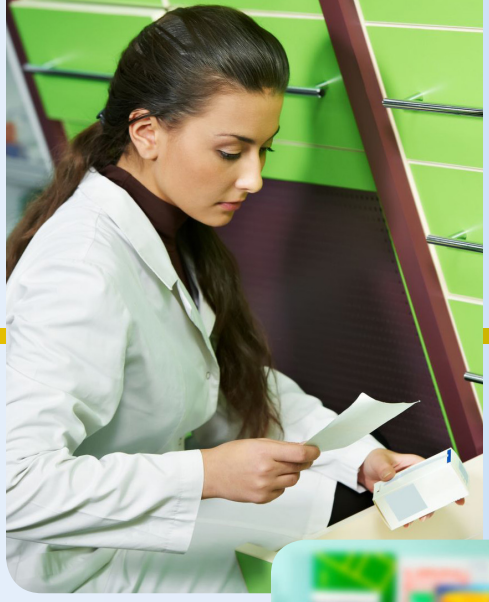

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

JUNE 2015

Q3

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PN Q3

The Pharmacy Newsletter is published quarterly as a service for the provider community of Gold Coast Health Plan.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Pharmacy Director Anne Freese, at afreese@goldchp.org or 1-805-437-5652.

Pharmacy Director:
Anne Freese, Pharm. D.

Chief Medical Officer:
C. Albert Reeves, MD

Editor:
Steven Lalich

CMO Message

C. Albert Reeves, MD

The use of opiates for chronic conditions continues to be a concern for the medical, law enforcement, and legislative communities. The State Legislature is currently considering requiring providers to consult the Controlled Substance Utilization Review and Evaluation System (CURES) before prescribing controlled medications.

Fatal overdoses in Ventura County were the topic of a June 6 article in the Ventura County Star. In 2012, the most recent year for which statistics were available, there were 103 deaths in the county from fatal overdoses. Of those, 43 were from heroin overdoses; the rest were from other drugs, many of which were prescribed medications.

Substance use and abuse pose significant problems to Medicaid and Gold Coast Health Plan (GCHP) member populations.

In May, the No. 1 prescribed medication for GCHP members was Hydrocodone/APAP. It's followed by narcotic analgesics, which closely trail anti-diabetic medications in the number of prescriptions (7500 vs. 7079).

I would like to make our providers aware of a resource on the Medical Board of California's website. It is titled "Guidelines for Prescribing Controlled Substances for Pain." This set of guidelines, published in November, has valuable information and tools that can be used for evaluating patients with pain who may be candidates for pain medications. Please take the time to review this resource and consider incorporating some of the tools included in the guideline.

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.

Effectiveness of Pain Medication

The National Safety Council released a white paper that discusses the efficacy of various pain medications including opioids, NSAIDs, and acetaminophen. Click here to access the National Safety Council's white paper "Evidence for the Efficacy of Pain Medications."

Among the report's key findings are the Cochrane Collaboration's reviews of post-operative pain. The table below summarizes those reviews:

Medication	Number Needed to Treat (NNT)
Oxycodone 15 mg	4.6
Oxycodone 10 mg + acetaminophen 650 mg	2.7
Naproxen 500 mg	2.7
Ibuprofen 200 mg + acetaminophen 500 mg	1.6

Bandolier issued a report in 2003 on the treatment of acute pain. In 2007, the journal issued the below table that summarizes the efficacy of different oral and injectable pain medications:

Medication	Type of Medication	# of Patients Studied	NNT
Diclofenac 100 mg	NSAID	545	1.8
Celecoxib 400 mg	NSAID	298	2.1
ibuprofen 400 mg	NSAID	5456	2.5
Naproxen 400 mg	NSAID	197	2.7
ibuprofen 200 mg	NSAID	3248	2.7
Oxycodone 10 mg + acetaminophen 1000 mg	Opioid Combination	83	2.7
morphine 10 mg (IM)	Opioid	948	2.9
Oxycodone 5 mg + acetaminophen 325 mg	Opioid Combination	149	5.5
Tramadol 50 mg	Opioid	770	8.3

