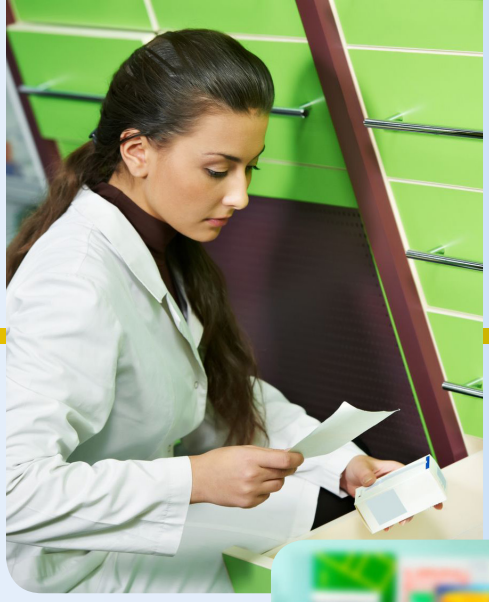

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

APRIL 2015

Q2

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CMO Message

C. Albert Reeves, MD

Springtime is here and Gold Coast Health Plan (GCHP) is in the middle of the HEDIS® reporting season. I want to take this opportunity to remind our providers of the pharmacy issues that affect the Plan's HEDIS® rates and are also indicative of good care. Our current HEDIS® audit will be measuring care given in 2014, so what you do today will not affect our 2015 rates; however, what you do today *will* affect our 2016 rates. Remember, there's no time like the present to follow the guidelines of good care.

The following are pharmacy issues related to our HEDIS® outcomes:

1. **Antibiotic Use in the Treatment of Bronchitis:** Antibiotics are not indicated for the treatment of a viral bronchitis and would be considered inappropriate to use in those circumstances.
2. **Hypertension:** It is expected that medications will be given to control hypertension to recommended levels.
3. **Hemoglobin A1c:** It is expected that patients will have their Hgb A1C measured and controlled to at least a level under 9%. Of course, the control includes all of the life style changes to lower blood sugars and A1C as well as the medications needed to get those values to recommended levels.

   GCHP recently approved The American Diabetes Assn. Standards of Medical Care in Diabetes-2015 as the guideline to be used for diabetes care of GCHP members. This publication includes comprehensive guidelines for the use of medications in the treatment of diabetics.

   Click here to access all clinical practice guidelines established by GCHP's Medical Advisory Committee (MAC), on the GCHP website.

4. **Treatment of Asthma:** It is expected that patients with persistent asthma be treated with preventive medications.
5. **Use of Certain Drugs:** ACE Inhibitors, Digoxin and diuretics – it is expected that appropriate (at least annually) monitoring of electrolytes is done when patients are taking these medications.

I know that all of our providers are interested in providing the best care possible to their patients and GCHP members. In our 2014 HEDIS® survey, GCHP met the 25th percentile requirement which is the minimum set by the Department of Healthcare Services (DHCS).

GCHP's goal is to provide the recommended care to our members 100% of the time. With your help, I'm hopeful we'll accomplish this goal. Thanks again for your effort and as always, please do not hesitate to contact me or GCHP's Director of Pharmacy, Anne Freese if you have any questions or if we can be of further assistance.

