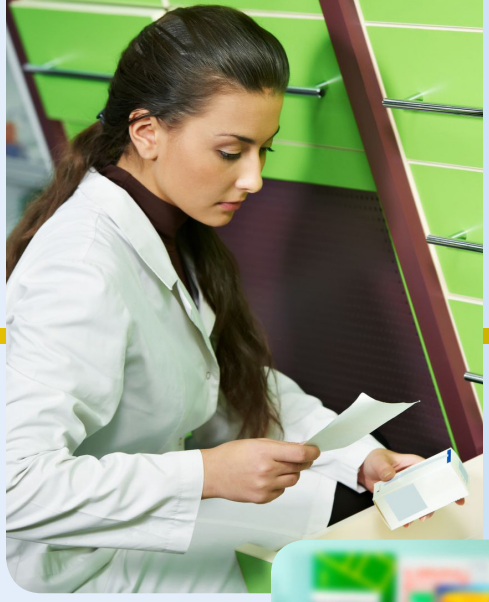

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

APRIL 2016

Q2 2016

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PN Q2 2016

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

The goal of Gold Coast Health Plan is to provide all medically-necessary pharmaceuticals in the most economical way possible.

In the last several years, many high-cost, brand name drugs have become available as generics. Generic drugs are almost always available without approval. The Plan's requirement that a generic drug be used whenever one is available has allowed GCHP to provide these drug treatments much more economically.

The Plan will provide a brand name drug when a generic is available when a prior authorization has been submitted documenting why the brand name drug needs to be used. Prior authorization forms are available on the Plan's website.

Here are a few other things to know when it comes to GCHP's pharmacy benefit:

Step therapy requirements – Some drugs on the Plan's formulary are available on a step therapy basis. This means that certain other drugs must be tried before the step therapy drug will be allowed. If there is evidence in the member's drug history that he/she has had the lower step drug or drugs, no authorization is necessary for the member to receive the medication. If the step 1 drug is not appropriate or contraindicated for a member, an authorization can be requested and the step 2 drug will be approved. For example, to get Crestor, the step therapy atorvastatin must first be tried and failed.

Prior authorization – There are medications – usually expensive brand medications – that will always require a prior authorization. Usually, there will be a requirement that the prescribing doctor documents that the patient meets certain requirements or guidelines. For example, to obtain Sovaldi, the patient must meet the requirements of the guideline for the use hepatitis C agents.

Quantity limits – There are quantity limits on certain medications. Most quantity limits are for narcotic medications. An amount larger that the quantity limit may be provided when there is good documentation for the need for a larger amount of the medication. The Plan usually will not allow more than a month's supply for any drug.

Finally, the Plan wants to be sure that all drugs are available to its members when the drugs are indicated. Any drug that is limited on GCHP's formulary or is not listed may be available via prior authorization. Additionally, there is a process to evaluate all drugs that are newly-approved by the FDA within 180 days of approval or when the drug becomes available in the market.

If you have any questions, please do not hesitate to contact me or GCHP's Director of Pharmacy, Annie Freese.

Regards,

C. Albert Reeves, M.D.

C. Albert Reeves, MD

Disease State Topic: How to Obtain Prior Authorization

All drugs that have a limit or require authorization are listed on the formulary on GCHP's website. Click here to see GCHP's List of Covered Drugs (LCD).

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:

- The member goes to the pharmacy with a prescription.
- The pharmacy processes the prescription that rejects for one of the above reasons.
- The pharmacy informs the MD that an authorization is necessary.
- The MD contacts Script Care (1-888-531-0998) to start the prior authorization process.
- Script Care faxes a blank prior authorization form to the MD.
- The MD completes the form and faxes it back to Script Care (1-888-392-4890).
- Script Care receives the completed authorization request form.
- The authorization request form is reviewed for compliance with the formulary guidelines and is either approved or denied.
- The MD and the pharmacy receive faxes documenting the outcome of the request as approved or denied within one 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.

Pharmacy Department Update

Have a Formulary Suggestion?