Formulary Changes

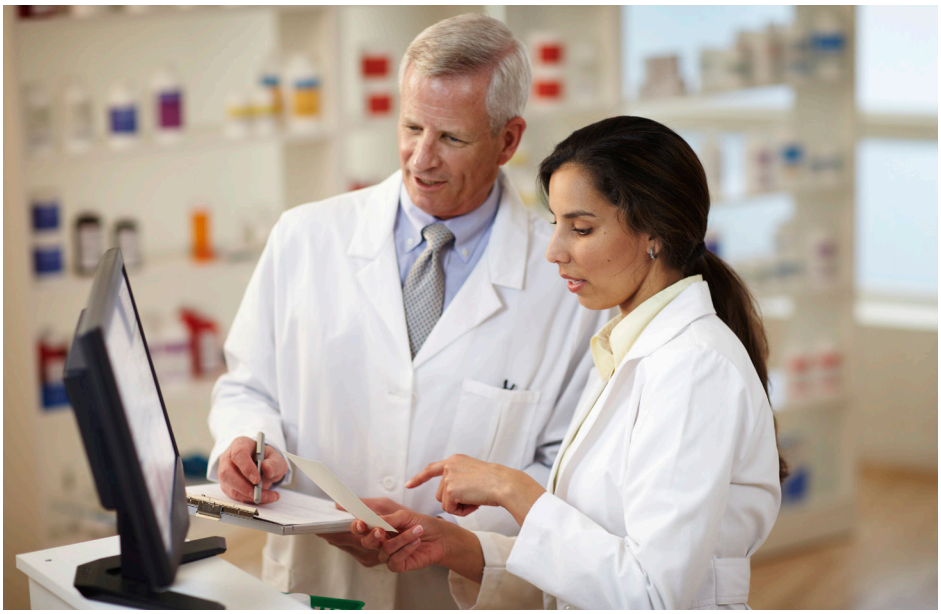
The following changes to the GCHP formulary will be effective July 1:

Additions

Drug	Formulary Status/Change
Kitabus Pak	Added to the formulary as preferred over generic tobramycin
Soolantra 1% cream	Added to the formulary with prior authorization
Glyxambi	Added to the formulary with step therapy
Toujeo Solostar 300u/ml	Added to the formulary with prior authorization
Contrave	Added to the formulary with prior authorization
Lynparza	Added to the formulary with prior authorization
Viekira Pak	Added to the formulary with prior authorization
Syvasya	Added to the formulary with step therapy
Cosentyx	Added to the formulary with prior authorization
Ibrance	Added to the formulary with a prior authorization
Lenvima	Added to the formulary with prior authorization

Removals

Drug	Formulary Status/Change
Enablex extended release tablets	Removed from the formulary, generic now available
Revatio injection	Removed from the formulary, generic now available
Copaxone injection	Removed from the formulary, generic now available



