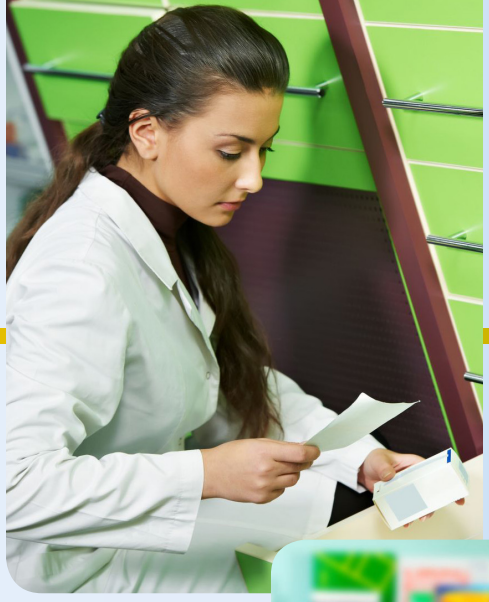

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

JUNE 2016

Q3 2016

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The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

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.

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CMO Message

C. Albert Reeves, MD

Last year, I wrote to you about how opiate use by members of Gold Coast Health Plan (GCHP) was increasing. Since then, the epidemic of opiate-induced deaths has become much more prominent in the news.

Opiate use by GCHP members has not diminished. In April, the second-most prescribed drug was acetaminophen/hydrocodone, with 3,719 prescriptions. During the same month last year, there were 3,772 prescriptions. For the narcotic analgesic class of drugs, GCHP's pharmacists filled 7,174 prescriptions in April at a cost of $214,536, compared to 7,127 prescriptions last year at a cost of $250,132.

Outside of GCHP's membership, Ventura County maintains a high rate of opiate overdose related deaths in the state.

The Plan is initiating a program to lower the use of opiates – the use of dangerous dosages, in particular – by its members.

To date, the Plan has:

- Identified members who have been taking 100 morphine equivalents of a narcotic medication on a chronic basis and who do not have a cancer diagnosis.
- Approved, through the Pharmacy & Therapeutics (P&T) Committee, requiring approval for members taking high dosages for non-cancer pain. When approval is granted, an approval letter will be sent to the provider and member stating that the dose is potentially dangerous and that a prescription for the rescue medication, naloxone, should be provided.
- Awarded $51,000 to the Ventura County Drug and Alcohol Program to provide 1,000 naloxone rescue kits for distribution to people who are at risk for overdosing.
- Identified, with the help of Beacon Health Options, behavioral health providers who will teach members with chronic pain methods to cope with the pain rather than relying on long term, high-dose opiates.
- Been working to convene a meeting of provider advisors to help identify strategies for the Plan to lower the usage of opiates among its members.

Health plans are in a unique position to fight the opiate overdose crisis. Plans are capable of tracking how often opiates are prescribed, no matter where the member gets the prescription filled – giving a glimpse into how much the member is taking on a monthly, even daily, basis. By working with providers, the Plan can develop strategies to limit the prescribing of these drugs, make providers and members aware of the dangers, and provide alternatives methods to deal with chronic pain issues.

If you have any questions, please feel free to contact me or Anne Freese, GCHP's Director of Pharmacy.

Regards,

C. Albert Reeves, M.D.

C. Albert Reeves, MD

Disease State Topic: Opioids

Prescribing Guidelines: CDC and Medical Board of California:

The CDC and the Medical Board of California have both issued guidelines for the prescribing of opioids. GCHP strongly encourages prescribers to adopt and follow the best practices identified within these guidelines.

The CDC Guideline for Prescribing Opioids for Chronic Pain website includes guidelines along with links to patient resources and prescribing resources, including fact sheets, clinical tools, and other related materials. Below are a few quick links:

- CDC Guideline for Prescribing Opioids for Chronic Pain
- Guideline Resources
- Checklist for Prescribing Opioids for Chronic Pain

The Medical Board of California issued Guidelines for Prescribing Controlled Substances for Pain in November 2014. These guidelines address many issues surrounding the use of opioids for pain and contain sample patient pain consent and agreement documents, treatment plans, and other practice materials.