GCHP has developed a generic-first formulary that serves to provide all medically necessary medications in the most cost effective manner. Over the past year, GCHP has worked to ensure that its formulary is aligned with current medical practice and offers prescribers enough flexibility to treat their patients without undue restrictions.

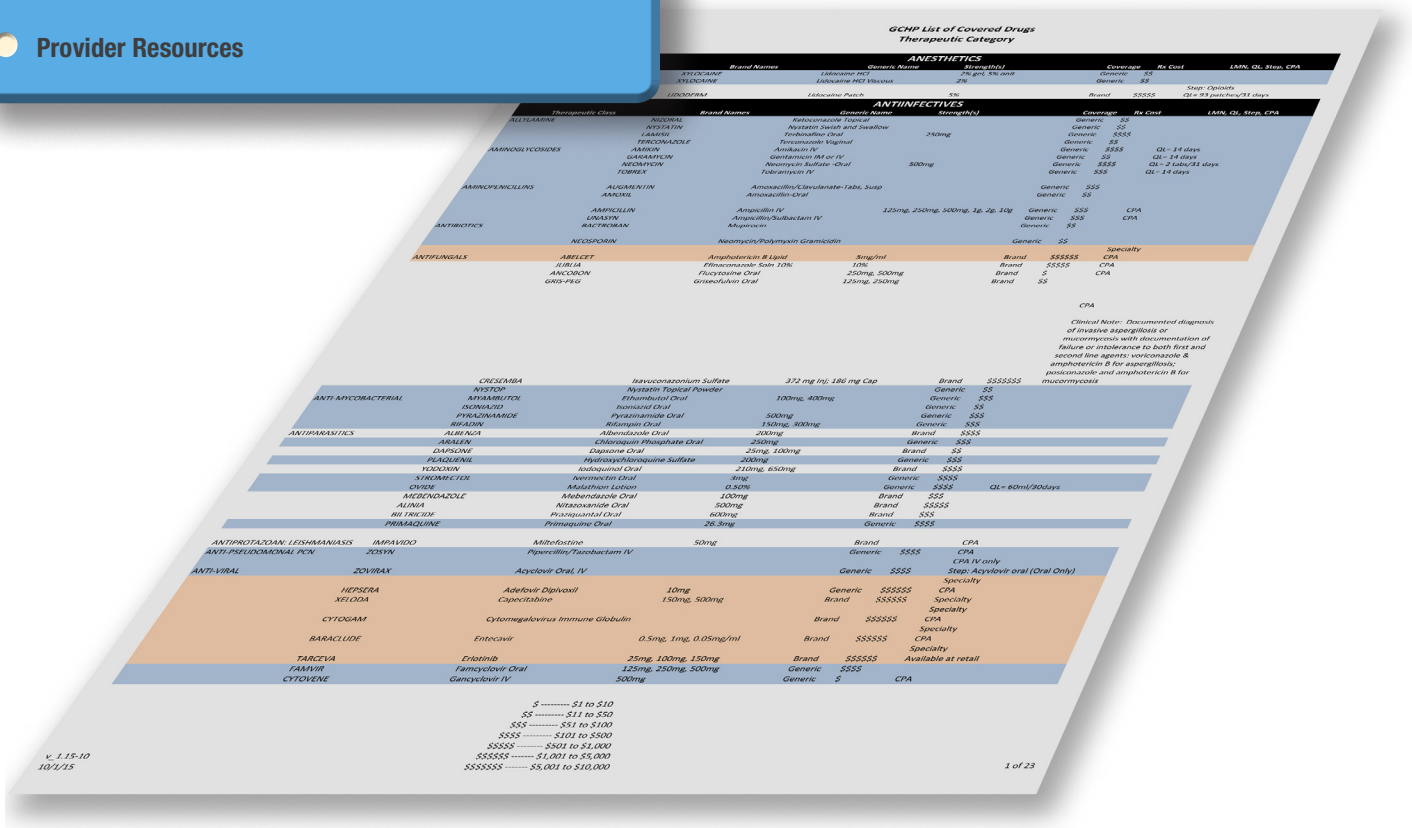
To that end, if you or one of your fellow prescribers sees an area of the formulary that should be reviewed or would like to make any suggestions, please contact the GCHP Pharmacy Director, Annie Freese via email at afreese@goldchp.org or via regular mail by writing to GCHP at the following address:

GCHP Pharmacy Director
711 E. Daily Dr. Suite 106
Camarillo, CA 93010

Quick Links

CLICK EACH TOPIC FOR MORE INFORMATION

- GCHP Formulary
- List of Participating Pharmacies
- Provider Resources


GCHP List of Covered Drugs
Therapeutic Category

ANESTHETICS

Therapeutic Class	Brand Names	Generic Name	Strength(s)	Coverage	Rx Cost	LMN, QL, Step, CPA
	XYLOCAINE	Lidocaine HCl	1% and 2%, 5% /pkt	Generic	$$	
	XYLOCAINE	Lidocaine HCl Viscous	2%	Generic	$$	
	LIDODERM	Lidocaine Patch	5%	Brand	$$$$$	Step: Opioids QL= 90 patches/31 days

ANTIINFECTIVES

Therapeutic Class	Brand Names	Generic Name	Strength(s)	Coverage	Rx Cost	LMN, QL, Step, CPA
ALLYLAMINE	NIZORAL	Ketoconazole Topical		Generic	$$	
	NYSTATIN	Nystatin Swish and Swallow		Generic	$$	
	LAMISIL	Terbinafine Oral	250mg	Generic	$$$$	
	TERCONAZOLE	Terconazole Vaginal		Generic	$$	
AMINOGLYCOSIDES	AMIKIN	Amikacin IV		Generic	$$$$	QL - 14 days
	GARAMYCIN	Gentamicin IM or IV		Generic	$$	QL - 14 days
	NEOMYCIN	Neomycin Sulfate -Oral	500mg	Generic	$$$$	QL - 2 tabs/31 days
	TOBREX	Tobramycin IV		Generic	$$$	QL - 14 days
AMINOPENICILLINS	AUGMENTIN	Amoxacillin/Clavulanate-1abs, Susp		Generic	$$$	
	AMOXIL	Amoxacillin-Oral		Generic	$$	
	AMPICILLIN	Ampicillin IV	125mg, 250mg, 500mg, 1g, 2g, 10g	Generic	$$$	CPA
	UNASYN	Ampicillin/Sulbactam IV		Generic	$$$	CPA
ANTIBIOTICS	BACTROBAN	Mupirocin		Generic	$$	
	NEOSPORIN	Neomycin/Polymyxin Gramicidin		Generic	$$	
ANTIFUNGALS	ABELCET	Amphotericin B Lipid	5mg/ml	Brand	$$$$$$	Specialty CPA
	JUBLIA	Efinaconazole Soln 10%	10%	Brand	$$$$$	CPA
	ANCOBON	Flucytosine Oral	250mg, 500mg	Brand	$	CPA
	GRIS-PEG	Griseofulvin Oral	125mg, 250mg	Brand	$$	

CPA

Clinical Note: Documented diagnosis of invasive aspergillosis or mucormycosis with documentation of failure or intolerance to both first and second line agents: voriconazole & amphotericin B for aspergillosis; posiconazole and amphotericin B for mucormycosis