FDA Alerts

FDA New Drug Approvals

This is 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's 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.
IBRANCE	palbociclib	Oral capsule	Kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.
DUTREBIS	lamivudine: raltegravir potassium	Oral tablet	Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.
LENVIMA	lenvatinib mesylate	Oral capsule	Kinase inhibitor indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.
FARYDAK	panobinostat lactate	Oral capsule	Histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent.
AVYCAZ	avibactam sodium: ceftazidime	Powder: IV infusion	A combination of a cephalosporin and a beta-lactamase inhibitor indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms: Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole (1.1) and Complicated Urinary Tract Infections (cUTI), including Pyelonephritis (1.2), to reduce the development of drug-resistant bacteria and maintain the effectiveness of AVYCAZ and other antibacterial drugs, AVYCAZ should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.
TOUJEO SOLOSTAR	Insulin glargine recombinant	Solution: subcutaneous	Long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.
LILETTA	levonorgestrel	Intrauterine device: intrauterine	Sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to three years.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ELEPSIA XR	levetiracetam	Extended release oral tablet	Indicated for adjunctive therapy in the treatment of partial onset seizures in patients ≥12 years of age with epilepsy.
CRESEMBA	isavuconazonium sulfate	Oral capsule	Azole antifungal indicated for use in the treatment of: Invasive aspergillosis and Invasive mucormycosis.
CRESEMBA	isavuconazonium sulfate	Powder: IV infusion	Azole antifungal indicated for use in the treatment of: Invasive aspergillosis and Invasive mucomycosis.
CHOLBAM	cholic acid	Oral capsule	Bile acid indicated for: Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) and Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.
KALYDECO	ivacaftor	Oral granule	Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients ages 2 years and older who have one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R, also who have an R117H mutation in the CFTR gene.
ORALTAG	ohexol	Oral solution	Radiographic contrast agent indicated for use in opacification of the gastrointestinal tract during computed tomography (CT) of the abdomen and pelvis.
JADENU	deferasirox	Oral tablet	Iron chelator indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. This indication is approved under accelerated approval based on a reduction of liver iron concentrations and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials, also indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L. This indication is approved under accelerated approval based on a reduction of liver iron concentrations (to less than 5 mg Fe/g dw) and serum ferritin levels.
PROAIR RESPICLICK	albuterol sulfate	Powder, metered; inhalation	Beta-adrenergic agonist indicated for: Treatment or prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease and prevention of exercise-induced bronchospasm in patients 12 years of age and older.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
CORLANOR	ivabradine	Oral tablet	Hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta blockers or have a contraindication to beta-blocker use.
APTENSIO XR	methylphenidate hydrochloride extended-release	Extended release oral capsule	Central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
KYBELLA	Deoxycholic acid	Subcutaneous solution	Cytolytic drug indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.
MEROPENEM AND SODIUM CHLORIDE IN DUPLEX CONTAINER	meropenem	Powder; IV infusion	Meropenem for Injection USP and Sodium Chloride Injection USP is a penem antibacterial indicated as single agent therapy for the treatment of: Complicated skin and skin structure infections (adult patients and pediatric patients 3 months of age and older requiring the full adult dose only), Complicated intra-abdominal infections (adult patients and pediatric patients 3 months of age and older requiring the full adult dose only), Bacterial meningitis (pediatric patients 3 months of age and older requiring the full adult dose only).
TUZISTRA XR	codeine polistirex and chlorpheniramine polistirex	Extended release oral solution	An opiate agonist antitussive, and chlorpheniramine, a histamine (H1) receptor antagonist indicated for relief of cough and symptoms associated with upper respiratory allergies or a common cold.

FDA Safety Labeling Changes

This section includes all new safety labeling changes or updated boxed warnings or contraindications. Click here to access this information on the FDA's website.

Drug	Type of Change	Change
OSPHENA (ospemifene)	Updated contraindications	• Hypersensitivity (for example, angioedema, urticaria, rash, pruritis) or any ingredients
SUPRANE (desflurane, USP)	Updated contrainidications	• Patients with a history of moderate to severe hepatic dysfunction following anesthesia with SUPRANE or other halogenated agents and not otherwise explained
BYDUREON (exenatide extended-release) for injectable suspension	Edited boxed warning	• Warning: Risk of Thyroid C- Cell Tumors
ESTRASORB (estradiol topical emulsion)	Edited boxed label warning and updated contraindications	• Warning: Risk of Endometrial Cancer, Cardiovascular Disorders, Breast Cancer and Probable Dementia • Known anaphylactic reaction or angioedema with Estrasorb • Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders
TANZEUM (albiglutide) Injection, for Subcutaneous Use	Edited boxed label warning	• Warning: Risk of Thyroid C- Cell Tumors
TRULICITY (dulaglutide) Injection, for Subcutaneous Use	Edited boxed label warning	• Warning: Risk of Thyroid C- Cell Tumors
VICTOZA (Liraglutide [rDNA orgin]) Injection	Edited boxed label warning	• Warning: Risk of Thyroid C- Cell Tumors
ATELVIA (risedronate sodium) Delayed-release Tablets, ACTONEL WITH CALCIUM (risedronate sodium tablets with calcium carbonate) Tablets, ACTONEL (risedronate sodium) Tablets	Updated contraindications	• Bullet added -Known hypersensitivity to any component of this product. Angioedema, generalized rash, bullous skin reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported [see Adverse Reactions (6.2)]
AVANDARYL (rosiglitazone maleate, glimepiride) Tablets	Updated contraindications	• Avandaryl is contraindicated in patients with a history of a hypersensitivity reaction to rosiglitazone or glimepiride or any of the product's ingredients • Patients who have developed an allergic reaction to sulfonamide derivatives may develop an allergic reaction to Avandaryl. Do not use Avandaryl in patients who have a history of an allergic reaction to sulfonamide derivatives. Reported hypersensitivity reactions include cutaneous eruptions with or without pruritis as well as more serious reactions (e.g. anaphylaxis, angioedema, Stevens-Johnson syndrome, and dyspnea) [see Warnings and Precautions (5.9) and Adverse Reactions (6.3)]

