Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

July 23, 2014 - Q3

www.goldcoasthealthplan.org

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SECTION 1: CMO Message

The use of opioid medications continues to be very high by Gold Coast Health Plan (GCHP) members. In June 2014, the single medication that was the most prescribed with 4480 prescriptions was hydrocodone/acetaminophen. The next most used medication was metformin with 3298 prescriptions. The class of opioid medications had 7897 prescriptions filled. This was second to the antidepressant class that had 8640 prescriptions provided. There is increasing evidence that the use of opioid medications for chronic pain is not effective and potentially harmful.

Attached for your review is a **power point presentation** on the use of opioids for chronic non-cancer pain. I encourage you to go through the slides and take the test at the end. The presentation was prepared by Dr. Binit Shah. Dr. Shah is the Director of the Intensive Care Unit at Ohio Hospital for Psychiatry. He received his medical degree from Northeast Ohio Medical University. Dr. Shah completed both a psychiatry and anesthesiology residency at George Washington University Hospital in Washington, D.C. and a pain management fellowship at University Hospitals Case Medical Center. He is board certified by the American Board of Psychiatry and Neurology in both psychiatry and pain management.

Also, I am providing a link to the **Medical Board of California Guidelines** for Prescribing Controlled Substances for Pain. I would also encourage our providers to be familiar with these guidelines and apply them to your process when prescribing controlled medications.

SECTION 2: Disease State Focus: Hepatitis C Treatment with Sovaldi or Olysio

On July 1, 2014, the Department of Health Care Services (DHCS), which provides oversight of GCHP, established a statewide guideline for the treatment of Hepatitis C with the newly approved drugs Sovaldi and Olysio. This guideline will be implemented across the state for Medi-Cal Fee-For-Service members and members in a Medi-Cal managed care plan. GCHP supports the guideline and will assess requests for the use of Solvadi and Olysio as outlined in the policy. **Click here** to access the policy.

SECTION 3: Prior Authorization Process and Statistics

Gold Coast Health Plan employs the following types of formulary utilization management edits:

- *Prior Authorization:* this means that approval will be needed from GCHP before the medication can be covered by GCHP
- *Quantity Limit:* this limits the amount of drug that GCHP will cover
- *Step Therapy:* GCHP requires that certain drugs to treat the condition are tried before another drug for that condition can be covered

All drugs that have a limit or require authorization are listed on the formulary that is available on the website. **Click here** to access the List of Covered Drugs.

In order to exceed the quantity limit, bypass the step therapy, or get authorization, a prior authorization must be completed by the prescribing physician. GCHP's Pharmacy Benefits Manager (PBM), Script Care LTD., handles the prior authorization process. Below are the usual steps taken to complete a prior authorization:

- Member goes to the pharmacy with a prescription
- Pharmacy processes the prescription that rejects for one of the above reasons
- Pharmacy informs the MD that an authorization is necessary
- MD contacts Script Care (1-888-531-0998) to start the prior authorization
- Script Care faxes a blank prior authorization from to the MD
- MD completes the form and faxes it back to Script Care (1-888-392-4890)
- Script Care receives the complete authorization request form
- The authorization request form is reviewed for compliance with the formulary guidelines and is approved or denied
- The MD and pharmacy receive faxes documenting the outcome of the request as approved or denied within 1 business day of receipt of the completed form
- The member receives a letter, if denied, with the outcome and reason for denial

Tips to Help the Prior Authorization Process Work Smoothly

- Ensure that the form is completed and has a signature by the physician
- Ensure that all writing is legible
- Ensure that a diagnosis is listed
- List all prior tried and failed medications; state doses, dates, and outcomes
- List common drugs that might be used to treat the condition that are contraindicated in the member and state why

- List all pertinent medical information such as allergies, co-morbid conditions, etc. that affected the selection of the particular drug product
- Include chart notes, lab values/results, etc. to further document the medical necessity of the drug product requested

Current Prior Authorization and Appeal Statistics:

Month	Total Requests	Approvals	Denials	Appeals	% Denials Appealed	Overturned	Upheld	% Appeals Overturned
Jan-14	2,288	1,914	374	12	3.21%	9	3	75.00%
Feb-14	1,534	1,286	248	37	14.92%	30	7	81.08%
Mar-14	1,610	1,356	254	40	15.75%	36	4	90.00%
Apr-14	1,571	1,284	287	26	9.06%	19	7	73.08%
May-14	1,594	1,305	289	31	10.73%	21	10	67.74%
2014 Totals	8,597	7,145	1452	146	10.06%	115	31	78.77%

SECTION 4: Medicare Part D Cost Share Reminder

Gold Coast Health Plan wanted to remind all providers regarding the requirement for the member cost share of Medicare Part D drugs. All GCHP members who are eligible for Medicare Part D are required, per federal law, 42 U.S.C. § 1396u-5(d)(1), to pay for their Part D drug cost sharing. GCHP is unable to cover the member cost share. Members should pay no more than $2.55 for each generic and $6.35 for each brand-name covered drug in 2014.

