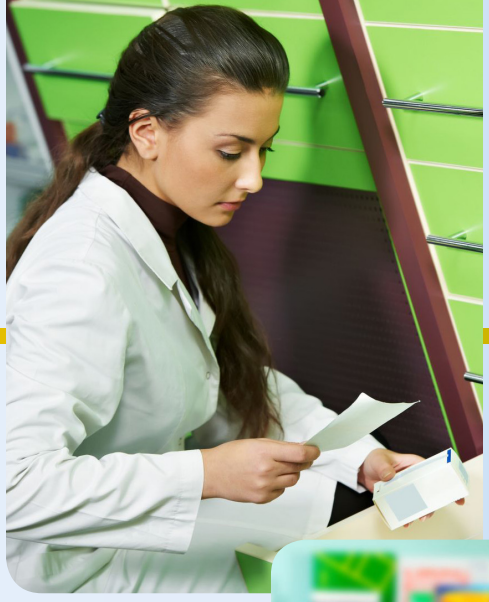

Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

MARCH 2019

Q2 2019

Table of Contents

PN Q2 2019

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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A Message from the Gold Coast Health Plan Pharmacy Director

Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to the Plan's formulary, new drug approvals, and safety labeling changes.

GCHP's goal is to provide all medically-necessary pharmaceuticals in the most economical way possible. The Plan's formulary was developed by the Pharmacy & Therapeutics (P & T) Committee. It is reviewed and updated quarterly due to advances in therapeutic treatment regimens and newly-approved products by the U.S. Food and Drug Administration (FDA).

GCHP wants to ensure that all drugs are available to its members when the drugs are indicated. To help manage drug utilization, the formulary employs several mechanisms: Step therapy protocols, prior authorizations, quantity limits, and age restrictions. Any drug that is limited or is not listed may be available via prior authorization.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and the Plan's members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me.

Sincerely,

Anne Freese, Pharm.D.
Director of Pharmacy

Formulary Changes

The following changes to GCHP's formulary are effective as of April 1:

Additions

Drug	Formulary Status/Change
TALZENNA (talazoparib)	Add with a PA for FDA approved indication.
LORBRENA (lorlatinib)	Add with a PA for FDA approved indication.
DAURISMO (glasdegib)	Add with a PA for FDA approved indication.
VITRAKVI (larotrectinib)	Add with a PA for FDA approved indication.
XOSPATA (gilteritinib fumarate)	Add with a PA for FDA approved indication.
TEGSEDI (inotersen)	Add with a PA for medically accepted indication.
FIRDAPSE (amifampridine phosphate)	Add with a PA for medically accepted indication.
KRINTAFEL (tafenoquine)	Add with a PA for medically accepted indication.
Olmesartan	Removed step therapy requirement.
Irbesrtan	Removed step therapy requirement.
Irbesartan-HCTZ	Removed step therapy requirement.
UDENYCA (pegfilgrastim-cbqv)	Add to formulary.

Removals

Drug	Formulary Status/Change
ELIDEL (pimecrolimus) Cream, 1%	Brand removed, generic now available.
AMICAR (aminocaproic acid) Tablets, 500 mg, 1000 mg	Brand removed, generic now available.
FINACEA (azelaic acid) Gel , 15%	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
TOLSURA	*Itraconazole*	Oral capsule	Azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: • Blastomycosis, pulmonary and extrapulmonary • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and • Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. Limitations of use: TOLSURA is not indicated for the treatment of onychomycosis. TOLSURA is NOT interchangeable or substitutable with other itraconazole products.
MOTEGRITY	*Prucalopride*	Oral tablet	Serotonin-4 (5-HT4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.
HERZUMA (biosimilar* to HERCEPTIN)	*Trastuzumab-pkrb*	Injectable	HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast cancer.
EZALLOR	*Rosuvastatin*	Oral capsule	HMG Co-A reductase inhibitor indicated for: • Adult patients with hypertriglyceridemia as an adjunct to diet. • Adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet. • Adult patients with homozygous familial • Hypercholesterolemia (hofh) to reduce LDL-C, total-C, and apob. Limitations of use: • EZALLOR has not been studied in Fredrickson Type I and V dyslipidemias.
LICART	*Diclofenac epolamine*	Topical shampoo	Nonsteroidal anti-inflammatory drug (NSAID) indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ASPARLAS	*Calaspargase pegol-mknl*	Injectable	Asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients ages 1 month to 21 years.
INBRIJA	*Levodopa*	Inhalation powder	Intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa / levodopa.
BRIXADI	*Buprenorphine*	Extended release subQ injectable	
ELZONRIS	*Tagraxofusp-erzs*	IV solution	Blastic plasmacytoid dendritic cell neoplasm (BP-DCN) in adults and in pediatric patients 2 years of age and older.
ONTRUZANT	*TRASTUZUMAB-DTTB (Biosimilar to Herceptin)*	Injectable	• The treatment of HER2-overexpressing breast cancer. • The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
TOSYMRA	*Sumatriptan*	Nasal Spray	Acute treatment of migraine with or without aura in adults.
EVEKEO ODT	*Amphetamine sulfate*	Orally disintegrating tablet	Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
GLOPERBA	*Colchicine*	Oral solution	Prophylaxis of gout flares in adults.
Dolutegravir; lamivudine; tenofovir disoproxil fumarate	*Dolutegravir; lamivudine; tenofovir disoproxil fumarate*	Oral tablet	HIV-1 infection
JEUVEAU	*Prabotulinumtoxina-xvfs*	Injectable	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
CABLIVI	*Caplacizumab-yhdp*	Injectable	Adult patients with acquired thrombotic
EGATEN	*triclabendazole*	Oral tablet	Fascioliasis in patients 6 years of age and older.
ADHANSIA XR	*Methylphenidate hydrochloride*	Extended release oral capsule	Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.
HERCEPTIN HYLECTA	*Trastuzumab; hyaluronidase-oysk*	SubQ injectable	The treatment of HER2-overexpressing breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for trastuzumab.