Drug	Type of Change	Change
CENESTIN (Synthetic Conjugated Estrogens, A) Tablets	Updated contraindications	• Cenestin therapy should not be used in patients with known hypersensitivity to its ingredients • Known or suspected pregnancy. There is no indication for Cenestin in pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins from oral contraceptives inadvertently during early pregnancy
DUETACT (pioglitazone HCl plus glimepiride) fixed-dose combination tablets	Updated contraindications	• Reported hypersensitivity reactions with glimepiride include cutaneous eruptions with or without pruritus as well as more serious reactions (e.g. anaphylaxis, angioedema, Stevens-Johnsons Syndrome, dyspnea)
POMALYST (pomalidomide) Capsules	Boxed warning	• Venous and Arterial Thromboembolism • Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with Pomalyst. Antithrombotic prophylaxis is recommended
SPORANOX (itraconazole) oral solution and capsules	Boxed warning and Updated contraindications	• Congestive Heart Failure, Cardiac Effects and Drug Interactions • Coadministration of a number of CYP3A4 substrates are contraindicated with SPORANOX • Plasma concentrations increase for the following drugs: …ticagrelor, and, in subjects with varying degrees of renal or hepatic impairment, colchicine, fesoterodine, telithromycin and solifenacin
ADCIRCA(tadalafil) 20 mg Tablets	Updated contraindications	• Do not use Adcirca in patients who are using a GC stimulator, such as riociguat, Adcirca may potentiate the hypotensive effects of GC stimulators.
BIDIL (isosorbide dinitrate/hydralazine hydrochloride) Tablets	Updated contraindications	• BiDil is contraindicated in patients who are allergic to organic nitrates • Do not use BiDil in patients who are taking PDE-5 inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil. Concomitant use can cause severe hypotension, syncope, or myocardial ischemia [see Drug Interactions] • Do not use BiDil in patients who are taking the soluble guanylate cyclase (sGC) stimulator riociguat. Concomitant use can cause hypotension
REVATIO (sildenafil)	Updated contraindications	• Concomitant use of riociguat, a guanylate cyclase stimulator. PDE5 inhibitors, including sildenafil, may potentiate the hypotensive effects of riociguat

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 on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Acamprosate Calcium Tablets	Glenmark, Mylan Pharmaceuticals	No product available from Glenmark or Mylan, manufacturers cannot provide a reason for the shortage, no estimate for release of additional product.
Acetaminophen and Codeine Phosphate 300mg/30mg tablets	Amneal, Aurobindo, Mallinckrodt	Teva has product available in the 100-count and 1000-count sizes, Mallinckrodt states the shortage is due a variety of market conditions, Amneal and Aurobindo could not provide a reason for the shortage, Mallinckrodt is releasing monthly allocations of the product, Amneal and Aurobindo cannot estimate a release date.
Acetylcysteine inhalation Solution	American Regent, Fresenius Kabi	American Regent has 200mg/ml, 4ml vials available, 100mg/ml, 4ml and 10ml vials with expiration date of October 2015, Fresenius Kabi has 200mg/ml, 4ml and 10ml vials available with an expiration date of less than five months, Hospira has 100mg/ml, 30ml vials and 200mg/ml, 30ml vials available, American Regent state shortage is due to manufacturing delays, Fresenius Kabi state shortage is due to increased demand.
Amoxicillin 875mg Tablets	Dr.Reddy's, Ranbaxy, Sandoz	Dr.Reddy's discontinued product in June 2014, Ranbaxy has an FDA import ban on product, Sandoz and Ranbaxy cannot provide a reason for the shortage and cannot provide an estimated release date.
Anagrelide Capsules	Mylan Pharmaceuticals	Mylan Pharmaceuticals discontinued anagrelide capsules in 2015. Teva has 0.5mg and 1mg capsules available in the 100-count size.
Atenolol Tablets	Avkare, Ingenus, Mylan Pharmaceuticals, Pack, Ranbaxy, Sandoz, Almatica	Almatica has new NDC numbers for Tenormin tablets, Avkare and Mylan could not provide a reason for the shortage, Pack Pharmaceuticals discontinued atenolol tablets in October 2014, Ranbaxy states shortage is due to manufacturing delays, Mylan discontinued atenolol 100mg, 30-count bottles, Avkare has product available in the 90-, 500- and 1000-count bottles, 45- and 180-count bottles and 100mg 90-count bottles are on backorder with no estimated release date, Mylan has product available in the 100- and 1000-count bottles, Sandoz has product available in the 100- and 1000-count bottles except for 100mg, 1000-count bottles which have an estimated release date of early June 2015 and 25mg, 1000-count bottles with no estimated release date, Ranbaxy has atenolol on backorder with no estimated release date.