CURES 2.0:

CURES 2.0 (Controlled Substance Utilization Review and Evaluation System) is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California serving the public health, regulatory oversight, and law enforcement agencies.

GCHP would like to remind all plan partners that California law (Health and Safety Code Section 11165.1) **requires all California licensed prescribers authorized to prescribe scheduled drugs to register for access to CURES 2.0 by July 1** or upon issuance of a Drug Enforcement Administration Controlled Substance Registration Certificate, whichever occurs later.

California licensed pharmacists must also register for access to CURES 2.0 by July 1, or upon issuance of a Board of Pharmacy Pharmacist License, whichever occurs later.

Prescriber and dispenser registration to access CURES 2.0 is simple and fully automated. Prescribers and dispensers can register here.

CURES 2.0

Pharmacy Department Update

Opioid Prior Authorizations

GCHP's P&T Committee voted to add a statement to all approved prior authorization prescriber fax notices and member letters for opioids prescribed at **above 100 mg morphine equivalent daily dosing**. The statement says:

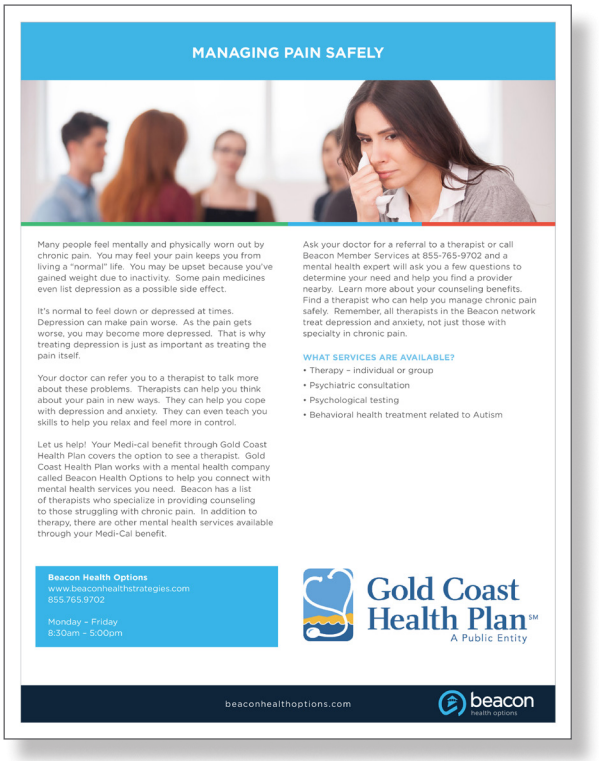
This quantity of narcotics
exceeds safe prescribing guidelines.
Please co-prescribe naloxone injection
1 vial for overdose rescue.

We urge prescribers to consider the total daily morphine equivalent dosing and to co-prescribe naloxone, which is covered for all GCHP members via Medi-Cal Fee-For-Service (FFS).

Beacon Health Options

Beacon Health Options has behavioral health providers who specialize in treating the mental health symptoms related to chronic pain. Members or providers can request a referral by contacting Beacon at 1-855-765-9702, Monday to Friday from 8:30 a.m. to 5 p.m.

