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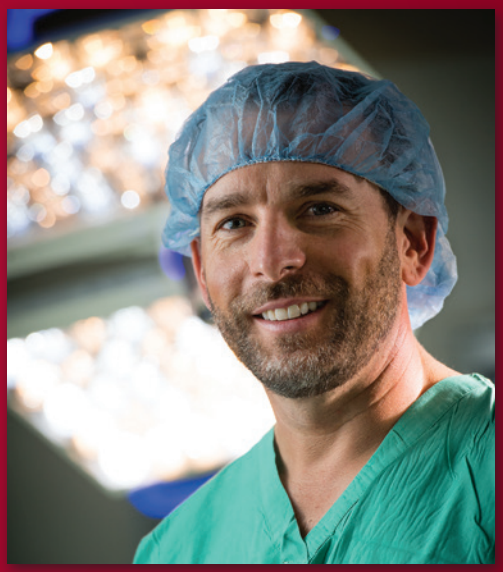
Presbyterian Health Plan, Inc.
Presbyterian Insurance Company, Inc.

Pharmacy and Therapeutics (P&T) Committee Provider Update

SECOND QUARTER 2019



P&T Committee Decisions Effective June 1, 2019

The Presbyterian Health Plan, Inc., and Presbyterian Insurance Company, Inc., (Presbyterian) P&T Committee meets quarterly to promote the appropriate use of drugs, to maintain the Presbyterian formularies and to support our network of practitioners and providers. The P&T Committee met on **April 24, 2019**, and we would like to share the decisions made at the meeting that affect our formularies and pharmacy benefits.

Centennial, Commercial, Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care	Commercial	Metal Level Plans
Formulary Additions				
Xolair (omalizumab) 150mg/mL (0.5mL, 1mL prefilled syringe)	Anti-asthmatic	MB, SP, PA	MB, SP, PA	MB, SP, PA
Xarelto® rivaroxaban 2.5 mg tablets	Anticoagulant	F, PA, QL	T2, PA, QL	T3, PA, QL
Lumoxiti™ (oxetumomab pasudotox-tdfk) 1mg powder per vial	Antineoplastic	F, MB, PA	MB, PA	MB, PA
Ultomiris™ (ravuliumab-cwvz) 300 mg/30mL single dose vial	Complement Inhibitor	MB, SP, PA	MB, SP, PA	MB, SP, PA
Astagraf XL® (tacrolimus extended release capsules) 0.5mg, 1mg, 5mg capsules	Immunosuppressant	F, PA, QL	0.5 mg: F, PA, QL 1mg 5mg: T4, PA, QL	0.5mg: T4, PA, QL 1mg 5mg: T5, PA, QL
Zortress® (everolimus) 1 mg capsule	Immunosuppressant	F, PA	T4, PA	T5, PA
Lotemax® **SM** (loteprednol) 3.8 mg /gram gel in 5mL bottle	Ophthalmic Steroid	F, ST	T2, ST	T3, ST
New Generics – Unless otherwise noted, when a generic product becomes available, the brand-name product will be removed from the formularies.				
pyridostigmine bromide (generic for Mestinon®) 60mg/5mL oral syrup	Acetylcholine-sterase Inhibitor	F	T3	T4
ranolazine (generic for Ranexa®) 500mg, 1000mg tablet	Antianginal Agent	F, ST	T3, ST	T4, ST

*Medicare formulary changes may be pending approval from Centers for Medicare & Medicaid Services (CMS).
MB = Medical Benefit, ME = Medical Exception, NF = Non-Formulary, PA = Prior Authorization Required, QL = Quantity Limits Apply, SP = Specialty Pharmacy Mandated, ST = Step Therapy Required, AL = Age Limit, BE = Benefit Exclusion