Regards,

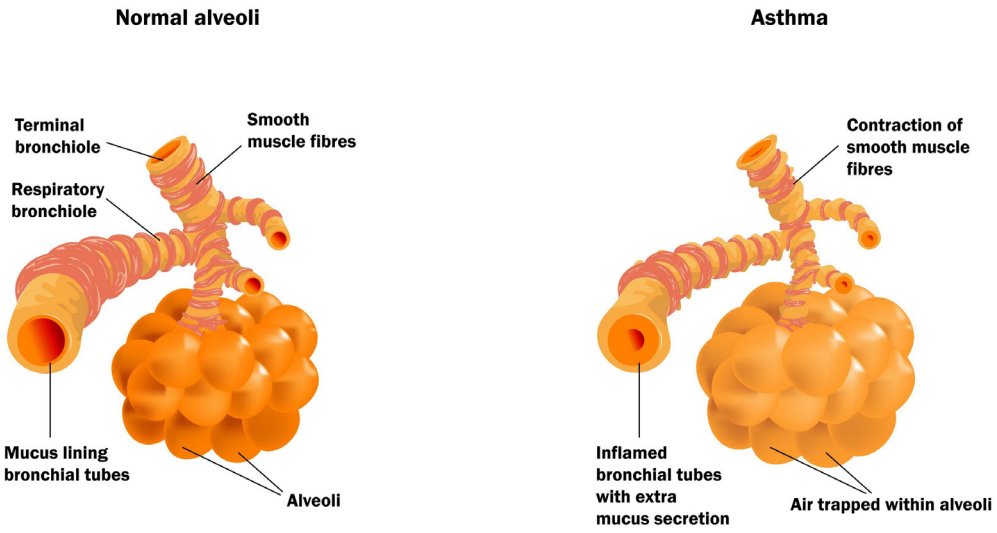
C. Albert Reeves M.D.

Asthma/COPD Inhaler Update

GCHP wanted to take this opportunity to discuss several new inhalers that were added to the formulary for GCHP members.

The table below lists all of the available maintenance inhalers, their components, mechanisms of action and formulary status. Additionally, the AWP of each inhaler is included for price comparisons.

Mechanism of Action	Brand Name	Generic Name	Formulary Status	Cost
Anticholinergic-Long Acting	Incruse ELLIPTA	umeclindinium	Formulary	$269.71
	Tudorza	aclidinium	Formulary	$337.68
	Spiriva Handihaler	tiotropium	Formulary	$357.37
	Spiriva Respimat	tiotropium	Formulary	$357.37
Inhaled Corticosteroid	Aerospan	flunisolide	Non-formulary	$193.75
	Pulmicort Flexhaler	budesonide	Formulary	$204.20
	Arnuity ELLIPTA	fluticasone	Formulary	$209.48
	Qvar	beclomethasone	Formulary	$209.48
	Flovent Diskus	fluticasone	Formulary	$218.24
	Alvesco	ciclesonide	Non-formulary	$227.44
	Asmanex Twisthaler	mometasone	Step Therapy – Must T/F Flovent	$315.50
	Flovent HFA	fluticasone	Requires a step therapy for age > 12 (T/F Arnuity ELLIPTA)	$338.98
Long Acting Beta-Agonist (LABA)	Striverdi Respimat	olodaterol	Non-formulary	$186.84
	Arcapta Neohaler	indacaterol	Non-formulary	$220.04
	Foradil	formoterol	Requires PA	$265.28
	Serevent Diskus	salmeterol	Formulary	$266.11
LABA-Anticholinergic	Anoro ELLIPTA	umeclindinium / vilanterol	Requires PA for age < 18	$337.14
LABA-Corticosteroid	Symbicort	budesonide / formoterol	Formulary	$207.42
	Dulera	mometasone / formoterol	Non-formulary	$287.64
	Breo ELLIPTA	fluticasone / vilanterol	Non-formulary	$321.20
	Advair Diskus	fluticasone / salmeterol	Formulary	$447.82
	Advair HFA	fluticasone / salmeterol	Formulary	$447.82



GCHP would like to draw your attention to the ELLIPTA product line available by GSK. The ELLIPTA is the inhaler device used for each of the inhalers that include ELLIPTA in its name. It is an inhaler device very similar to the diskus device currently available with Advair and Flovent. However, the device has a larger dose counter for greater visibility, stands up, and removes the step of having to pierce the cartridge separately from opening the device.

All of the ELLIPTA products which are maintenance products for the treatment of COPD or Asthma are to be used in a similar fashion which helps to streamline the administration process for members. This is a huge patient convenience factor for members who are having trouble remembering how to use the different inhaler devices that they may be using.

Please consider the use of ELLIPTA devices for members who are having difficulty with using their inhaler devices.