Drug Product	Affected Manufacturers	Summary
Atorvastatin Tablets	Apotex, Greenstone, Ranbaxy, Sandoz	Ranbaxy discontinued atorvastatin in late 2014, Apotex has all atorvastatin on allocation due to increased demand, Greenstone and Sandoz state the shortage is due to demand exceeding the supply. Greenstone has product available but the company is allocating to non-primary customers due to market supply constraints, Sandoz has atorvastatin 40mg and 80mg on backorder and cannot supply a release date, Sandoz has 10mg and 20mg available in 90-count bottles.
Azathioprine Tablets	Roxanne, Zydus	Roxanne discontinued product in mid-January due to problems obtaining active ingredient, Zydus cannot provide a reason for the shortage, Mylan has 50mg tablets available in the 50- and 100-count bottles; Valeant (formerly Salix) has 75mg and 100mg tablets available in the 100-count bottles. Zydus has product available on allocation.
Benzonatate Capsules	Amneal, Ascend, Caraco, Major	Amneal and Ascend cannot provide a reason for the shortage, Caraco discontinued product in mid-2015, Vertical has Zonatuss 150mg capsules available in the 100-count bottles, Amneal estimates a release date of late-May 2015, Ascend has 200mg, 100- and 500-count bottles in limited supply, no estimated release date for the 100mg capsules, 100- and 500-count bottles. Major has 100mg capsules on backorder with no estimated release date.
Bupropion Hydrochloride 24 Hour ER tablets	Actavis	Actavis began transitioning to new NDC numbers in February 2015. Product is available with the new NDC numbers in the 150mg and 300mg, 90-count bottles and 300mg, 30-count bottles. Bupropion XL 300mg, 500-count bottles are on backorder with no estimated release date.
Carbidopa and Levodopa Extended-Release Tablets	Accord Healthcare, Caraco	Accord Healthcare has 25mg/100mg tablets available in the 100-count bottles and 50mg/200mg tablets available in the 1000-count bottles, Accord Healthcare and Caraco could not provide a reason for the shortage, both companies estimate a release date for backordered strengths in mid-to late May 2015.
Chloroquine Tablets	Ranbaxy, West-Ward	West-Ward has product available with short dating of July 2015, Ranbaxy states shortage is due to third party supply issues, and West-Ward cannot provide a reason for the shortage, no estimated release date for additional product.