Centennial, Commercial, Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care	Commercial	Metal Level Plans
New Generics – Unless otherwise noted, when a generic product becomes available, the brand-name product will be removed from the formularies. (continued)				
cinacalcet (generic for Sensipar®) 30mg, 60mg, 90mg tablet	Calcimimetic	F, PA	T4, PA	T5, PA
pimecrolimus (generic for Elidel®) 1% topical cream	Calcineurin Inhibitor	F, ST	T3, ST	T4, ST
drospirenone/ethinyl estradiol generic for Jasmiel™ 3/0.02mg tablet	Contraceptive	F	T1	T2
betamethasone sodium phosphate/ betamethasone acetate (generic for Celestone® intramuscular suspension) 6 mg/mLl (3mg-3mg /mL)	Corticosteroid	MB	MB	MB
sirolimus oral solution (generic for Rapamune®) 1 mg/mL	Immunosuppressant	NF	NF	T5, QL
fluticasone/salmeterol (authorized generic for Advair®) (100/50, 250/50, 500/50mcg/actuation); powder	Inhaled corticosteroid/ long-acting beta agonist	PA, QL, AL	T3, ST, QL	T4, ST, QL
Wixela (generic for Advair®) (100/50, 250/50, 500/50mcg/actuation); Powder	Inhaled corticosteroid/ long-acting beta agonist	PA, QL, AL	T3, ST, QL	T4, ST, QL
buprenorphine/naloxone (generic for Suboxone®) 2/0.5mg, 4/1mg, 8/2mg, 12/3mg films	Opioid, Partial Agonist	F, AL, QL	T3, AL, QL	T4, AL, QL
sevlamer HCl (generic for Renagel®) 400 mg tablet	Phosphate Binder	NF	NF	T3
Other Formulary Changes				
testosterone topical gel (generic for Androgel®) 1% topical gel *Changing preferred products from brand to generic, covering generic pumps and tubes in addition to packets.*	Androgen	F, PA, QL	T1, PA, QL	T2, PA, QL
testosterone topical gel (generic for Androgel®) 1.62% topical gel *Changing preferred products from brand to generic, covering generic pumps and tubes in addition to packets.*	Androgen	NF	T3, PA, QL	T4, PA, QL
Levemir® (insulin detemir) 100unit/mL *Removing from Centennial Care.*	Insulin	F	T2, QL	T3, QL
Tresiba® (insulin degludec) 100unit/mL, 200unit/mL *Adding to Centennial Care.*	Insulin	F, ST, QL	T2, QL	T3, QL
Vivitrol® (naltrexone extended-release injectable suspension) 380mg vial *Removing prior authorization criteria.*	Opioid Antagonist	F, QL, SP	T4, QL, SP	T5, QL, SP
Sublocade® (buprenorphine extended-release injectable suspension) 300mg, 100mg prefilled syringe *Updating prior authorization criteria to remove the requirement for counseling during treatment.*	Opioid, Partial Agonist	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP

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Medicare Formulary Updates

Drug Name	Therapeutic Class	Coverage
Formulary Additions		
Vigadrone™ (vigabatrin) 500mg packet	Anticonvulsant	T5
Epidiolex® (cannabidiol) 100mg/mL oral solution	Anticonvulsant, cannabinoid	T5, PA
Firvanq® vancomycin oral solution (25mg/ml, 50mg/mL)	Antimicrobial	T3, QL
Mektovi® (binimetinib) 15mg tablet	Antineoplastic	T5, PA, QL
Vizimpro® (dacomitinib) 15mg 30mg, 45mg tablet	Antineoplastic	T5, PA, QL
Delstrigo™ (doravirine/ lamivudine/ tenofovir disoproxil fumarate) 100mg/300mg/300mg tablets	Anti-viral	T5
Pifeltro™ (doravirine) 100mg tablet	Anti-viral	T5
Symtuza™ (cobicistat/darunavir/emtricitabine/Tenofovir) 150/800/200/10mg tablet	Anti-viral	T5
Aristada Initio® (aripiprazole lauroxil) 675mg prefilled syringe	Atypical Antipsychotic	T5
Nuplazid® (pimavanserin) 10mg,17mg, 34mg tablet	Atypical Antipsychotic	T5, PA, SP, QL
Perseris™ (risperidone) 150mg/mL prefilled syringe	Atypical Antipsychotic	T5, PA
Cyred-28™(desogestrel/ethinyl estradiol) 0.15/0.03mg tablets	Contraceptive	T3
Flac™ (fluocinolone acetonide) 0.1mg/ml otic solution	Corticosteroid, Otic	T2
Tiglutik™ (riluzole) 5mg/ml oral suspension	Glutamate Inhibitor	T5
Firdapse® (amifampridine) 10mg tablet	Potassium Channel Blocker, Cholinergic Agonist	T5, PA, QL
New Generics		
albendazole (generic for Albenza®) 200mg oral tablet	Anthelmintic	T5
clobazam (generic for Onfi®) 10mg, 20mg tablets; 2.5mg/mL oral solution	Anticonvulsant, Benzodiazepine	10mg- T4, ST, QL 20mg-T5, ST, QL 2.5mg/mL-T5, ST
bupropion (generic for Forfivo XL®); oral (450mg); tablet	Anti-depressant	T4 QL
itraconazole (generic for Sporanox®) 10mg/mL solution	Anti-fungal	T4
ertapenem (generic for Invanz®) 1gm vial for injection	Antimicrobial	T4
abiraterone acetate (generic for Zytiga®) 250mg tablet	Antineoplastic	T5, PA, QL
nevirapine (generic for Viramune®) 10mg/mL oral suspension	Anti-viral	T4
mesalamine (generic for Lialda®) 1.2gm tablet	Inflammatory Bowel Agent	T4, QL
fluticasone/salmeterol (authorized generic for Advair®) 100/50, 250/50, 500/50 mcg/inhalation	Inhaled corticosteroid/long-acting beta agonist	T4, ST
Wixela™ (generic for Advair®) 100/50, 250/50, 500/50mcg/inhalation	Inhaled corticosteroid/long-acting beta agonist	T4, ST
tadalafil (generic for Adcirca®) 20mg tablet	Phosphodiesterase-5 Enzyme Inhibitor	T5, PA, QL
tadalafil (generic for Alyq™) 20mg tablet	Phosphodiesterase-5 Enzyme Inhibitor	T5, PA, QL
azelaic acid (generic for Fincea®) 15% topical gel	Topical dermatologic	T4
Other Formulary Changes		
Xolair® (omalizumab) 75mg,150mg prefilled syringe *New dosage form added to Senior Care formulary.*	Anti-asthmatic	T5, PA,SP
Xarelto® (rivaroxaban) 2.5mg tablet *New strength added to Senior Care formulary.*	Anticoagulant	T3
Sympazan™ (clobazam) 5mg, 10mg, 20mg oral film *New dosage form added to Senior Care formulary.*	Anticonvulsant, Benzodiazepine	T5,ST,QL
*Medicare formulary changes may be pending approval from Centers for Medicare & Medicaid Services (CMS). MB = Medical Benefit, ME = Medical Exception, NF = Non-Formulary, PA = Prior Authorization Required, QL = Quantity Limits Apply, SP = Specialty Pharmacy Mandated, ST = Step Therapy Required, AL = Age Limit, BE = Benefit Exclusion		