Reference Links for Additional Information Regarding the Treatment of Asthma and COPD:

Global Strategy for Diagnosis, Management, and Prevention of COPD (GOLD Guidelines) can be accessed at www.goldcopd.org

GINA Report, Global Strategy for Asthma Management and Prevention (GINA) can be accessed at www.ginaasthma.org

Formulary Changes

The following changes to the Gold Coast Health Plan formulary will be effective 4/1/2015:

Additions

Drug	Formulary Status/Change
Incruse Ellipta	Added to the formulary
Afrezza	Added to the formulary with a prior authorization
Trulicity	Added to the formulary with a step therapy
Harvoni	Added to the formulary with a prior authorization
Esbriet	Added to the formulary with a prior authorization
Ofev	Added to the formulary with a prior authorization
Arnuity Ellipta	Added to the formulary
Spiriva Respimat	Added to the formulary
Uceris	Added to the formulary with a step therapy
Sotylize	Added to the formulary with a prior authorization

Criteria Changes

Drug	Formulary Status/Change
Flovent HFA	Added a step therapy for all new starts for age greater than 12
All antidiabetic steps (Actos, oOnglyza, Januvia, Invokana, Jardiance, Tanzeum, Byetta, Victoza product families)	Loosened the step therapy requirement to require only metformin as the step 1 agent and if HbA1c is greater than 9 at time of prescribing, the step therapy is not required
Anoro Ellipta	Loosened the prior authorization requirement to only individuals less than 18 years of age

Removals

Drug	Formulary Status/Change
Valcyte Tablets	Removed from the formulary, generic now available
Taxotere Injection	Removed from the formulary, generic now available
Cellcept for Oral Suspension	Removed from the formulary, generic now available
Vivelle Dot	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
OBREDON	Guaifenesin; hydrocodone bitartrate	Oral solution	Symptomatic relief of cough and to loosen mucus associated with the common cold
HYSINGLA	hydrocodone bitartrate	24H ER tablet	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (i.e. nonopioid analgesics, immediate-relief opioids) are inadequate
BLINCYTO	blinatumomab	IV Solution	Treatment of Philadelphia chromosome-negative relapsed or refractory β-cell precursor acute lympho-blastic leukemia
XTORO	finafloxacin	Otic suspension	Treatment of acute otitis externa, commonly known as swimmer's ear, caused by *P. aeruginosa* and *S. aureus*
LYNPARZA	olaparib	Oral capsule	Treatment (monotherapy) of deleterious or suspect-ed deleterious germline BCRA mutated (as detected by an approved test) advanced ovarian cancer in patients who have been treated with 3 or more prior lines of chemotherapy
RAPIVAB	peramivir	IV solution	Treatment of acute, uncomplicated influenza in adults who have been symptomatic for 2 days or less
VIEKIRA PAK	dasabuvir; ombitasvir; paritaprevir; ritonavir	Tablet therapy pack	Treatment of genotype 1 chronic hepatitis C virus infection, with or without ribavirin, including those with compensated cirrhosis
ZERBAXA	ceftolozane; tazo-bactam	IV solution	Treatment of complicated intra-abdominal infections in adults, in combination with metronidazole, and complicated urinary tract infections in adults caused by susceptible organisms
OPDIVO	nivolumab	IV solution	Treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and (if BRAF V600 mutation positive) a BRAF inhibitor; Treatment of metastatic squamous cell non-small cell lung cancer that has progressed on or after plati-num-based chemotherapy

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SAVAYSA	edoxaban	Oral tablet	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF)
COSENTYX	secukinumab	Prefilled syringe (SQ)	Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
NATPARA	parathyroid hormone	Multi-dose pen device	Adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
TRIFERIC	ferric pyrophosphate citrate	Injection solution	Replacement of iron to maintain hemoglobin in adults patients with hemodialysis-dependent chronic kidney disease (HDD-CKD)
GLYXAMBI	empagliflozin; linagliptin	Oral tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (non-insulin dependent)