beacon health options



Formulary Changes

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

Additions

Drug	Formulary Status/Change
VISTOGARD (uridine triacetate)	Add with a PA.
XURIDEN *(uridine triacetate)*	Add with a PA.
ZEPATIER *(elbasvir; grazoprevir)*	Add with a PA to meet the DHCS Clinical Policy.
Diphtheria/Pertussis/Tetanus Vaccine	Add; limited to ages greater than 18.
Human Papillomavirus Vaccine	Add; limited to ages greater than 18.
Measles, Mumps, and Rubella Virus Vaccine	Add; limited to ages greater than 18.
Meningococcal Group B Vaccine	Add; limited to ages greater than 18.
Meningococcal Oligosaccharide Diptheria Conjugate Vaccine	Add; limited to ages greater than 18.
Meningococcal Polysaccharide Diptheria Conjugate Vaccine	Add; limited to ages greater than 18.
Meningococcal Polysaccharide Vaccine	Add; limited to ages greater than 18.
Rabies Vaccine	Add; limited to ages greater than 18.
Tetanus and Diphtheria Toxoids Adsorbed Vaccine	Add; limited to ages greater than 18.
Varicella Virus Vaccine	Add; limited to ages greater than 18.
Fluzone Intradermal Flu Vaccine	Add; limited to ages greater than 18.
Flumist Quadrivalent Nasal Flu Vaccine	Add; limited to ages greater than 18.
BRILINTA *(ticagrelor)*	Add with a step therapy.
EFFIENT *(prasugrel)*	Add with a step therapy.
BREO ELLIPTA *(fluticasone furoate/vilanterol)*	Add with a step therapy.

Removals

Drug	Formulary Status/Change
DAPSONE tablets	Brand removed; generic now available.
AVALIDE oral tablets	Brand removed; generic now available.
UROXATRAL ER oral tablets	Brand removed; generic now available.
MAXALT, MAXALT MLT oral tablets	Brand removed; generic now available.
VALCYTE oral tablets	Brand removed; generic now available.
TEMODAR oral capsule	Brand removed; 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
ODEFSEY	*emtricitabine; rilpivirine hydrochloride; tenofovir alafenamide fumarate*	TABLET; ORAL	ODEFSEY is a three-drug combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors (NRTIs), and rilpivirine (RPV), a non-nucleoside reverse transcriptase inhibitor (NNRTI), and is indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years of age and older as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of ODEFSEY.
EVOMELA	*melphalan hydrochloride*	POWDER; IV (INFUSION)	Evomela is an alkylating drug indicated for: • Use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma. • The palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.
TALTZ	*ixekizuma*	INJECTABLE; INJECTION	TALTZ™ is a humanized interleukin-17A antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
CINQAIR	*reslizumab*	INJECTABLE; INJECTION	CINQAIR is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) indicated for add-on maintenance treatment of patients with severe asthma ages 18 years and older, and with an eosinophilic phenotype.
DEFITELIO	*defibrotide sodium*	SOLUTION; IV (INFUSION)	DEFITELIO is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT).