Medicare Formulary Updates

Drug Name	Therapeutic Class	Coverage
Other Formulary Changes (continued)		
Mondoxyne® (doxycycline monohydrate) 100mg capsule *New strength added to Senior Care formulary.*	Anti-microbial	T2
Lenvima® (lenvatinib) 4mg tablets (to make 12mg) pack *New dosage pack added to Senior Care formulary.*	Antineoplastic	T5, PA, QL
Zortress® (everolimus) 1mg tablet *New strength added to Senior Care formulary.*	Immunosuppressant	T5, PA (B vs D), QL
Promacta® (eltrombopag) 12.5mg packet *New dosage form added to Senior Care formulary.*	Thrombopoietin Receptor Agonist	T5, PA, QL
*Medicare formulary changes may be pending approval from Centers for Medicare & Medicaid Services (CMS). MB = Medical Benefit, ME = Medical Exception, NF = Non-Formulary, PA = Prior Authorization Required, QL = Quantity Limits Apply, SP = Specialty Pharmacy Mandated, ST = Step Therapy Required, AL = Age Limit, BE = Benefit Exclusion		

ANNOUNCEMENTS

New Presbyterian Pain and Addictions Project ECHO (Extension for Community Healthcare Outcomes) Clinic

On Jan. 4, 2018, Presbyterian launched the Pain and Addiction ECHO (Extension for Community Healthcare Outcomes) Clinic, which is designed to expand the reach of expertise and knowledge about substance use disorders, addictions and pain management across the state of New Mexico. ECHO helps improve outcomes for patients, members and the communities Presbyterian serves. The clinic is led by Presbyterian's Medical Director of Addiction Services, Dan Duhigg, DO, and Christine Gilmore, CNP. The Pain and Addictions ECHO Clinic will take place every Thursday from 12 to 2 p.m. To participate, connect through ZOOM via your computer, iPad or phone. These sessions are CME accredited for physicians. For connection details, contact the clinic coordinator at PA_ECHO@phs.org or (505) 559-6725. Visit the following link for a topic schedule and access information: http://presnet.phs.org/frpas/PublishingImages/Pages/Interested-in-Pain-and-Addiction-Case-based-Learning/ECHO%20Poster%2011x17%20FINAL.pdf.