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
Arava (leflunomide)	Updated contraindications	• Arava is contraindicated in patients with known hypersensitivity to leflunomide, teriflunomide, or any other components of Arava.
Unasyn (ampicillin/sulbactam)	Updated contrainidications	• Unasyn is contrainidicated in patients with a previously history of cholestatic jaundice/hepatic dysfunction associated with Unasyn.
Aciphex (rabeprazole); Nexium (esomeprazole)	Updated contraindications	• ...contraindicated in patients with a known hypersensitivity to substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.
Dexilant (dexlansoprazole)	Updated contraindications	• ...acute interstitial nephritis has been reported with other proton pump inhibitors, include lansoprazole.
Prevacid (lansoprazole); Protonix (pantoprazole	Updated contraindications	• ...hypersensitivity reactions include anaphylacis, anaphylactic shock, angioedema, bronchospasms, acute interstitial nephritis, and urticaria.
Lastacaft (alcaftadine)	New contraindication	• Lastacaft is contraindicated in patients with hypersensitivity to any component in the product.
Onfi (clobazam)	New contraindication	• ...contraindicated in patients with a known history of hypersensitivity to the drug or its ingredients.
Somatuline (lanreotide)	Updated contraindications	• Somatuline Depot is contraindicated in patients with history of hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide...
Tecfidera (dimethyl fumarate)	New contraindication	• Tecfidera is contraindicated in patients with known hypersensitivity to dimethyl fumarate or to any of the excipients of Tecfidera. Reactions have included anaphylaxis and angioedema.

Drug	Type of Change	Change
Vibativ (telavancin)	New contrainidication	• Intravenous Unfractionated Heparin Sodium: Use of intravenous unfractionated heparin sodium in contraindicated with Vibativ administration because the activated partial thromboplastin time (aPTT) test results are expected to be artificially prolonged for 0 to 18 hours after Vibativ administration.
Wellbutrin (bupropion)	Updated contraindications	• Wellbutrin XL is contraindicated in patients undergoing abrupt discontinuation of … barbiturates, and antiepileptic drugs. • ...there is an increased risk of hypertensive reactions when Wellbutrin XL is used concomitantly with MAOIs. • Wellbutrin XL is contraindicated in patients with known hypersensitivity to bupropion or other ingredients of Wellbutrin XL. • Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported.
Fragmin (dalteparin sodium)	Updated blackbox warning	• Optimal timing between the administration of Fragmin and neuraxial procedures is not known.
Remicade (infliximab)	Edited blackbox warnings	• Changes to the Warnings: Serious Infections and Malignancy were made. Please see the FDA website for specific details.
Atripla (efavirenz/ emtricitabine/ tenofovir)	Updated contraindications	• Coadministration of Atripla with vorizonazole is contraindicated. Efavirenz, a component of Atripla, significantly decreases voriconazole plasma concentrations , and coadministration may decrease the therapeutic effectiveness of voriconazole. Also, voriconazole significantly increase efavirenz plasma concentrations, which may increase the risk of efavirnez-associated side effects. Because Atripla is a fixed dose combination product, the dose of efavirenz cannot be altered.
Isordil Titradose (isosorbide dinitrate)	Updated contraindications	• Do not use Isordil Titradose 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 Isordil Titradose in patients who are taking the soluble guanylate cyclase stimulator riociguat. Concomitant use can cause hypotension.
Lotensin (benazepril)	Updated contraindications	• Do not co-administer aliskiren with angiotension receptor blockers, ACE inhibitors, including Lotensin in patients with diabetes.
Nitrolingual (nitroglycerin)	Update contraindications	• Severe Anema: Nitrolingual Pumpspray is contraindicated in patients with severe anemia (large doses of nitroglycerin may cause oxidation of hemoglobin to methemoglobin and could exacerbate asthma. • Increase intracranial pressure: Nitrolingual Pumpspray may precipitate or aggravate intracrandial pressure and thsu should not be used in patients with possible increased intracranial pressure (e.g. cerebral hemorrhage or traumatic brain injury). • Hypersensitivity: Nitrolingual Pumpspray is contraindicated in patients who are allergic to nitroglycerin, other nitrates, or nitrates or any excipient. • Circulatory Failure and Block: Nitrolingual Pumpspray is contraindicated in patients with acute circulatory failure or shock.