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
GLUCOVANCE *(glyburide; metformin hydrochloride)*	Boxed Warning and Contraindications	Boxed Warning: Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate / pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided. If metformin-associated lactic acidosis is suspected, immediately discontinue GLUCOVANCE and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. Contraindications: GLUCOVANCE is contraindicated in patients with: • Severe renal impairment (eGFR below 30 mL/min/1.73 m2). • Hypersensitivity to metformin or glyburide. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. • Concomitant administration of bosentan.
TYZEKA *(telbivudine)*	Contraindications	TYZEKA is contraindicated in combination with pegylated interferon alfa-2a because of increased risk of peripheral neuropathy.

Drug	Type of Change	Change
SEREVENT *(salmeterol xinafoate)*	Boxed Warning and Contraindications	Boxed Warning **WARNING: ASTHMA-RELATED DEATH** Long-acting beta2-adrenergic agonists (LABA), such as salmeterol, the active ingredient in SEREVENT DISKUS, as monotherapy (without inhaled corticosteroids [ICS]) increase the risk of asthma-related death. Data from a large placebo-controlled U.S. trial that compared the safety of salmeterol with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol (13 deaths out of 13,176 subjects treated for 28 weeks on salmeterol versus 3 deaths out of 13,179 subjects on placebo). Use of background ICS was not required in this study. When LABA are used in fixed-dose combination with inhaled corticosteroids (ICS), data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone. Use of SEREVENT DISKUS for the treatment of asthma as monotherapy without a concomitant ICS is contraindicated. Use SEREVENT DISKUS only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an ICS. Do not use SEREVENT DISKUS for patients whose asthma is adequately controlled on low- or medium-dose ICS. Pediatric and Adolescent Patients Available data from controlled clinical trials suggest that LABA as monotherapy increase the risk of asthma-related hospitalization in pediatric and adolescent patients. For pediatric and adolescent patients with asthma who require addition of a LABA to an ICS, a fixed-dose combination product containing both an ICS and a LABA should ordinarily be used to ensure adherence with both drugs. In cases where use of an ICS and a LABA is clinically indicated, appropriate steps must be taken to ensure adherence with both treatment components. If adherence cannot be assured, a fixed-dose combination product containing both an ICS and a LABA is recommended. Contraindications The use of SEREVENT DISKUS is contraindicated in the following conditions: • Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to salmeterol or any of the excipients.
APIDRA *(insulin glulisine recombinant)*	Contraindications	APIDRA is contraindicated in patients with known hypersensitivity to APIDRA or to any of its excipients; systemic allergic reactions have occurred with APIDRA.
FACTIVE *(gemifloxacin mesylate)*	Contraindications	FACTIVE is contraindicated in patients with a history of hypersensitivity to gemifloxacin, other fluoroquinolone antibacterial agents, or any of the product components.