Therapeutic Class	Brand Names	Generic Name	Strength(s)	Coverage	Rx Cost	LMN, QL, Step, CPA
	CRESEMBA	Isavuconazonium Sulfate	372 mg Inj; 186 mg Cap	Brand	$$$$$$$	
	NYSTOP	Nystatin Topical Powder		Generic	$$	
ANTI MYCOBACTERIAL	MYAMBUTOL	Ethambutol Oral	100mg, 400mg	Generic	$$$	
	ISONIAZID	Isoniazid Oral		Generic	$$	
	PYRAZINAMIDE	Pyrazinamide Oral	500mg	Generic	$$$	
	RIFADIN	Rifampin Oral	150mg, 300mg	Generic	$$$	
ANTIPARASITICS	ALBENZA	Albendazole Oral	200mg	Brand	$$$$	
	ARALEN	Chloroquin Phosphate Oral	250mg	Generic	$$$	
	DAPSONE	Dapsone Oral	25mg, 100mg	Brand	$$	
	PLAQUENIL	Hydroxychloroquine Sulfate	200mg	Generic	$$$	
	YODOXIN	Iodoquinol Oral	210mg, 650mg	Brand	$$$$	
	STROMECTOL	Ivermectin Oral	3mg	Generic	$$$$	
	OVIDE	Malathion Lotion	0.50%	Generic	$$$$	QL= 60ml/30days
	MEDENDAZOLE	Mebendazole Oral	100mg	Brand	$$$	
	ALINIA	Nitazoxanide Oral	500mg	Brand	$$$$$	
	BILTRICIDE	Praziquantal Oral	600mg	Brand	$$$	
	PRIMAQUINE	Primaquine Oral	26.3mg	Generic	$$$$	
ANTIPROTAZOAN; LEISHMANIASIS	IMPAVIDO	Miltefostine	50mg	Brand		CPA
ANTI-PSEUDOMONAL PCN	ZOSYN	Piperacillin/Tazobactam IV		Generic	$$$$	CPA
						CPA IV only
ANTI-VIRAL	ZOVIRAX	Acyclovir Oral, IV		Generic	$$$$	Step: Acyclovir oral (Oral Only)
	HEPSERA	Adefovir Dipivoxil	10mg	Generic	$$$$$$	CPA Specialty
	XELODA	Capecitabine	150mg, 500mg	Brand	$$$$$$	Specialty
	CYTOGAM	Cytomegalovirus Immune Globulin		Brand	$$$$$$	CPA Specialty
	BARACLUDE	Entecavir	0.5mg, 1mg, 0.05mg/ml	Brand	$$$$$$	CPA Specialty
	TARCEVA	Erlotinib	25mg, 100mg, 150mg	Brand	$$$$$$	Available at retail
	FAMVIR	Famcyclovir Oral	125mg, 250mg, 500mg	Generic	$$$$	
	CYTOVENE	Gancyclovir IV	500mg	Generic	$	CPA

$ --------- $1 to $10
$$ --------- $11 to $50
$$$ --------- $51 to $100
$$$$ --------- $101 to $500
$$$$$ --------- $501 to $1,000
$$$$$$ ------- $1,001 to $5,000
$$$$$$$ ------ $5,001 to $10,000

v_1.15-10
10/1/15

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Formulary Changes

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

Additions

Drug	Formulary Status/Change
ALECENSA (alectinib)	Add to the formulary with a prior authorization documenting indication.
COTELLIC *(cobimetinib)*	Add to the formulary with a prior authorization documenting indication.
LONSURF *(tipiracil hydrochloride:trifluridine)*	Add to the formulary with a prior authorization documenting indication.
NINLARO *(ixazomib)*	Add to the formulary with a prior authorization documenting indication.
TAGRISSO *(osimertinib)*	Add to the formulary with a prior authorization documenting indication.
TRESIBA *(insulin degludec)*	Add to the formulary.
UPTRAVI *(selexipag)*	Add to the formulary with a prior authorization documenting indication.
VARUBI *(rolapitant hydrochloride)*	Add to the formulary with a prior authorization documenting indication.

Removals

Drug	Formulary Status/Change
CANASA rectal suppository	Brand removed; generic now available.
GLEEVEC oral tablets	Brand removed; generic now available.
PATANOL ophthalmic solution	Brand removed; generic now available.
DIFFERIN topical solution	Brand removed; generic now available.
EXJADE tablets for oral suspension	Brand removed; generic now available.
SAVELLA tablets	Brand removed; generic now available.

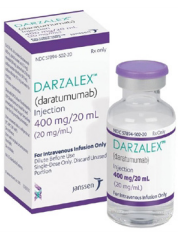
FDA Alerts

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.

