophy)
- Severe disorders of the immune system (HIV infection)
- Disabling conditions or poisonings requiring intensive care or rehabilitation (severe head, brain, or spinal cord injuries, severe burns)
- Complications of premature birth requiring an intensive level of care
- Disorders of the skin and subcutaneous tissue (severe hemangioma)
- Medically handicapping malocclusion (severely crooked teeth)

GCHP Pharmacy Services CCS Guidelines:

GCHP has reviewed the "List of Covered Drugs" and has established "trigger medications" that prompt a review for CCS eligibility of the member. Certain formulary agents have been identified and coded to force a prior authorization if the member is under the age of 21 and the agent is applicable to a CCS covered condition. If a member is under age 21 and presents with an agent that may be used for a CCS covered condition to the pharmacy, the claim will be allowed to pay for 30 days. During those 30 days, Script Care, LTD. will work in conjunction with GCHP to identify those members who need a referral to CCS or who are already eligible for CSS and have an active service authorization request (SAR). If the member is already eligible for CCS and has an active SAR for the medication, the pharmacy will be instructed to bill the prescription to CCS and

will not be able to bill GCHP anymore for those CCS covered medications. If the member is not active with CCS or the current SAR with CCS does not cover the medication, the pharmacy will be allowed to continue billing GCHP for the medication.

Providers and pharmacies should be aware of CCS eligibility and billing requirements. Click here for further information regarding CCS policy and procedure.

Highlight: 2013-2014 Flu Season

The 2013-2014 flu season has arrived. The first week of 2014 shows continuing spread of influenza-like illness (ILI). The H1N1 virus has continued to dominate across the country. Thirty-five states are reporting wide spread geographic influenza activity; this is an increase from 25 states from the prior week. Of the 2,622 influenza-related hospitalizations reported since October 1, 2013, 61.2% are reported in individuals aged 18 to 64 years old which is a departure from the common pattern of most hospitalization being in individuals greater than 64 years old. The proportion of deaths attributed to pneumonia and influenza remains below the epidemic threshold to date. Four pediatric deaths occurred in the first week of 2014, 3 of the deaths were attributed to the H1N1 strain.

Anyone aged 6 months and older who has not yet received their vaccination this year should get one now. All flu vaccines for 2013-2014 are made to target this strain of the virus.

Since October 1, 2013, the CDC has tested 1,100 2009 H1N1, 79 influenza A (H3N2) and 17 influenza B virus samples for resistance to oseltamivir and zanamivir. To date this season, 13 H1N1 samples have shown resistance to oseltamivir while no virus samples have showed resistance to zanamivir.

GCHP covers oseltamivir (Tamiflu) and zanamivir (Relenza) without a prior authorization. Both agents have quantity restrictions which limit a prescription to a 5 or 10 day supply of medication appropriate to their respective dosing regimens.

Disease State Focus: Asthma

The following is a summary of the guidelines for the treatment of asthma. The information has been developed from the *Expert Panel Report 3: (EPR3): Guidelines for the Diagnosis and Management of Asthma* as published by the National Heart, Lung, and Blood Institute. Click here to access the full report.

The goals of therapy of asthma care are to reduce impairment and to reduce risk. Impairment is assessed by the presence of chronic and troublesome symptoms, use of short acting beta agonists, pulmonary function, ability to maintain normal activity levels and the expectations/ satisfaction of care. Risks are recurrent exacerbations, emergency department visits, hospitalizations, loss of lung function and potential adverse events of pharmacotherapy.

There are 4 components of asthma care: assessing and monitoring asthma severity and control, education, control of environmental factors and comorbid conditions, and medications. This article will focus on the medications component and the availability of those medications on the GCHP List of Covered Drugs.

The *Asthma Care Quick Reference: Diagnosing and Managing Asthma* is a streamlined easy-to-use summary of the current recommendations from the *EPR3*. Click here to access the document. The table on the following page is an excerpt from the reference that addresses the stepwise approach for managing asthma long term.