Drug	Type of Change	Change
OXTELLAR XR *(oxcarbazepine)*	Contraindications	Oxtellar XR® is contraindicated in patients with a known hypersensitivity to oxcarbazepine, to any of the components of Oxtellar XR, or to eslicarbazepine acetate. Reactions have included anaphylaxis and angioedema.
EXJADE *(deferasirox);* JADENU *(deferasirox);* JADENU SPRINKLE *(deferasirox)*	Contraindications	High-risk myelodysplastic syndromes (this patient population was not studied and is not expected to benefit from chelation therapy).
BRINEURA *(cerliponase alfa)*	Contraindications	• Any sign or symptom of acute, unresolved localized infection on or around the device insertion site (e.g. cellulitis or abscess); or suspected or confirmed CNS infection (e.g. cloudy CSF or positive CSF gram stain, or meningitis). • Any acute intraventricular access device-related complication (e.g., leakage, extravasation of fluid, or device failure).
EMTRIVA *(emtricitabine)*	Boxed Warning	**WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B** Severe acute exacerbations of hepatitis B (HBV) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued EMTRIVA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue EMTRIVA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.
LUPRON DEPOT *(leuprolide acetate)*	Contraindications	Embryo-Fetal Toxicity Based on findings in animal studies, LUPRON DEPOT may cause fetal harm when administered to a pregnant woman. In animal developmental and reproductive toxicology studies, administration of the monthly formulation of leuprolide acetate on day six of pregnancy (sustained exposure was expected throughout the period of organogenesis) caused adverse embryo-fetal toxicity in animals at doses less than the human dose, based on body surface area, using an estimated daily dose. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.
UNITHROID *(levothyroxine sodium)*	Boxed Warning	**WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS** • Thyroid hormones, including UNITHROID, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. • In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

Drug	Type of Change	Change
NASCOBAL *(cyanocobalamin)*	Contraindications	NASCOBAL is contraindicated in patients with hypersensitivity to cobalt and/or vitamin B12 or any of its excipients. Anaphylactic shock and death have been reported after parenteral vitamin B12 administration in sensitive patients.
Cisplatin	Contraindications	Cisplatin for injection is contraindicated in patients with severe hypersensitivity to cisplatin.
XIGDUO XR *(dapagliflozin propanediol; metformin hydrochloride)*	Boxed Warning and Contraindications	Boxed Warning **WARNING: LACTIC ACIDOSIS** • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate / pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. • Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the full prescribing information. If metformin-associated lactic acidosis is suspected, immediately discontinue XIGDUO XR and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. Contraindications XIGDUO XR is contraindicated in patients with severe renal impairment (eGFR below 30 mL/min/1.73 m2), end stage renal disease or patients on dialysis.
XULTOPHY 100/3.6 *(insulin degludec; liraglutide)*	Contraindications	In patients with hypersensitivity to XULTOPHY 100/3.6, either insulin degludec or liraglutide, or any of its excipients. Serious hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with liraglutide, one of the components of XULTOPHY 100/3.6.

Drug	Type of Change	Change
OSPHENA *(ospemifene)*	Boxed Warning	**WARNING: ENDOMETRIAL CANCER AND CARDIOVASCULAR DISORDERS** OSPHENA is an estrogen agonist / antagonist with tissue selective effects. In the endometrium, OSPHENA has estrogen agonistic effects. There is a potential increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adequate diagnostic measures, including directed and random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding. Cardiovascular Disorders In the clinical trials for OSPHENA (duration of treatment up to 15 months), the incidence rates of thromboembolic and hemorrhagic stroke were 1.13 and 3.39 per thousand women years, respectively in the OSPHENA 60 mg treatment group and 3.15 and 0 with placebo. The incidence of DVT was 2.26 per thousand women years (two reported cases) in the OSPHENA 60 mg treatment group and 3.15 per thousand women years (one reported case) with placebo. OSPHENA should be prescribed for the shortest duration consistent with treatment goals and risks for the individual woman. There is a reported increased risk of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) who received daily oral conjugated estrogens (CE) [0.625 mg]-alone therapy over 7.1 years as part of the Women's Health Initiative (WHI).
RITUXAN *(rituximab)*	Boxed Warning	**WARNING: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY** Infusion-Related Reactions RITUXAN administration can result in serious, including fatal, infusion-related reactions. Deaths within 24 hours of RITUXAN infusion have occurred. Approximately 80% of fatal infusion reactions occurred in association with the first infusion. Monitor patients closely. Discontinue RITUXAN infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions.
SYMTUZA *(cobicistat; darunavir ethanolate; emtricitabine; tenofovir alafenamide fumarate)*	Contraindications	• Hepatitis C direct acting antiviral: elbasvir / grazoprevir • Lipid modifying agents: lomitapide, lovastatin, simvastatin