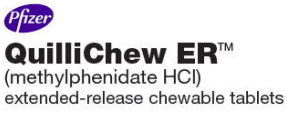
Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
NUCALA	*mepolizumab*	INJECTABLE; SUBCUTANEOUS LYOPHILIZED POWER	NUCALA is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients 12 years of age and older with severe asthma and with an eosinophilic phenotype. Limitations of use: • Not for treatment of other eosinophilic conditions. • Not for relief of acute bronchospasm or status asthmaticus.
GENVOYA	*cobicistat; elvitegravir; emtricitabine; tenofovir alafenamide fumarate*	TABLET; ORAL	GENVOYA is a four-drug combination of elvitegravir, an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat, a CYP3A inhibitor, and emtricitabine and tenofovir alafenamide (TAF), both HIV1 nucleoside analog reverse transcriptase inhibitors (NRTIs) and is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of GENVOYA.
ULTRAVATE	*halobetasol propionate*	LOTION; TOPICAL	ULTRAVATE lotion is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.
COTELLIC	*cobimetinib fumarate*	TABLET; ORAL	COTELLIC is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. Limitation of use: COTELLIC is not indicated for treatment of patients with wild-type BRAF melanoma.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
TAGRISSO	*osimertinib mesylate*	TABLET; ORAL	TAGRISSO is a kinase inhibitor indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
DARZALEX	*daratumumab*	INJECTABLE; INJECTION	DARZALEX is a human CD38-directed monoclonal antibody indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
NARCAN	*naloxone hydrochloride*	SPRAY, METERED; NASAL	NARCAN Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present. NARCAN Nasal Spray is not a substitute for emergency medical care.
NINLARO	*ixazomib citrate*	CAPSULE; ORAL	NINLARO is a proteasome inhibitor indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.



Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
NEXIUM 24HR	*esomeprazole magnesium*	TABLET, DELAYED RELEASE; ORAL	**Gastroesophageal reflux disease (Rx only):** Healing of erosive esophagitis: Short-term (4 to 8 weeks) treatment in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For infants 1 month to younger than 1 year with acid-mediated erosive esophagitis, treat up to 6 weeks (esomeprazole magnesium only). **Maintenance of healing of erosive esophagitis:** To maintain symptom resolution and healing of erosive esophagitis. **Symptomatic gastroesophageal reflux disease:** Short-term (4 to 8 weeks) treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) in adults (esomeprazole magnesium and esomeprazole strontium) and children 1 year and older (esomeprazole magnesium only). **Heartburn (OTC only):** Treatment of frequent heartburn (2 or more days per week). **Helicobacter pylori eradication (Rx only):** Triple therapy (esomeprazole plus amoxicillin and clarithromycin): In combination with amoxicillin and clarithromycin for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or within the past 5 years) to eradicate H. pylori. **Pathological hypersecretory conditions, including Zollinger-Ellison syndrome (Rx only):** Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome. **Risk reduction of nonsteroidal anti-inflammatory drug-associated gastric ulcer (Rx only):** Reduction in the occurrence of gastric ulcers associated with continuous nonsteroidal anti-inflammatory drug (NSAID) therapy in patients at risk of developing gastric ulcers (e.g., 60 years and older, history of gastric ulcers).
PORTRAZZA	*necitumumab*	INJECTABLE; INTRA-ARTICULAR, INTRAMUSCULAR, INTRAVITREAL	PORTRAZZA™ is an epidermal growth factor receptor (EGFR) antagonist indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. Limitation of use: PORTRAZZA is not indicated for treatment of non-squamous non-small cell lung cancer.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
PRAXBIND	*idarucizumab*	Injectable; injection	PRAXBIND is a humanized monoclonal antibody fragment (Fab) indicated in patients treated with Pradaxa® when reversal of the anticoagulant effects of dabigatran is needed: • For emergency surgery/urgent procedures. • In life-threatening or uncontrolled bleeding.
EMPLICITI	*elotuzumab*	INJECTABLE; INJECTION	EMPLICITI is a SLAMF7-directed immunostimulatory antibody indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies.
QUILLI-CHEW ER	*methylphenidate hydrochloride*	TABLET, EXTENDED RELEASE, CHEWABLE; ORAL	QuilliChew ER is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
BENDEKA	*bendamustine hydrochloride*	SOLUTION; IV (INFUSION)	Bendamustine hydrochloride is an alkylating drug indicated for treatment of patients with: • Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. • Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
KANUMA	*sebelipase alfa*	INJECTABLE; INJECTION	KANUMA™ is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.
OTIPRIO	*ciprofloxacin*	INJECTABLE, SUSPENSION; OTIC	OTIPRIO is a fluoroquinolone antibacterial indicated for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement.



Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
VISTOGARD	*uridine triacetate*	GRANULE; ORAL	VISTOGARD® is a pyrimidine analog indicated for the emergency treatment of adult and pediatric patients: • following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or • who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration. Limitations of use: • VISTOGARD is not recommended for the non-emergent treatment of adverse reactions associated with fluorouracil or capecitabine because it may diminish the efficacy of these drugs. • The safety and efficacy of VISTOGARD initiated more than 96 hours following the end of fluorouracil or capecitabine administration have not been established.
ALECENSA	*alectinib hydrochloride*	CAPSULE; ORAL	ALECENSA is a 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. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
BRIDION	*sugammadex sodium*	SOLUTION; INTRAVENOUS	BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.
BASAGLAR	*insulin glargine*	SOLUTION; SUBCUTANEOUS	BASAGLAR® is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for treating diabetic ketoacidosis.
EMEND	*aprepitant*	FOR SUSPENSION; ORAL	EMEND for oral suspension is indicated in combination with other antiemetic agents, in patients 6 months of age and older for prevention of: • acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. • nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
UPTRAVI	*selexipag*	TABLET; ORAL	UPTRAVI® is a prostacyclin receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.
DOCETAXEL	*Docetaxel*	SOLUTION; IV (INFUSION)	Docetaxel Injection is a microtubule inhibitor indicated for: • Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC. • Non-Small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC. • Hormone Refractory Prostate Cancer (HRPC): with prednisone in androgen independent (hormone refractory) metastatic prostate cancer. • Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction. • Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN.
ZURAMPIC	*Lesinurad*	TABLET; ORAL	ZURAMPIC is a URAT1 inhibitor indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. Limitations of use: • ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia. • ZURAMPIC should not be used as monotherapy.
ZOLEDRONIC ACID	*zoledronic acid*	SOLUTION; IV (INFUSION)	Zoledronic acid is a bisphosphonate indicated for the treatment of: • Hypercalcemia of malignancy. • Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy. Important limitation of use: The safety and efficacy of zoledronic acid has not been established for use in hyperparathyroidism or nontumor-related hypercalcemia.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
DEXILANT SOLUTAB	*dexlansoprazole*	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE; ORAL	DEXILANT delayed-release capsules (DEXILANT capsules) are indicated in adults for: • Healing of all grades of erosive esophagitis (EE). • Maintaining healing of EE and relief of heartburn. • Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD). DEXILANT SoluTab delayed-release orally disintegrating tablets (DEXILANT SoluTab) are indicated in adults for: • Maintaining healing of EE and relief of heartburn. • Treating heartburn associated with GERD.
ONZETRA XSAIL	*sumatriptan succinate*	POWDER; INHALATION	ONZETRA Xsail is a serotonin 5-HT1B/1D receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults. Limitations of use: • Use only if a clear diagnosis of migraine headache has been established. • Not indicated for the prophylactic therapy of migraine attacks. • Not indicated for the treatment of cluster headache.
ADZENYS XR-ODT	*amphetamine*	TABLET, ORALLY DISINTEGRATING, EXTENDED RELEASE; ORAL	ADZENYS XR-ODT is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.
ZEMBRACE SYMTOUCH	*sumatriptan succinate*	SOLUTION; SUBCUTANEOUS	ZEMBRACE SymTouch is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for: • Acute treatment of migraine with or without aura in adults. Limitations of use: • Use only if a clear diagnosis of migraine has been established. • Not indicated for the prophylactic therapy of migraine.
ZEPATIER	*Elbasvir; grazoprevir*	TABLET; ORAL	ZEPATIER is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
CETYLEV	*acetylcysteine*	TABLET, EFFERVESCENT; ORAL	CETYLEV is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with acute ingestion or from repeated supratherapeutic ingestion.