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
Azathioprine	Roxane, Salix, and Zydus	Product is available from Mylan and Prometheus
Disopyramide	Pfizer	Product is available from Actavis and Teva
Fluoxymesterone	Upsher-Smith	FDA is awaiting for a supplemental approval from another manufacturer
Thyrolar	Forest	No anticipated release date; potentially up to 1 year
Namenda XR	Forest	Blister packs are being discontinued; available as 30 count bottles
Methylin Chewables	Shinogi	Unavailable at this time
Methylphenidate ER tablets	Actavis, Janssen, Sandoz, Teva	Available from Mallinckrodt and UCB (as Metadate)
Bystolic 20 mg	Forest	Available as 10 mg tablets
Doral	Sciecure	Unavailable at this time
Reserpine	Sandoz	Unavailable at this time

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
Feraheme (ferumoxytol) 	The U.S. Food and Drug Administration (FDA) is strengthening an existing warning that serious, potentially fatal allergic reactions can occur with the anemia drug Feraheme (ferumoxytol). We have changed the prescribing instructions and approved a *Boxed Warning*, FDA's strongest type of warning, regarding these serious risks. Also added is a new Contraindication, a strong recommendation against use of Feraheme in patients who have had an allergic reaction to any intravenous (IV) iron replacement product. Health care professionals should follow the new recommendations in the drug label. Patients should immediately alert their health care professional or seek emergency care if they develop breathing problems, low blood pressure, lightheadedness, dizziness, swelling, a rash, or itching during or after Feraheme administration.
Sofosbuvir and Amiodarone 	The U.S. Food and Drug Administration (FDA) is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. We are adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. We are recommending that health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct acting antiviral, such as the investigational drug daclatasvir or Olysio (simeprevir), with amiodarone. Patients should not stop taking any of their medicines without first talking to their health care professionals.

Drug	Communications Summary
Zyprexa Relprevv (olanzapine pamoate) 	The U.S. Food and Drug Administration (FDA) has concluded a review of a study undertaken to determine the cause of elevated levels of the injectable schizophrenia drug Zyprexa Relprevv (olanzapine pamoate) in two patients who died. The study results were inconclusive. We are unable to exclude the possibility that the deaths were caused by rapid, but delayed, entry of the drug into the bloodstream following intramuscular injection. The study suggested that much of the drug level increase could have occurred after death, a finding that could explain the extremely high blood levels found in the two patients who died 3 to 4 days after receiving injections of appropriate doses of Zyprexa Relprevv. On the basis of all of the information reviewed, we are not recommending any changes to the current prescribing or use of Zyprexa Relprevv injection at this time. Patients should not stop receiving treatment without first talking to their health care professionals.
Chantix (varenicline) 	The U.S. Food and Drug Administration (FDA) is warning that the prescription smoking cessation medicine Chantix (varenicline) can change the way people react to alcohol. In addition, rare accounts of seizures in patients treated with Chantix have been reported. We have approved changes to the Chantix label to warn about these risks. Until patients know how Chantix affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink. Patients who have a seizure while taking Chantix should stop the medicine and seek medical attention immediately.
Testosterone 	The U.S. Food and Drug Administration (FDA) cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone. We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.
Injectable antidiabetic pen devices 	In an effort to reduce the serious risk of infection spread through sharing of multi-dose diabetes pen devices intended for single patient use only, the U.S. Food and Drug Administration (FDA) is requiring additional label warnings prohibiting sharing of these injectable medicines. Insulin pens and pens for other injectable diabetes medicines should never be shared among patients, even if the needle is changed. Sharing pens can result in the spread of serious infections from one patient to another. To promote safe use, we are requiring that pens and packaging containing multiple doses of insulin and other injectable diabetes medicines display a warning label stating "For single patient use only."
Pain medication during pregnancy 	The U.S. Food and Drug Administration (FDA) is aware of and understands the concerns arising from recent reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, we evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. We urge pregnant women to always discuss all medicines with their health care professionals before using them.