Controlled Substance Analysis Program

Presbyterian Health Plan (PHP) adopted a Drug Management Program (DMP) beginning Jan. 1, 2019, to monitor opioid and benzodiazepine use among our Senior Care members. The DMP provides a framework from the Centers for Medicare and Medicaid Services (CMS) for retrospective Part D Opioid Drug Utilization Review (DUR). This program will focus on opioids and benzodiazepines. Members can be identified by CMS and/or PHP Pharmacy Services. Members who use opioids with an average daily morphine milligram equivalent (MME) equal to or exceeding 90mg for any duration during the most recent six months AND either: three or more opioid prescribers and three or more opioid dispensing pharmacies OR five or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. PHP has also opted to monitor members who have opioid claim history (regardless of average daily MME) during the most recent six months with seven or more opioid prescribers OR seven or more opioid dispensing pharmacies. When potentially unsafe prescribing patterns have been recognized, the PHP may enact the following interventions:

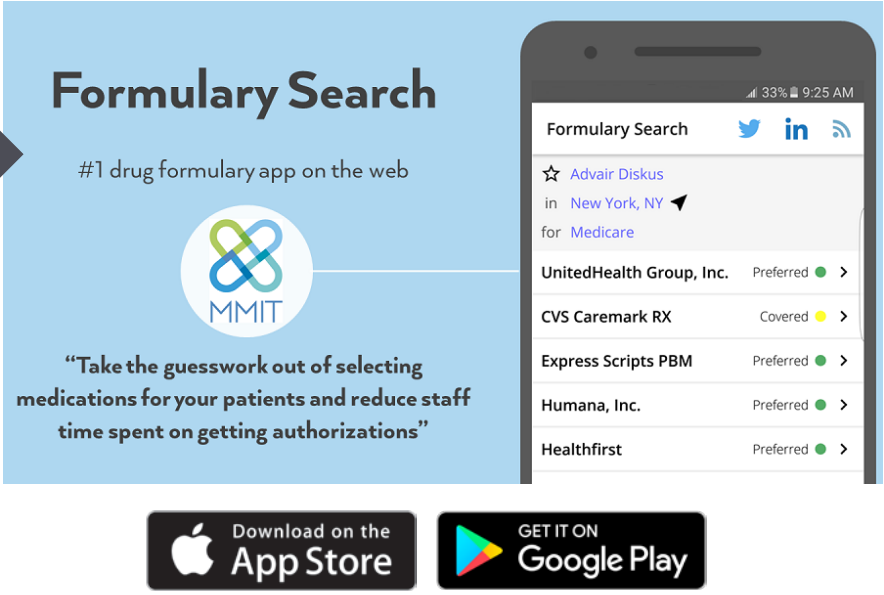
1. Inform prescriber of potential misuse or abuse by the beneficiary identified. Alternative therapies can be discussed.
2. Consider a "Lock-in" with a pharmacy and provider.
3. Refer the case to the Program Integrity Department to investigate potential fraud, waste and abuse activities.

Requests for Formulary Additions, Deletions or Modifications

Use the Formulary Addition Request form to request medication additions, deletions or other changes to the Presbyterian formularies. Complete and submit the form to the ASK PHP P&T mailbox at askphppt@phs.org. The form can be accessed at http://docs.phs.org/idc/groups/public/documents/communication/pel_00251399.pdf.

Formulary Search App

As a reminder, Presbyterian formularies are also accessible through the Managed Markets Insights & Technology, LLC (MMIT) Formulary Search App. No registration, username or passwords are required. Search from your desktop at www.FormularyLookup.com or download the free app today.



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Presbyterian formularies and updates, including restrictions (e.g., quantity limits, step therapy and prior authorization criteria) and preferences, are available online at https://www.phs.org/providers/formularies/Pages/default.aspx.

Current and past issues of the Pharmacy & Therapeutics (P&T) Committee Provider Updates are available online at https://www.phs.org/providers/contact-us/news-and-communications/Pages/default.aspx.

Providers must register with Presbyterian to receive the Pharmacy & Therapeutics (P&T) Committee Provider Update via email. Register for Presbyterian eNews at https://www.phs.org/providers/contact-us/news-and-communications/Pages/default.aspx.

The Universal Practitioner and Provider Manual and the CentennialCare Practitioner and Provider Manuals are also available online at https://www.phs.org/providers/resources/training-education/Pages/outreach.aspx and include information about pharmacy benefits, the prior authorization process, generic substitution and requesting non-formulary medications based on medical necessity. A printed copy of the Centennial Care Practitioner and Provider Manual is available at no cost from Presbyterian by contacting your Provider Network Management relationship executive.

Contact Us

Changes to our formularies are based on requests from our practitioners/providers and by the recommendations of the P&T Committee. We value your input. If you have any questions or concerns, please email us at askphppt@phs.org.