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
DESCOVY	*emtricitabine; tenofovir alafenamide fumarate*	TABLET; ORAL	DESCOVY is a two-drug combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors (NRTIs), and is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.
INFLECTRA	*infliximab-dyyb*	INJECTABLE; INJECTION	INFLECTRATM is a tumor necrosis factor (TNF) blocker indicated for: • Crohn's Disease • Pediatric Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis in combination with methotrexate • Ankylosing Spondylitis • Psoriatic Arthritis • Plaque Psoriasis
BROMSITE	*bromfenac sodium*	SOLUTION/ DROPS; OPHTHALMIC	BromSite is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.
VENCLEXTA	*venetoclax*	TABLET; ORAL	VENCLEXTA is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
PHOTREXA	*riboflavin 5'-phosphate sodium*	SOLUTION/ DROPS; OPHTHALMIC	PHOTREXA VISCOUS and PHOTREXA are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
SIMVASTATIN	*simvastatin*	SUSPENSION; ORAL	SIMVASTATIN oral suspension is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. • Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and non-familial) and mixed dyslipidemia. • Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. • Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. • Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.
ORFADIN	*nitisinone*	SUSPENSION; ORAL	ORFADIN is a 4-hydroxyphenylpyruvate dioxygenase inhibitor indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.
BEVESPI AEROSPHERE	*formoterol fumarate; glycopyrrolate*	AEROSOL, METERED; INHALATION	BEVESPI AEROSPHERE is a combination of glycopyrrolate, an anticholinergic, and formoterol fumarate, a long-acting beta2-adrenergic agonist (LABA) indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).
CABOMETYX	*cabozantinib s-malate*	TABLET; ORAL	CABOMETYX is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior antiangiogenic therapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
XTAMPZA ER	*OXYCODONE HYDROCHLORIDE*	CAPSULE, EXTENDED RELEASE; ORAL	XTAMPZA ER is an opioid agonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Limitations of use: • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve XTAMPZA ER is for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • XTAMPZA ER is not indicated as an as-needed (prn) analgesic.
ACTICLATE CAP	*doxycycline hyclate*	CAPSULE; ORAL	ACTICLATE® and ACTICLATE® CAP are tetracycline class drugs indicated for: • Rickettsial infections • Sexually transmitted infections • Respiratory tract infections • Specific bacterial infections • Ophthalmic infections • Anthrax, including inhalational anthrax (post-exposure) • Alternative treatment for selected infections when penicillin is contraindicated • Adjunctive therapy for acute intestinal amebiasis and severe acne • Prophylaxis of malaria To reduce the development of drug-resistant bacteria and maintain the effectiveness of ACTICLATE and ACTICLATE CAP and other antibacterial drugs, ACTICLATE and ACTICLATE CAP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria
NUPLAZID	*pimavanserin tartrate*	TABLET; ORAL	NUPLAZID is an atypical antipsychotic indicated for the treatment of NUPLAZID dosage may be needed.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
OTOVEL	*ciprofloxacin hydrochloride; fluocinolone acetonide*	SOLUTION/ DROPS; OTIC	OTOVEL is a combination of ciprofloxacin, a fluoroquinolone antibacterial, and fluocinolone acetonide, a corticosteroid, indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa.
FYCOMPA	*perampanel*	SUSPENSION; ORAL	FYCOMPA, a non-competitive AMPA glutamate receptor antagonist, is indicated as adjunctive therapy for the treatment of: • Partial-Onset Seizures with or without secondarily generalized seizures in • Patients with epilepsy 12 years of age and older. • Primary Generalized Tonic-Clonic Seizures in patients with epilepsy 12 years of age and older.
AMELUZ	*aminolevulinic acid hydrochloride*	GEL; TOPICAL	AMELUZ gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.
PROBUPHINE	*buprenorphine hydrochloride*	IMPLANT; IMPLANTATION	PROBUPHINE contains buprenorphine, a partial opioid agonist. PROBUPHINE is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). PROBUPHINE should be used as part of a complete treatment program to include counseling and psychosocial support. PROBUPHINE is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
JENTADUETO XR	*linagliptin; metformin hydrochloride*	TABLET, EXTENDED RELEASE; ORAL	JENTADUETO XR is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate. Important limitations of use: • Not for treatment of type 1 diabetes or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.

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
Invega *(paliperidone)* Extended-Release Tablets	CONTRAINDICATION	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.
Invega Sustenna *(paliperidone palmitate)* Extended-release Injectable Suspension	CONTRAINDICATION	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.
Invega Trinza *(paliperidone palmitate)* Extended-release Injectable Suspension	CONTRAINDICATION	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.
Invokamet *(canagliflozin and metformin hydrochloride)* Tablets	CONTRAINDICATION	History of a serious hypersensitivity reaction to canagliflozin or metformin, such as anaphylaxis or angioedema.