Drug Product	Affected Manufacturers	Summary
Divalproex Sodium Delayed Release Tablets	Aurobindo, Dr.Reddy's, Lupin, Mylan Pharmacuticals, Teva, Upsher-Smith, Zydus	Aurobindo, Dr. Reddy's and Lupin have discontinued product, Upsher-Smith has transitioned product to new NDC numbers, and Zydus has product on allocation due to increased demand. Mylan has 125mg and 250mg available in 100-count bottles, Teva has 125mg available in 100-count bottles and 250mg & 500mg available in 500-count bottles. Zydus has all product on allocation and Teva has 250mg, 100-count bottles on backorder with an estimated release date in mid-July 2015 and 500mg, 100-count bottles on backorder with an estimated release date of late-June 2015.
Ethambutol Tablets	Akorn, Teva	Akorn could not provide a reason for the shortage, Akorn has no estimated release date for the 400mg, 90-count and 1000-count sizes, available sizes are 100mg, 100-count bottles, 400mg, 60-count and 100-count bottles. Teva has product on backorder with no estimated release date.
Ezetimibe and Atorvastatin Tablets	Merck	No product available from Merck, in January 2014, manufacturer recalled all Liptruzet lots from wholesalers due to packaging defects in the outer laminate foil pouches. No estimated release date for product.
Hydroxychloroquine Sulfate Tablets	Ranbaxy, Sandoz	No product available from Ranbaxy, manufacturer has no estimated release date. Sandoz states shortage is due to increased demand, manufacturer has 200mg, 100-count bottles available, 200mg, and 500-count bottles have an estimated release date of mid-July 2015.
Leflunomide Tablets	Apotex, Heritage, Sanofi-Aventis	No product available from Apotex, Heritage and Sanofi-Avntis, Apotex and Heritage state shortage is due to delay in obtaining active ingredient, Sanofi could not provide a reason for the shortage, Apotex and Heritage cannot estimate a release date, Sanofi has Arava 10mg and 20mg on backorder and estimates a release date in early-August 2015 for 10mg and August 2015 for 20mg tablets.
Liotrix Tablets	Forest Laboratories	No product available from Forest Laboratories, product is on backorder due to manufacturing changes, no estimated release for additional product.
Memantine Hydrochloride	Forest Laboratories	Product is available from Forest Laboratories, Namenda XR capsules 14mg, 90-count and Titration Pack, 28-count capsules are unavailable due to manufacturing delay, Forest estimates a release date of 4th quarter 2015.

Drug Product	Affected Manufacturers	Summary
Methylphenidate Hydrochloride Extended Release Oral Presentations	Actavis, Kremers-Urban, Teva	Product is available from Actavis and Kremers-Urban, Activas has methylphenidate ER 30mg on backorder with no estimated release date, shortage is due to increased demand, Kremers-Urban has all methylphenidate CD presentations available on allocation due to increased demand, Teva introduced generic methylphenidate extended release capsules (CD) in late September 2012, and the capsules are AB-rated to metadata CD capsules, Teva has all methylphenidate CD presentations on backorder with an estimated release date of mid-to-late June 2015.
Nimodipine Capsules	Caraco	No product available from Caraco, no reason provided for shortage, Caraco has temporarily discontinued product and no estimated date for when product will return.
Pantoprazole Tablets	Actavis, Aurobindo, Kermers-Urban, Mylan Pharmaceuticals, Prasco, Wockhardt,	Aurobindo, Kermers-Urban and Mylan have limited product available, Aurobindo, Actavis and Mylan cannot provide a reason for the shortage, Actavis discontinued pantoprazole 20mg tablets in October 2014, Kermers-Urban state shortage is due to increased demand, FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole, Actavis has 40mg tablets on backorder and no estimated release date, Aurbindo has 40mg tablets on backorder with an estimated release date in late-May 2015, Kremers-Urban is allocating pantoprazole 20mg tablets weekly, Mylan has pantoprazole 20mg and 40mg on backorder with an estimated release date in mid-May 2015, Wockhardt has pantoprazole on backorder with no estimated release date.
Phenazopyradine Hydrochloride	Avkare, Marlex	No product available from Avkare and Marlex, Avkare discontinued product, Marlex cannot provide a reason for the shortage, Marlex has no estimated release date for the product.
Tacrolimus Capsules	Mylan Pharmaceuticals, Sandoz, Novartis	Mylan and Sandoz have limited product available, Novartis discontinued all Hecoria presentations in February 2015, Mylan Pharmaceuticals discontinued the 500-count presentations in early 2015 and cannot provide a reason for the shortage, but has tacrolimus 0.5mg capsules, 100-count on intermittent backorder and is releasing product as it becomes available, Sandoz states the reason for the shortage is manufacturing delay and has tacrolimus 0.5mg capsules on intermittent backorder and is releasing product as it becomes available.