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
Methotrexate injection (preservative and preservative-free)	Boxed Warning	• For intrathecal and high-dose methotrexate therapy, use the preservative-free formulation of methotrexate. Do not use the preserved formulation of methotrexate for intrathecal or high dose therapy because it contains benzyl alcohol.
Harvoni (ledipasvir/ sofosbuvir) Fixed-dose Combination Tablet	Contraindications	• If Harvoni is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin.
Tybost (cobicistat) Tablet	Contraindications	Table 2 Drugs that are Contraindicated with Concomitant use with Tybost and Atazanavir or Darunavir • Anticonvulsants (carbamazepine, phenobarbital, phenytoin): Potential for decreased atazanavir or darunavir plasma concentrations, which may result in loss of therapeutic effect and development of resistance.
Gleostine (lomustine) Capsules	Boxed Warning	* Boxed warning updated to read: WARNING: DELAYED MYELOSUPPRESSION and RISK OF OVERDOSAGE DELAYED MYELOSUPPRESSION • Gleostine causes myelosuppression including fatal myelosuppression. Myelosuppression is delayed, dose-related, and cumulative; occurring 4 to 6 weeks after drug administration and persisting for 1 to 2 weeks. Thrombocytopenia is generally more severe than leukopenia. Cumulative myelosuppression from Gleostine is manifested by greater severity and longer duration of cytopenias. Monitor blood counts for at least 6 weeks after each dose. Do not give Gleostine more frequently than every 6 weeks. RISK OF OVERDOSAGE • PRESCRIBE, DISPENSE, AND ADMINISTER ONLY ENOUGH CAPSULES FOR ONE DOSE. Fatal toxicity occurs with overdosage of Gleostine. Both physician and pharmacist should emphasize to the patient that only one dose of Gleostine is taken every 6 weeks.

Drug	Type of Change	Change
Lotronex (*alosetron hydrochloride*) Tablets	Boxed Warning	* Boxed warning updated to read: WARNING: SERIOUS GASTROINTESTINAL ADVERSE REACTIONS • Infrequent but serious gastrointestinal adverse reactions have been reported with the use of Lotrenex. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization, and rarely, blood transfusion, surgery, and death. • Lotrenex is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy. • Lotrenex should be discontinued immediately in patients who develop constipation or symptoms of ischemic colitis. Patients should immediately report constipation or symptoms of ischemic colitis to their prescriber. Lotrenex should not be resumed in patients who develop ischemic colitis. Patients who have constipation should immediately contact their prescriber if the constipation does not resolve after Lotrenex is discontinued. Patients with resolved constipation should resume Lotrenex only on the advice of their treating prescriber.
Propylthiouracil tablets	Boxed Warning	WARNING • Severe liver injury and acute liver failure, in some cases fatal, have been reported in patients treated with propylthiouracil. These reports of hepatic reactions include cases requiring liver transplantation in adult and pediatric patients. • Propylthiouracil should be reserved for patients who cannot tolerate methimazole and in whom radioactive iodine therapy or surgery are not appropriate treatments for the management of hyperthyroidism. • Propylthiouracil may be the treatment of choice when an antithyroid drug is indicated during or just prior to the first trimester of pregnancy.
Topotecan Injection	Boxed Warning	WARNING: BONE MARROW SUPPRESSION • Topotecan injection can cause severe myelosuppression. Administer only to patients with baseline neutrophil counts of greater than or equal to 1,500 cells/mm3 and platelet counts greater than or equal to 100,000 cells/mm3. Monitor blood cell counts.
Fanapt (*iloperidone*) Tablets	Contraindications	• Anaphylaxis, angioedema, and other hypersensitivity reactions have been reported.
Orbactiv (*oritavancin diphosphate*) Lyophilized Powder for Injection	Contraindications	**Intravenous Unfractionated Heparin Sodium** • Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (five days) after Orbactiv administration because the activated partial thromboplastin time (aPTT) test results may remain falsely elevated for up to 120 hours (five days) after Orbactiv administration.