Drug	Type of Change	Change
RIFADIN *(rifampin);* RIFATER *(isoniazid; pyrazinamide; rifampin)*	Contraindications	Rifampin is contraindicated in patients receiving praziquantel since therapeutically effective blood levels of praziquantel may not be achieved. In patients receiving rifampin who need immediate treatment with praziquantel alternative agents should be considered. However, if treatment with praziquantel is necessary, rifampin should be discontinued four weeks before administration of praziquantel. Treatment with rifampin can then be restarted one day after completion of praziquantel treatment.
GILENYA *(fingolimod)*	Contraindications	Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
FOCALIN *(dexmethylphenidate hydrochloride);* FOCALIN XR *(dexmethylphenidate hydrochloride);* RITALIN *(methylphenidate hydrochloride);* RITALIN LA *(methylphenidate hydrochloride);* RITALIN-SR *(methylphenidate hydrochloride)*	Boxed Warning	**WARNING: ABUSE AND DEPENDENCE** CNS stimulants, including methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.
PEGINTRON *(peginterferon alfa-2b)*	Contraindications	PEGINTRON is contraindicated in patients with: • Known hypersensitivity reactions, such as urticaria, angioedema, bronchoconstriction, anaphylaxis, Stevens-Johnson syndrome, and toxic epidermal necrolysis to interferon alpha or any other component of the product. • Autoimmune hepatitis. • Hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic CHC patients before or during treatment.
ONCASPAR *(pegaspargase)*	Contraindications	ONCASPAR is contraindicated in patients with a: • History of serious hypersensitivity reactions, including anaphylaxis, to ONCASPAR or to any of the excipients. • History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis, including pancreatitis related to prior L-asparaginase therapy.

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
SHINGRIX *(recombinant zoster vaccine)*	GlaxoSmithKline	Reason for the shortage: • GlaxoSmithKline has Shingrix on shortage due to high demand for the product. Estimated resupply dates: • GlaxoSmithKline has Shingrix on intermittent back order and the company is shipping orders according to order date and supply available.
Diclofenac potassium oral tablet, 50 mg	Mylan Teva Sandoz	Reason for the shortage: • Mylan did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. • Sandoz discontinued diclofenac potassium tablets. Estimated resupply dates: • Mylan has diclofenac potassium 50 mg tablets on back order and the company estimates a release date of late-April to early-May 2019. • Teva has diclofenac potassium 50 mg tablets in 100 count and 500 count on back order and the company estimates a release date of early-June 2019.
Gentamicin Sulfate Ophthalmic Ointment 3%	Akorn	• Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays. • Akorn has Gentak 3.5 gram tubes on allocation.

Drug Product	Affected Manufacturers	Summary
Buspirone tablet 10 mg, 15 mg, 30 mg, 5 mg,	Accord Mylan Teva Par Zydus	Reason for the shortage: • Accord did not provide a reason for the shortage. • Mylan did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. Estimated resupply dates: • Accord has all buspirone on back order and the company estimates a release date of late-March 2019. • Mylan Institutional has buspirone 5 mg, 10 mg, 15 mg, and 30 mg tablets in 100-count unit-dose packs on back order and the company cannot estimate a release date. • Mylan has all buspirone presentations in bottles on long-term back order and the company cannot estimate a release date. • Par Pharmaceuticals has 7.5 mg tablets in 100 count on back order and the company estimates a release date of late-February 2018. • Teva has buspirone 5 mg, 10 mg, and 15 mg tablets in 100 and 500 count on back order and the company estimates a release date of mid-March 2019. However, there are 15 mg tablets in 100 count available with a short expiry of November 2019. The 30 mg tablets in 60 and 180 count are on back order and the company estimates a release date of mid-March 2019. • Zydus has all buspirone presentations on allocation.
Diltiazem Hydrochloride oral extended release capsule 60 mg, 90 mg, 120 mg	Mylan	• Mylan did not provide a reason for the shortage. • Mylan has diltiazem extended-release 60 mg, 90 mg, and 120 mg capsules in 100-count bottles on back order and the company estimates a release date of mid-February 2019.

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 on the FDA's website.

Drug	Communications Summary
Xeljanz, Xeljanz XR *(tofacitinib citrate)*	The FDA is alerting the public that a safety clinical trial found an increased risk of blood clots in the lungs and death when a 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR) was used in patients with rheumatoid arthritis (RA). The FDA has not approved this 10 mg twice daily dose for RA; this dose is only approved in the dosing regimen for patients with ulcerative colitis. In this ongoing safety trial required by FDA when it approved tofacitinib for RA, the drug manufacturer, Pfizer, is transitioning patients who were on the high 10 mg twice daily dose to the lower, currently-approved dose of 5 mg twice daily. This trial will continue and is expected to be completed by the end of 2019.
Uloric *(febuxostat)*	The FDA has concluded there is an increased risk of death with Uloric (febuxostat) compared to another gout medicine, allopurinol. This conclusion is based on the FDA's in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric.

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