Drug Product	Affected Manufacturers	Summary
Tamsulosin Hydrochloride Capsules	Aurobindo, Caraco, Citron Pharma, Mylan, Zydus, Boehringer Ingelheim	Mylan has limited product available, tamsulosin 0.4mg capsules, 1000-count are on backorder with an estimated release date of mid-May 2015, Boehringer Ingelheim and Caraco could not provide a reason for the shortage, Zydus states the reason for the shortage is increased demand and has product in 100- and 1000-count sizes on allocation to current customers, Aurobindo is not marketing the 100-count size, but has product on intermittent back order and is releasing product as it becomes available, Caraco has tamsulosin 0.4mg in 90, 100- and 500-count sizes on backorder and estimates a release date in late-May 2015, Citron Pharma has tamsulosin 0.4mg in 100-and 500-count sizes available on allocation to current customers, Boehringer Ingelheim has Flomax 0.4mg capsules in 100-count on backorder with an estimated release date in mid-August 2015.
Testosterone Cypionate Intramuscular Injection	Actavis, Paddock	No product available from Actavis and limited product available from Paddock, Actavis discontinued product in 2015, Paddock states shortage is due to increased demand and shipping delays from their contract manufacturer, Paddock has testosterone cypionate 1ml vials on allocation, 10ml vials are on backorder with an estimated release date in mid-June 2015.
Tolterodine Tartrate Extended Release Capsules	Mylan, Teva	Mylan has product available, 2mg capsules in the 30- and 500-count sizes and 4mg capsules in the 30-count size, Mylan discontinued tolterodine extended release 2mg and 4mg capsules in the 90-count bottles in April 2014, Mylan has tolterodine 4mg extended release in the 500-count on backorder with an estimated release date in late-May 2015, Teva could not provide a reason for the shortage, Teva has tolterodine 4mg extended release in 500-count on backorder with an estimated release date in late-June 2015.
Trypan Blue 0.15% Opthalmic Solution	There are no manufacturers of Trypan Blue	Product not available, Dutch Ophthalmic has VisionBlue 0.06% ophthalmic solution (NDC 68803-0612-10) available and MembraneBlue 0.15% solution, 0.5ml, 5 count (NDC 68803-0672-05).

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's website.

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. The FDA is 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, the FDA is 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.
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. The FDA is adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. The agency is 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.
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). The FDA has changed the prescribing instructions and approved a Boxed Warning, the agency'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.

Drug	Communications Summary
SGLT2 INHIBITORS 	The U.S. Food and Drug Administration (FDA) is warning that the type 2 diabetes medicines canagliflozin, dapagliflozin, and empagliflozin may lead to ketoacidosis, a serious condition where the body produces high levels of blood acids called ketones that may require hospitalization. The FDA is continuing to investigate this safety issue and will determine whether changes are needed in the prescribing information for this class of drugs, called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Patients should pay close attention for any signs of ketoacidosis and seek medical attention immediately if they experience symptoms such as difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness. Do not stop or change your diabetes medicines without first talking to your prescriber. Health care professionals should evaluate for the presence of acidosis, including ketoacidosis, in patients experiencing these signs or symptoms; discontinue SGLT2 inhibitors if acidosis is confirmed; and take appropriate measures to correct the acidosis and monitor sugar levels.
ZERBAXA (ceftolozane and tazobactam) 	The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the antibacterial drug Zerbaxa (ceftolozane and tazobactam) due to confusion about the drug strength displayed on the vial and carton labeling. Zerbaxa's vial label was initially approved with a strength that reflects each individual active ingredient (e.g. 1 g/0.5 g); however, the product is dosed based on the sum of these ingredients (e.g. 1.5 g). To prevent future medication errors, the strength on the drug labeling has been revised to reflect the sum of the two active ingredients. Thus, one vial of Zerbaxa will now list the strength as 1.5 grams equivalent to ceftolozane 1 gram and tazobactam 0.5 gram.

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Gold Coast Health Plan℠
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Pharmacy Newsletter

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For additional information, contact
Pharmacy Relations at 888.531.0998
Gold Coast Health Plan
711 East Daily Drive, Suite 106, Camarillo, CA 93010
www.goldcoasthealthplan.org