Drug	Type of Change	Change
Invokana *(canagliflozin)* Tablets	CONTRAINDICATION	History of a serious hypersensitivity reaction to Invokana, such as anaphylaxis or angioedema.
Plasma-Lyte 56 and 5% Dextrose Injection	CONTRAINDICATION	PLASMA -LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) must not be used in patients with clinically significant hyperglycemia.
Renagel *(sevelamer hydrochloride)* Tablets	CONTRAINDICATION	Renagel is contraindicated in patients with known hypersensitivity to sevelamer hydrochloride or to any of the excipients.
Renvela *(sevelamer carbonate)* Powder for Oral Suspension	CONTRAINDICATION	Renvela is contraindicated in patients with known hypersensitivity to sevelamer carbonate or to any of the excipients.
Risperdal *(risperidone)* Tablets, Oral Solution and Risperdal M-TAB *(risperidone)* Orally Disintegrating Tablets	CONTRAINDICATION	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.
Risperdal Consta *(risperidone)* Long Acting Injection	CONTRAINDICATION	RISPERDAL/RISPERDAL CONSTA/INVEGA(s) is contraindicated in patients with a known hypersensitivity to either risperidone or paliperidone, or to any of the excipients in the RISPERDAL/RISPERDAL CONSTA/INVEGA(s) formulation. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone and in patients treated with paliperidone. Paliperidone is a metabolite of risperidone.
Tudorza Pressair *(aclidinium bromide inhalation powder)*	CONTRAINDICATION	The use of TUDORZA PRESSAIR is contraindicated in the following conditions: • Severe hypersensitivity to milk proteins. • Hypersensitivity to aclidinium bromide or any of the excipients.
Kadcyla *(ado-trastuzumab emtansine)* for Injection, for Intravenous Use	CONTRAINDICATION	Embryo-Fetal Toxicity: Exposure to KADCYLA during pregnancy can result in embryo-fetal harm. Advise patients of these risks and the need for effective contraception.
Aciphex *(rabeprazole sodium)* Delayed-release Tablets, for Oral Use and Aciphex Sprinkle *(rabeprazole sodium delayed-release capsules)*	CONTRAINDICATION	PPIs, including ACIPHEX, are contraindicated with rilpivirine-containing products.
Lopid *(gemfibrozil Tables, USP)*	CONTRAINDICATION	Combination therapy of gemfibrozil with dasabuvir.
Ringer's Injection, USP in VIAFLEX Plastic Container	CONTRAINDICATION	Concomitant treatment with ceftriaxone and Ringer's Injection, USP is contraindicated in newborns (=28 days of age), even if separate infusion lines are used due to the risk of fatal ceftriaxone-calcium salt precipitation in the neonate's blood-stream.

Drug Shortages

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
Acetylcysteine Oral and Inhalation Solution	American Regent, Fresenius Kabi	American Regent has a consistent supply of acetylcysteine oral and inhalation solution. Fresenius Kabi states the reason for the shortage is increased demand. American Regent has acetylcysteine solution 100 mg/mL 10 mL vials on back order and the company cannot estimate a release date. Fresenius Kabi has acetylcysteine solution 100 mg/mL 10 mL vials on back order and the company estimates a release date in mid-April.
Anagrelide Capsules	Teva	Teva cannot provide a reason for the shortage. Teva has anagrelide 0.5 mg and 1 mg capsules on back order and the company estimates a release date of late-March for the 0.5 mg capsules and late-April for the 1 mg capsules.
Atropine Sulfate Ophthalmic Solution	Alcon Labs, Akorn, Sandoz	Alcon has discontinued Isopto Atropine. Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015. Sandoz could not provide a reason for the shortage. Akorn has atropine sulfate ophthalmic solution in 2 mL, 5 mL, and 15 mL bottles available in limited supply through April.

Drug Product	Affected Manufacturers	Summary
Carvedilol Tablets	Glenmark, Major, Mylan, Mylan Institutional, Sun Pharma	Glenmark cannot provide a reason for the shortage. Mylan cannot provide a reason for the shortage. Sun Pharma cannot provide a reason for the shortage. Glenmark has carvedilol 12.5 mg tablets in 100 count and 500 count, 6.25 mg tablets in 100 count and 500 count, and 3.125 mg tablets in 100 count on intermittent back order and the company is releasing product as it becomes available. Major has carvedilol 3.125 mg tablets on back order and the company cannot estimate a release date. Mylan has carvedilol 12.5 mg tablets in 100 count, 500 count (NDC 00378-3633-07), and 500 count (NDC 00378-3633-05), 25 mg in 500 count, 3.125 mg in 500 count, and 6.25 mg tablets in 500 count on back order and the company cannot estimate a release date. Mylan Institutional has 6.25 mg in 25-count unit-dose and 100-count unit-dose tablets available with an expiration date of January 2017. Carvedilol 12.5 mg in 25 count unit-dose are available with an expiration date of August. Sun has all carvedilol tablet presentations on back order and the company cannot estimate a release date.
Cefpodoxime	Aurobindo, Sandoz	Aurobindo could not provide a reason for the shortage. Sandoz could not provide a reason for the shortage. Aurobindo has cefpodoxime oral suspension 50 mg/5 mL 50 mL bottles and 100 mg/5 mL 50 mL and 100 mL bottles on back order and the company cannot estimate a release date. Sandoz has cefpodoxime 50 mg/5 mL oral suspension in 50 mL and 100 mL bottles on back order and the company cannot estimate a release date.
Chloroquine Tablets	Ranbaxy, West-Ward	Ranbaxy has chloroquine tablets on shortage due to third party supply issues. West-Ward has chloroquine tablets on shortage due to manufacturing delays.
Cyclopentolate Hydrochloride and Phenylephrine Hydrochloride Ophthalmic Solution	Alcon Labs	Alcon has Cyclomydril ophthalmic solution on back order due to production delays. Alcon has Cyclomydril ophthalmic solution in 5 mL sizes on back order and the company estimates a release date in early-April for the 5 mL bottles.
Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution	Akorn	Akorn has Paremyd on shortage due to manufacturing delays. Akorn has Paremyd ophthalmic solution available in limited supply.