GCHP has identified a processing error that inappropriately covered the cost sharing for some members. The pharmacy adjudication system will be corrected on October 1, 2014 and will no longer cover the member cost share. GCHP will be notifying members on or about August 1, 2014 regarding the error and to expect to pay their cost share beginning October 1, 2014. GCHP will send a follow-up communication to members on or about September 1, 2014.

GCHP is providing this notice to you as a courtesy prior to the member notifications so that if members come to you with questions, you are aware. **Click here** to access the member notification letter and FAQ documents that will be sent to members in both English and Spanish.

SECTION 5: Formulary Changes

The following changes to the Gold Coast Health Plan formulary were made, effective 7/1/2014:

Drug	Formulary Status/Change
Anoro Ellipta	Add to the formulary with a prior authorization
Northera	Add to the formulary with a prior authorization
Hetlioz	Add to the formulary with a prior authorization
Myrbetriq	Add to the formulary with a step therapy where oxybutynin must be tried and failed first
Apidra Pen	Add to the formulary with a prior authorization
Bravelle	Removed from the formulary
Cetrotide	Removed from the formulary
Follistim	Removed from the formulary
Ganirelix	Removed from the formulary
Repronex	Removed from the formulary
Polygam	Removed from the formulary; covered as a medical benefit
Vivaglobulin	Removed from the formulary; covered as a medical benefit
Ferrlecit	Removed from the formulary; covered as a medical benefit
Desferal	Removed from the formulary; covered as a medical benefit
Synagis	Removed from the formulary; covered as a medical benefit
Phytonadione	Removed from the formulary; covered as a medical benefit
All short acting opioid-acetaminophen analgesic combinations	Quantity limit changed to 124 tablets/31 days

SECTION 6: FDA Alerts – New FDA Drug Approvals, Drug Safety Labeling Changes, Drug Shortage, FDA Safety Alerts

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
Jublia	Efinaconazole	Topical solution	Jublia is a new azole antifungal indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrphytes*
Sivextro	Tedizolid	Oral tablet; injection, for intravenous use	Sivextro is a new oxazolidinone-class antibacterial drug indicted for the treatment of acute bacterial skin and skin-structure infections (ABSSSI) caused by designated susceptible bacteria
Zontivity	Vorapaxar	Oral tablet	Zontivity is a new protease-activated receptor -1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral artery disease (PAD)
Dalvance	Dalbavancin	Injection, for intravenous use	Dalvance is a new lipoglycopeptide indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of gram-positive bacteria
Zykadia	Ceritinib	Oral capsule	Zykadia is a new kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib

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
Accupril (quinapril)/ Accuretic (quinapril HCTZ)	Added contraindications	Do not co-administer ACCUPRIL with aliskiren in patients with diabetes
Avandia (rosiglitazone), Avandamet (rosiglitazone/ metformin), Avandaryl (rosiglitazone/glimepride)	Added contraindications	... is contraindicated in patients with a history of hypersensitive to rosiglitazone or any of the product's ingredients.
Edurant (rilpivirine)	Updated contraindications	The antimycobacterials rifampin, rifapentine
Tradjenta (linafliptan), Jentadueto (linagliptan/ metformin)	Updated contraindications	Tradjenta/Jentadueto is contraindicated in patients with a history of a hypersentivity reaction to linagliptan, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hypersensitivity.
Soriatane (acitretin)	Updated contraindications	Angioedema, urticarial hypersensitivity

Drug	Type of Change	Change
ER/LA opioid analgesics: • Avinza (morphine) • Butrans (buprenorphine) • Dolophin (methadone) • Duragesic (fentanyl) • Embeda (morphine/ naltrexone) • Exalgo (hydromorphone) • Kadian (morphine) • MS Contin (morphine) • Nucynta ER (tapentalol) • Opana ER (oxymorphone) • Oxycontin (oxycodone) • Palladone (hydromophone)	New black boxed warning	***BOXED WARNING TEMPLATE*** WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and INTERACTION WITH ALCOHOL (last warning only for products that have an interaction with alcohol) **Addiction, Abuse, and Misuse** [Tradename] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [Tradename], and monitor all patients regularly for the development of these behaviors or conditions [see Warnings and Precautions (5.1)]. **Life-threatening Respiratory Depression** Serious, life-threatening, or fatal respiratory depression may occur with use of [Tradename]. Monitor for respiratory depression, especially during initiation of [Tradename] or following a dose increase. Instruct patients to swallow [Tradename] (formulation; e.g., tablets, capsules) whole; crushing, chewing, or dissolving [Tradename] (formulation) can cause rapid release and absorption of a potentially fatal dose of (active opioid) [see Warnings and Precautions(5.2)]. **Accidental Exposure** Accidental [ingestion/exposure] of even one dose of [Tradename], especially by children, can result in a fatal overdose of (active opioid) [see Warnings and Precautions (5.2)]. **Neonatal Opioid Withdrawal Syndrome** Prolonged use of [Tradename] 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 [see Warnings and Precautions (5.3)].