STEPWISE APPROACH FOR MANAGING ASTHMA LONG TERM

ASSESS CONTROL:

STEP UP IF NEEDED (first, check medication adherence, inhaler technique, environmental control, and comorbidities)

STEP DOWN IF POSSIBLE (and asthma is well controlled for at least 3 months)

		STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
At each step: Patient education, environmental control, and management of comorbidities							
0–4 years of age		**Intermittent Asthma**	**Persistent Asthma: Daily Medication** Consult with asthma specialist if step 3 care or higher is required. Consider consultation at step 2.				
	Preferred Treatment†	SABA* as needed	low-dose ICS*	medium-dose ICS*	medium-dose ICS* + either LABA* or montelukast	high-dose ICS* + either LABA* or montelukast	high-dose ICS* + either LABA* or montelukast + oral corticosteroids
	Alternative Treatment†,‡		cromolyn or montelukast				
		If clear benefit is not observed in 4–6 weeks, and medication technique and adherence are satisfactory, consider adjusting therapy or alternate diagnoses.					
	Quick-Relief Medication	• SABA* as needed for symptoms; intensity of treatment depends on severity of symptoms. • With viral respiratory symptoms: SABA every 4–6 hours up to 24 hours (longer with physician consult). Consider short course of oral systemic corticosteroids if asthma exacerbation is severe or patient has history of severe exacerbations. • Caution: Frequent use of SABA may indicate the need to step up treatment.					
5–11 years of age		**Intermittent Asthma**	**Persistent Asthma: Daily Medication** Consult with asthma specialist if step 4 care or higher is required. Consider consultation at step 3.				
	Preferred Treatment†	SABA* as needed	low-dose ICS*	low-dose ICS* + either LABA,* LTRA,* or theophylline[(b)] **OR** medium-dose ICS	medium-dose ICS* + LABA*	high-dose ICS* + LABA*	high-dose ICS* + LABA* + oral corticosteroids
	Alternative Treatment†,‡		cromolyn, LTRA,* or theophylline§		medium-dose ICS* + either LTRA* or theophylline§	high-dose ICS* + either LTRA* or theophylline§	high-dose ICS* + either LTRA* or theophylline§ + oral corticosteroids
			Consider subcutaneous allergen immunotherapy for patients who have persistent, allergic asthma.**				
	Quick-Relief Medication	• SABA* as needed for symptoms. The intensity of treatment depends on severity of symptoms: up to 3 treatments every 20 minutes as needed. Short course of oral systemic corticosteroids may be needed. • Caution: Increasing use of SABA or use >2 days/week for symptom relief (not to prevent EIB*) generally indicates inadequate control and the need to step up treatment.					
≥12 years of age		**Intermittent Asthma**	**Persistent Asthma: Daily Medication** Consult with asthma specialist if step 4 care or higher is required. Consider consultation at step 3.				
	Preferred Treatment†	SABA* as needed	low-dose ICS*	low-dose ICS* + LABA* **OR** medium-dose ICS*	medium-dose ICS* + LABA*	high-dose ICS* + LABA* **AND** consider omalizumab for patients who have allergies††	high-dose ICS* + LABA* + oral corticosteroid§§ **AND** consider omalizumab for patients who have allergies††
	Alternative Treatment†,‡		cromolyn, LTRA,* or theophylline§	low-dose ICS* + either LTRA,* theophylline,§ or zileuton‡‡	medium-dose ICS* + either LTRA,* theophylline,§ or zileuton‡‡		
			Consider subcutaneous allergen immunotherapy for patients who have persistent, allergic asthma.**				
	Quick-Relief Medication	• SABA* as needed for symptoms. The intensity of treatment depends on severity of symptoms: up to 3 treatments every 20 minutes as needed. Short course of oral systemic corticosteroids may be needed. • Caution: Use of SABA >2 days/week for symptom relief (not to prevent EIB*) generally indicates inadequate control and the need to step up treatment.					

* **Abbreviations:** EIB, exercise-induced bronchospasm; ICS, inhaled corticosteroid; LABA, inhaled long-acting beta$_2$-agonist; LTRA, leukotriene receptor antagonist; SABA, inhaled short-acting beta$_2$-agonist.

† Treatment options are listed in alphabetical order, if more than one.

‡ If alternative treatment is used and response is inadequate, discontinue and use preferred treatment before stepping up.

§ Theophylline is a less desirable alternative because of the need to monitor serum concentration levels.

** Based on evidence for dust mites, animal dander, and pollen; evidence is weak or lacking for molds and cockroaches. Evidence is strongest for immunotherapy with single allergens. The role of allergy in asthma is greater in children than in adults.

†† Clinicians who administer immunotherapy or omalizumab should be prepared to treat anaphylaxis that may occur.

‡‡ Zileuton is less desirable because of limited studies as adjunctive therapy and the need to monitor liver function.

§§ Before oral corticosteroids are introduced, a trial of high-dose ICS + LABA + either LTRA, theophylline, or zileuton, may be considered, although this approach has not been studied in clinical trials.