Drug Product	Affected Manufacturers	Summary
Indomethacin Capsules	Glenmark, Heritage, Teva, Mylan	Mylan, Glenmark, and Teva did not provide a reason for the shortage. Glenmark has all indomethacin presentations on intermittent back order and is releasing product as it becomes available. Heritage has indomethacin 50 mg capsules in 500 count on back order and the company cannot estimate a release date. Mylan Institutional has indomethacin 50 mg unit-dose capsules in 300 count available with an expiration date of February 2017. The 25 mg unit-dose in 100 count are on back order and the company estimates a release date of mid-June. The 50 mg unit-dose in 100 counts are on back order and the company estimates a release date of mid-June. Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.
Leflunomide Tablets	Heritage	Heritage states the shortage is due to a delay in obtaining active ingredient. Heritage has leflunomide 10 mg and 20 mg tablets on tight allocation. The company estimates a return to full supply in March.
Liotrix Tablets	Actavis	Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes. Actavis (formerly Forest) has all Thyrolar presentations on long-term back order and the company cannot estimate a release date.
Methylphenidate Hydrochloride Chewable Tablets	Shionogi Pharma	Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues. Shionogi Pharma has all Methylin chewable tablets on long-term back order and the company cannot estimate a release date.
Methylphenidate Transdermal	Noven	Noven has Daytrana patches on shortage due to shipping delays. Noven has all Daytrana presentations on back order and the company estimates a release date in late-April.
Mupirocin Calcium 2% Cream	GlaxoSmithKline, Prasco	GlaxoSmithKline could not provide a reason for the shortage. Prasco discontinued mupirocin calcium 2% cream in February 2016. GlaxoSmithKline has Bactroban 2% cream in 30 gram sizes on back order and the company cannot estimate a release date.
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment	Perrigo	Perrigo has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to manufacturing issues. Perrigo has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on allocation.