Drug	Type of Change	Change
ER/LA opioid analgesics (continued)	New black boxed warning (continued)	***BOXED WARNING TEMPLATE*** (continued) **Interaction with Alcohol** (This subheading and text should be included in the boxed warning only for products that have an interaction with alcohol.) Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while taking [Tradename]. The co-ingestion of alcohol with [Tradename] may result in increased plasma levels and a potentially fatal overdose of (active opioid) [see Warnings and Precautions (5.4)].
Aptivus (tipranavir)	Updated contraindications	Drug interactions: pimozide
Vfend (voriconazole)	Updated contraindications	Coadministration of standard doses of voriconazole with efavirenz doses of 400 mg q24h or higher is contraindicated, because efavirenz significantly decreases plasma voriconazole concentrations in healthy subjects at these doses. Voriconazole also significantly increases efavirenz plasma concentrations [see Drug Interactions (7), and Clinical Pharmacology (12.3)].

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
Ethambutol	VersaPharm	All product from Versapharm is temporarily unavailable with an anticipated released date of September 2014; currently product is available from Lupin Pharmaceuticals
Belphamide S.O.P. Ophthalmic Ointment	Allergan	Product is on backorder and the company expects a release date of late-July 2014

Drug Product	Affected Manufacturers	Summary
Thiola	Mission Pharmacal	Thiola 100 mg tablets are on backorder with no estimated date. Emergency supplies are available for drop shipment (2 bottles per patient).
Bumetanide 1 mg and 2 mg	Teva	Product is on backorder with an estimated release date of late-July to early-August 2014. Bumetanide 0.5 mg is 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
Lidocaine	The FDA is warning that oral viscous lidocaine 2 % solution should not be used to treat infants and children with teething pain. When too much viscous lidocaine is given to infants and young children or they accidentally swallow too much, it can result in seizures, severe brain injury, and problems with the heart. In 2014, the FDA reviewed 22 case reports of serious adverse reactions, including death, in infants and children 5 months to 3.5 years of age who were given oral viscous lidocaine 2 % solution for the treatment of mouth pain, including teething and stomatitis, or who had accidental ingestions. A new black boxed warning will be added to the drug label to highlight this information.
Topical acne products	The FDA is warning that topical OTC acne products may cause rare, but serious and potentially life threatening allergic reactions or severe irritation. Based on the information provided to the FDA, it is unclear if the reactions are due to the active ingredients, benzoyl peroxide or salicylic acid, the inactive ingredients or both. Manufacturers of OTC topical acne products have been asked to add label directions for sensitivity testing for new users of their products. The OTC topical acne products are marketed under various names such as Proactiv, Neutrogena, MaxClarity, Oxy, Ambi, Aveeno, Clean & Clear, and as store brands. They are available as gels, lotions, face washes, solutions, cleansing pads, toners, face scrubs, and other products.

Drug	Communication Summary
Benicar (olmesartan)	The FDA is announcing that it has completed its safety review and there is no clear evidence of increased cardiovascular risks associated with use of the blood pressure medication olmesartan in diabetic patients. The study was prompted by the results of the ROADMAP (**R**andomized, **O**lmesartan **A**nd **D**iabetes **M**icro**A**lbuminemia **P**revention) trial which examined the effects of olmesartan in patients with type 2 diabetes to see whether olmesartan can delay kidney damage. There was an unexpected finding of increased risk of cardiovascular death in the olmesartan group compared to the group taking a placebo. While data from the ROADMAP trial and from a large study in Medicare patients suggested that high-dose olmesartan may increase cardiovascular risk, the data is not conclusive when you consider the data from all trials and studies. Due to this, the recommendations for olmesartan will not change, but the labeling will include more information about these studies.
Docetaxel	The FDA is warning that docetaxel contains ethanol which may cause patients to experience intoxication or feel drunk during and after treatment. The alcohol content should be considered when docetaxel is to be used in those whom alcohol intake should be avoided or minimized and when used in conjunction with other medications. Several forms of docetaxel are currently marketed, including generics and brand-name products: Taxotere, Docefrez, and docetaxel injection. The various products contain different amount of alcohol, which is used to dissolve the active ingredients so docetaxel can be given intravenously. Health care professionals should be aware of the differences in the formulations in order to monitor and counsel patients appropriately.
Lunesta (eszopiclone)	The FDA is warning that the previously recommended dose of Lunesta, 3 mg, can cause impairment to driving, skills, memory, and coordination that may last more than 11 hours after receiving an evening dose. Despite these driving and other problems, patients were often unaware they were impaired. As a result, the FDA has decreased the recommended starting dose to 1 mg at bedtime. The new lower dose will result in less drug in the blood the next day.
Warfarin, Pradaxa (dabigatran)	The FDA recently completed a new study in Medicare patients comparing Pradaxa to warfarin for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal bleeding, myocardial infarction, and death. The study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death than warfarin. The study also found an increased risk of major gastrointestinal bleeding with the use of Pradaxa as compared to warfarin.