The drug classes noted in the table above are listed below with the specific agents that are available on the GCHP List of Covered Drugs with any restrictions noted. Any agents not listed in the tables below will require an approved prior authorization in order to be covered and generally will require trial and failure of all agents listed below. Brand drugs are listed in all capitals and generics are listed in lower case and italicized.

Short Acting Beta Agents

COVERED AGENT	RESTRICTIONS
VENTOLIN HFA	Limited to 2 inhalers per 31 days
XOPENEX/XOPENEX HFA	Requires prior trial and failure of albuterol

Inhaled Corticosteroid

COVERED AGENT	RESTRICTIONS
FLOVENT HFA	Limited to 2 inhalers per 31 days for the 44 mcg product, and 1 inhaler per 31 days for the 110 mcg and the 220 mcg products
ASMANEX	Requires prior trial and failure of Flovent
PULMICORT FLEXHALER	Limited to 1 inhaler per 31 days
PULMICORT (solution for nebulizer)	Requires prior trial and failure of Flovent HFA or Pulmicort HFA

**At this time, Qvar is being evaluated by the P&T Committee for potential addition to the formulary and may result in the removal of one of the above listed agents.

Leukotriene Receptor Modifier

COVERED AGENT	RESTRICTIONS
montelukast	Requires a prior authorization stating that long term controller medications (inhaler corticosteroids and long-acting beta agonists) have been tried and failed
zafirlukast	Requires a prior authorization stating that long term controller medications (inhaler corticosteroids and long-acting beta agonists) have been tried and failed

Long Acting Beta Agonist

COVERED AGENT	RESTRICTIONS
FORADIL	Limited to 1 pack per 31 days
BROVANA	Requires prior trial and failure of Foradil
SEREVENT	Requires prior trial and failure of Foradil

Combination Products

COVERED AGENT	RESTRICTIONS
ADVAIR HFA/ADVAIR Diskus	Limited to 1 pack or 1 inhaler per 31 days
SYMBICORT	Limited to 1 inhaler per 31 days

Other Agents

COVERED AGENT	RESTRICTIONS
Aerochamber	Limited to 1 per year
theophylline	
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

FDA Alerts

The following FDA Alerts sections will be a new standard feature of the GCHP Pharmacy Newsletter.

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
Farxiga	Dapagliflozin	Oral tablet	Farxiga is a new sodium-glucose transporter 2 inhibitor (SGT2) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Isentress	Reltegravir	Oral suspension	Isentress is now available as an oral suspension for the treatment of HIV-1.
Orenitram	Teprostinil	Extended release oral tablet	Orenitram is a prostacyclin vasodilator indicator for the treatment of pulmonary arterial hypertension (WHO group 1) to increase exercise capacity. Teprostinil is already available to treat PAH as an injection (Remodulin) and an inhalation product (Tyvaso). Orenitram is an extended release oral tablet taken 2 to 3 times a day.

BRAND NAME	GENERIC NAME	Dosage Form	Summary of Indication and Mechanism of Action
Kuvan	Sapropterin	Powder for oral suspension	Kuvan is now available in a powder for oral suspension to reduce the blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia caused by tetrahydrobiopterin (BH4) responsive phenylketonuria
Anoro Ellipta	Umeclidinium; vilanterol	Powder for inhalation	Anoro Ellipta is a combination or umeclidinium, an anticholinergic and vilanterol, a long acting beta-agonist, indicated for the long-term, once daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)
Sovaldi	Sofosbuvir	Oral tablet	Sovaldi is a hepatitis C virus (HCV) neucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Sovaldi is indicated for use in genotypes 1, 2, 3 and 4, in patients who are co-infected with HCV/HIV-1 infection, and for use in patients with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplant).
Velphoro	Sucroferric oxyhydroxide	Chewable oral tablet	Velphoro is a an iron-based, calcium-free, chewable phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.
Varithena	Polidocanol	Solution (IV)	Varithena is a sclerosing agent indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.
Noxafil	Posaconazole	Delayed release tablet	Noxafil is now available in a delayed release tablet formulation for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients, 13 year sof age and older, who are at increased risk of developing these infections due to being severely immunocompromised.
Olysio	Simprevir	Oral tablet	Olysio is a hepatits C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.
Luzu	Luliconazole	Topical cream	Lulu is an azole antifungal indicated for the treatment of topical interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum*, and *Epidermophyton floccusum* in patients 18 years of age and older.