Drug Product	Affected Manufacturers	Summary
Ofloxacin Otic Solution	Sandoz, Valeant	Sandoz discontinued ofloxacin otic solution in mid-2015. Valeant cannot provide a reason for the shortage. Valeant has temporarily discontinued ofloxacin otic 5 mL and 10 mL vials. The company cannot estimate a release date.
Ofloxacin Opthalmic Solution	Akorn, Rising Pharmaceuticals, Valeant	Akorn did not provide a reason for the shortage. Rising did not provide a reason for the shortage. Valeant did not provide a reason for the shortage. Akorn has ofloxacin ophthalmic solution in 5 mL and 10 mL bottles on back order and the company cannot estimate a release date. Rising has ofloxacin ophthalmic solution in 5 mL and 10 mL bottles on back order and the company estimates a release date of mid-May. Valeant has temporarily discontinued ofloxacin ophthalmic solution in 5 mL and 10 mL bottles and the company cannot estimate a release date.
Phenazopyridine Hydrochloride	Marlex	Marlex could not provide a reason for the shortage. Marlex has phenazopyridine 100 mg tablets on back order and the company cannot estimate a release date.
Propranolol Hydrochloride Tablets	Major, Teva	Teva could not provide a reason for the shortage. Major discontinued propranolol tablets in early 2016. Teva has propranolol 80 mg tablets in 500 count on back order and the company estimates a release date of mid- to late-June.
Sumatriptan Nasal Spray	GlaxoSmithKline, Sandoz	GlaxoSmithKline could not provide a reason for the shortage. Sandoz has sumatriptan nasal spray on shortage due to product constraints. GlaxoSmithKline has Imitrex 20 mg nasal spray on back order and the company estimates a release date in early-March. Sandoz has sumatriptan 5 mg and 20 mg nasal spray on back order and the company estimates a release date of mid-to-late March.
Synthetic Conjugated Estrogen	Teva	Teva discontinued Cenestin in late-August 2014. Premarin is not affected by this shortage. Teva has Enjuvia 0.625 mg, 0.9 mg, and 1.25 mg tablets temporarily unavailable and the company cannot estimate a release date.
Tamsulosin Hydrochloride Capsules	Mylan	Mylan has tamsulosin 0.4 mg capsules in 90 and 1,000 count and 100-count unit-dose on intermittent back order and the company is releasing supplies as they become available.

Drug Product	Affected Manufacturers	Summary
Testosterone Cypionate Intramuscular Injection	Sun Pharma	Sun Pharma did not provide a reason for the shortage. Sun Pharma has all testosterone cypionate presentations on back order and the company cannot estimate a release date.
Theophylline Extended-Release Tablets	Major, Teva	Major has theophylline extended-release tablets on shortage due to increased demand. Teva cannot provide a reason for the shortage. Major has theophylline extended-release tablets on back order and the company cannot estimate a release date. Teva has theophylline 300 mg extended-release tablets in 500 count on back order and the company estimates a release date of mid-April. The 100 mg tablets in 100 count and 500 count, 200 mg tablets in 100 count, 500 count, and 1,000 count, and 300 mg tablets in 1,000 count are on back order and the company cannot estimate a release date.
Tretinoin Oral Capsules	Par Pharmaceuticals, Teva	Par was not able to provide a reason for the shortage. Teva was not able to provide a reason for the shortage. Par has tretinoin 10 mg capsules on back order and the company estimates a release date of late-March. Teva has tretinoin 10 mg capsules on back order and the company estimates a release date of early-May 2016.
Tropicamide 1% Ophthalmic Solution	Alcon Labs, Sandoz	Sandoz cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution. Sandoz has tropicamide 1% ophthalmic solution 3 mL bottles on back order and the company estimates a release date of late-March. Alcon has Mydriacyl 1% 3 mL bottles on back order and the company estimates a release date in mid-March. Mydriacyl 1% 15 mL bottles are on back order and the company estimates a release date in mid-April.

Drug Product	Affected Manufacturers	Summary
Zolpidem Tartrate Immediate Release Tablets	Aurobindo, Major, Mylan, Mylan institutional, Sandoz, Teva	Aurobindo could not provide a reason for the shortage. Major could not provide a reason for the shortage. Mylan could not provide a reason for the shortage. Aurobindo has zolpidem 5 mg and 10 mg tablets on back order and the company cannot estimate a release date. Major has zolpidem 5 mg and 10 mg tablets on back order and the company cannot estimate a release date. Mylan has all zolpidem 5 mg and 10 mg tablets on back order and the company cannot estimate a release date. Sandoz has zolpidem 5 mg and 10 mg tablets in 500 count on back order with an estimated release date of mid-April for the 5 mg tablets and late-March for the 10 mg tablets. Teva has zolpidem 10 mg tablets on back order and the company estimates a release date in early-April.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three 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
Opioid pain medications	The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. The FDA is requiring changes to the labels of all opioid drugs to warn about these risks. • Opioids can interact with antidepressants and migraine medicines to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of the chemical serotonin build up in the brain and cause toxicity (see List of Serotonergic Medicines). • Taking opioids may lead to a rare, but serious, condition in which the adrenal glands do not produce adequate amounts of the hormone cortisol. Cortisol helps the body respond to stress. • Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility.
Onglyza *(saxagliptin)* and Kombiglyze XR *(saxagliptin and metformin extended release)*	A U.S. Food and Drug Administration (FDA) safety review has found that type 2 diabetes medicines containing saxagliptin and alogliptin may increase the risk of heart failure, particularly in patients who already have heart or kidney disease. Heart failure can result in the heart not being able to pump enough blood to meet the body's needs. As a result, the FDA is adding new warnings to the drug labels about this safety issue.