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.
Albuterol Sulfate Metered Dose Inhalers	GlaxoSmithKline	GlaxoSmithKline could not provide a reason for the shortage. GlaxoSmithKline has Ventolin HFA 8 gram inhalers on back order and the company estimates a release date of mid-April. Ventolin HFA 18 gram inhalers are on allocation with daily releases.
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.
Benzonatate Capsules	Vertical, Ascend, Major, Zydus	Zydus states the reason for the shortage is manufacturing delay. Vertical discontinued Zonatuss in 2016. Ascend has benzonatate 100 mg and 200 mg capsules on intermittent back order and the company is releasing product as it becomes available. Major has benzonatate 100 mg capsules on intermittent back order and the company is releasing product as it becomes available. Zydus has not launched benzonatate 200 mg capsules and the company cannot estimate when product will be available.

Drug Product	Affected Manufacturers	Summary
Carvedilol Tablets	Glenmakr, 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 2016. 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.
Dexamethasone 0.1% Ophthalmic Drops	Valeant	Valeant could not provide a reason for the shortage. Valeant has dexamethasone 0.1% ophthalmic solution on back order and the company estimates a release date of March 2016.

Drug Product	Affected Manufacturers	Summary
Dibucaine Ointment	Fougera, Perrigo	Perrigo and Fougera cannot provide a reason for the shortage. Perrigo has temporarily discontinued dibucaine ointment and the company cannot estimate a resupply date. Fougera has dibucaine ointment on long-term back order and the company cannot estimate a release date.
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.
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. 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.
Piroxicam Capsules	Teva	Teva could not provide a reason for the shortage. Teva has piroxicam capsules on back order and the company estimates a release date in late-March.
Reserpine Oral Tablets	Sandoz	Sandoz said the shortage is due to a delay in obtaining raw materials. Sandoz has all reserpine tablet presentations temporarily unavailable and the company cannot estimate a release date.
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 1000 count and 100-count unit-dose on intermittent back order and the company is releasing supplies as they become available.
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.

Drug Product	Affected Manufacturers	Summary
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.
Thrombin Topical Solution (Bovine)	Pfizer	Pfizer states the reason for the shortage is manufacturing delay. Recombinant thrombin topical solution products (Recothrom) are available and not affected by this shortage. Pfizer has Thrombin JMI 20,000 unit syringe spray kits on back order and the company estimates a release date of early-March. Thrombin JMI 5,000-unit syringe spray kits and 20,000-unit pump spray kits are on back order and the company estimates a release date of late-April.
Tretinoin Oral Capsules	Par Pahrmacuticals, 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.
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
Vitamin E Aqueous Oral Solution	Hospira, Geritrex	Hospira is changing manufacturing sites from a third-party manufacturer to in-house manufacturing. This has caused a delay in production. Geritrex could not provide a reason for the vitamin E drops shortage. Hospira has both Aquasol E Drop products on back order and the company cannot estimate a release date. Geritrex has vitamin E drops on back order and the company cannot estimate a release date.
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
Plavix (clopidogrel)	A U.S. Food and Drug Administration (FDA) review has determined that long-term use of the blood-thinning drug Plavix (clopidogrel) does not increase or decrease overall risk of death in patients with, or at risk for, heart disease. The FDA's evaluation of the Dual Antiplatelet Therapy (DAPT) 1 trial and several other clinical trials also does not suggest that clopidogrel increases the risk of cancer or death from cancer.
SGLT2 inhibitors for diabetes	A U.S. Food and Drug Administration (FDA) safety review has resulted in adding warnings to the labels of a specific class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors about the risks of too much acid in the blood and of serious urinary tract infections. Both conditions can result in hospitalization.

Drug	Communications Summary
Rosiglitazone-containing diabetes medicines	The U.S. Food and Drug Administration (FDA) is eliminating the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing type 2 diabetes medicines, which are approved as Avandia, Avandamet, Avandaryl, and generics. The REMS is no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks.
Noxafil (posaconazole)	The U.S. Food and Drug Administration (FDA) is cautioning that differences in dosing regimens between the two oral formulations of the antifungal Noxafil (posaconazole) have resulted in dosing errors. To help prevent additional medication errors, the drug labels were revised to indicate that the two oral formulations cannot be directly substituted for each other but require a change in dose. Direct mg-for-mg substitution of the two formulations can result in drug levels that are lower or higher than needed to effectively treat certain fungal infections.

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