BRAND NAME	GENERIC NAME	Dosage Form	Summary of Indication and Mechanism of Action
Imbruvica	Ibrutinib	Oral capsule	Imbruvica is a kinase inhibitor indicated for the treatment of patient with mantel cell lymphoma (MCL) who have received at least 1 prior therapy.
Aptiom	Eslicarbazepine Acetate	Oral tablet	Aptiom is indicated as adjunctive treatment of partial-onset seizures.
Gazyva	Obinutuzumab	Injectable	Gazyva is a CD20-directed cytolytic antibody and is indicated, in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia.

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
Iclusig (ponatinib)	New black boxed warning	Vascular Occlusion: • Arterial and venous thrombosis and occlusions have occurred in at least 27% of Iclusig treated patients, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors, including patients age 50 years or younger, experienced these events • Monitor for evidence of thromboembolism and vascular occlusion. Interrupt or stop Iclusig immediately for vascular occlusion. A benefit risk consideration should guide a decision to restart Iclusig therapy

DRUG	Type of Change	Change
Tysabri (natalizumab)	Updated black boxed warning	Progressive Multifocal Leukoencephalopathy • TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. These factors should be considered in the context of expected benefit when initiating and continuing treatment with TYSABRI • Healthcare professionals should monitor patients on TYSABRI for any new sign or symptom that may be suggestive of PML. TYSABRI dosing should be withheld immediately at the first sign or symptom suggestive of PML. For diagnosis, an evaluation that includes a gadolinium-enhanced magnetic resonance imaging (MRI) scan of the brain and, when indicated, cerebrospinal fluid analysis for JC viral DNA are recommended • Because of the risk of PML, TYSABRI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TOUCH Prescribing Program
Tikosyn (dofetilide)	Updated contraindication	…In addition, other known inhibitors of the renal cation transport system such as… dolutegravir should not be used in patients on TIKOSYN
PrevPac (lansoprazole, amoxicillin, clarithromycin)	Updated contraindications	• History of severe hypersensitivity reactions (e.g.,anaphylaxis or Stevens-Johnson syndrome) to amoxicillin or other beta-lactam antibiotics (e.g., penicillins and cephalosporins) is a contraindication. • Clarithromycin should not be given to patients with history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes. • Clarithromycin should not be used concomitantly with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.
Zestoretic (Lisinopril and hydrochlorothiazide)	Updated contraindication	• Do not co-administer aliskiren with ZESTORETIC in patients with diabetes
Zestoril (Lisinopril)	Updated contraindication	• Do not co-administer aliskiren with ZESTORIL in patients with diabetes

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
Tetracycline	Teva and Watson	Teva and Watson temporarily discontinued all tetracycline products; available from Heritage; Teva stated shortage is due to a raw material shortage
Buprenorphine 2 mg sublingual tablets	Teva	Updated 1/8, all products are available
Cephalexin Oral Susp 125 mg/5 ml	Lupid	Lupid is allocating all cephalexin oral suspension products; available from Ranbaxy
Clarithromycin IR tablets	Ranbaxy, Apotex, Teva, and Wockhardt	Shortage is due to regulatory delay, import bans, and halted production; Teva is expected to be available in February 2014
Doxazosin Tablets	Apotex, Dana	Shortage is due to high market demands; Dana is expected be available in January of 2014
Ethambutol tablets	Teva, X-Gen, Versa,	Shortage due to change in manufacturing facilities; expected to be available in late-February 2014
Tamoxifen	Mylan, Teva	Mylan has discontinued the product, but Teva has limited supply with release dates of March of 2014
Neostigmine Bromide tablets	Valeant	No additional information available

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
Iclusig	Increased reports of serious blood clots in arteries and veins were reported from Iclusig. The FDA asked the manufacturer of Iclusig to suspend marketing of the drug pending further investigation. The FDA required the manufacturer to add new safety measures for Iclusig and the labeling was updated with new black boxed warnings. The manufacturer is expected to resume marketing.
Methylphenidate and Risk of Long Acting Erections	The FDA warned of the rare risk of long acting erections in males taking methylphenidate for the treatment of ADHD. New safety labeling was approved.
Onfi	The FDA warned of the risk of rare skin reactions (Stevens Johnson Syndrome and Toxic Epidermal Necrolysis) with the anti-seizure drug Onfi. New safety labeling was approved.
Rosiglitazone	The FDA determined that recent data provided by the Duke Clinical Research Institute showed that rosiglitazone-containing medications used for the treatment of type 1 diabetes do not show an increase risk of heart attack compared to the standard treatment with metformin and a sulfonylurea. Prescribing and labeling restrictions added to the marketing of rosiglitazone products in 2010 have been removed.