Drug	Communications Summary
Metformin in certain patients with reduced kidney function	The U.S. Food and Drug Administration (FDA) is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin's use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. The FDA was asked to review numerous medical studies regarding the safety of metformin use in patients with mild-to-moderate impairment in kidney function and to change the measure of kidney function in the metformin drug labeling that is used to determine whether a patient can receive metformin. The FDA concluded its review, and is requiring changes to the labeling of all metformin-containing medicines to reflect this new information.
Diflucan *(fluconazole)*	The U.S. Food and Drug Administration (FDA) is evaluating the results of a Danish study that conclude there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. The FDA is also reviewing additional data and will communicate its final conclusions and recommendations when the review is complete.
Brintellix *(vortioxetine)*	The U.S. Food and Administration (FDA) has approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix, and it is expected to be available starting in June. No other changes will be made to the label or packaging, and the medicine is exactly the same. Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals and patients may continue to see bottles labeled with the brand name Brintellix during the transition period.
Abilify, Abilify Maintena, Aristada *(aripiprazole)*	The U.S. Food and Drug Administration (FDA) is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized. Although pathological gambling is listed as a reported side effect in the current aripiprazole drug labels, this description does not entirely reflect the nature of the impulse-control risk that the FDA has identified. In addition, the FDA has become aware of other compulsive behaviors associated with aripiprazole, such as compulsive eating, shopping, and sexual actions. These compulsive behaviors can affect anyone who is taking the medicine. As a result, the FDA is adding new warnings about all of these compulsive behaviors to the drug labels and the patient medication guides for all aripiprazole products.
Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax *(olanzapine)*	The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. The FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Drug	Communications Summary
fluoroquinolone	The U.S. Food and Drug Administration is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolone should be reserved for those who do not have alternative treatment options. An FDA safety review has shown that fluoroquinolones, when used systemically (i.e. tablets, capsules, and injectable), are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system. As a result, the FDA is requiring the drug labels and medication guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. The FDA is continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.
Invokana, Invokamet	The U.S. Food and Drug Administration (FDA) is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medicine canagliflozin (Invokana, Invokamet). The FDA has not determined whether canagliflozin increases the risk of leg and foot amputations. The FDA is currently investigating this new safety issue and will update the public when there is more information.
Nizoral *(ketoconazole)* oral tablets	The U.S. Food and Drug Administration (FDA) is warning health care professionals to avoid prescribing the antifungal medicine ketoconazole oral tablets to treat skin and nail fungal infections. Use of this medication carries the risk of serious liver damage, adrenal gland problems, and harmful interactions with other medicines that outweigh its benefit in treating these conditions, which are not approved uses of the drug. The FDA approved label changes for oral ketoconazole tablets in 2013 to reflect these serious risks and to remove the indication for treatment of skin and nail fungal infections. However, an FDA safety review found that oral ketoconazole continues to be prescribed for these types of conditions. In the 18 months ending in June 2015, skin and nail fungal infections were the only diagnoses cited for the use of oral ketoconazole in an office-based physician surveys database. Since the 2013 labeling change, one patient death has been reported to the FDA due to liver failure associated with oral ketoconazole prescribed to treat a fungal infection of the nails.
Zecuity *(sumatriptan)* migraine patch	The U.S. Food and Drug Administration (FDA) is investigating the risk of serious burns and potential permanent scarring with the use of the Zecuity (sumatriptan iontophoretic transdermal system) patch for migraine headaches. The FDA is investigating the cause and extent of these serious side effects and will update the public with new information when the review is complete.

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