Presbyterian Health Plan Formularies

Presbyterian Health Plan (Presbyterian) strives to give our providers access to the information and support they need. One way we do this is by providing information on medications that are covered by the plan. Presbyterian formularies may be accessed in the following ways:

- **New for 2019!** Searchable formularies will soon be available at www.phs.org/providers/formularies/Pages/default.aspx. You may search for a drug using this tool by viewing an alphabetical list of drugs, searching by drug name, or searching by therapeutic class. You may also find out if a covered drug has any restrictions by clicking on the link for the drug.
- Providers can find PDF versions of Presbyterian formularies and updates, including restrictions (e.g., quantity limits, step therapy and prior authorization criteria) and preferences, online at the webpage noted above.
- Presbyterian formularies may also be accessed using the Managed Markets Insights & Technology, LLC (MMIT) Formulary Search App. No registration, username or password required. Search from your desktop at www.FormularyLookup.com or download the free app from the App Store or Google Play.

For any questions about the formulary coverage of medications, call the Presbyterian Pharmacy Services Help Desk at (505) 923-5500 or toll-free at 1-888-923-5757. Help Desk business hours are Monday through Friday, from 8 a.m. to 5 p.m. You may also contact us via email at ASKRX@phs.org. The email box is monitored during regular business hours (Monday through Friday from 8 a.m. to 5 p.m.) and one of our clinical pharmacists will respond to your inquiry within one business day.

Food and Drug Administration (FDA) Alerts December 31, 2018 to March 31, 2019

For a full list of FDA alerts and additional information, see the FDA website at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts.

1. **Voluntary Recall on amlodipine/valsartan tablets, valsartan/HCTZ tablets and Valsartan tablets manufactured by Aurobindo Pharma USA, Inc. [12/31/2018, 02/25/2019]:** Products have been found to have trace amounts of an unexpected impurity in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.
   Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication lots.
2. **Voluntary Recall (expansion) on Losartan and Losartan/HCTZ tablets manufactured by Torrent Pharmaceuticals Limited. [01/03/2019, 01/22/2019, 03/01/2019]:** Products are being recalled due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. Torrent is only recalling lots of losartan-containing products that contain N-nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA. To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.
   Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication lots.
3. **Voluntary Recall on Ceftriaxone for Injection (250 mg, 500 mg, 1g, 2g vials) [01/05/2019]:** Products have been found to contain visual grey particulate matter in reconstituted vials. Improper piercing and use of a needle greater than 21 gauge while reconstituting the vial can push rubber flecks into the solution. If injected, this product (containing rubber particulate matter from the stopper) could cause vein irritation/phlebitis or pulmonary embolic events that could result in permanent impairment of body function or damage to body structures, such as the lungs and vascular system. In addition, as ceftriaxone can be administered intramuscularly, use of the product may result in local muscle inflammation and/or abscesses.
   Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to providers who had written prescriptions for this medication and to members who had prescription claims with potentially affected medication lots.
4. **Voluntary Recall on Irbesartan and Irbesartan/HCTZ tablets by Prinston Pharmaceutical Inc. [01/03/2019]:** These products are being recalled due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. Prinston is only recalling lots of Irbesartan-containing products that contain N- nitrosodiethylamine (NDEA) above the acceptable daily intake levels

released by the FDA. To date, Prinston Pharmaceutical Inc. has not received any reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication lots.

5. **Safety Communication on Olaratumab (Lartruvo) - Clinical benefit was not confirmed in expanded clinical trial [01/24/2019]:** The FDA approved Lartruvo in combination with doxorubicin for certain adult patients with soft tissue sarcoma not amenable to curative treatment under the agency's accelerated approval program. As a condition of approval, Eli Lilly conducted a larger study designed to confirm the clinical benefit of Lartruvo in these patients. This recently completed study did not confirm the clinical benefit of Lartruvo. Specifically, the study did not meet the primary endpoint of improvement in overall survival for Lartruvo and doxorubicin as compared with placebo and doxorubicin. In light of this information, the FDA recommends that patients who currently receive Lartruvo should consult with their healthcare provider about whether to remain on the treatment. The FDA also recommends that Lartruvo should not be initiated in new patients outside of an investigational study. The FDA is currently reviewing the data and working with the company to determine appropriate next steps.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter.
6. **Voluntary Recall on levoleucovorin injection manufactured by Mylan [02/01/2019]:** Products are being recalled due to the presence of sub-visible particulate matter exceeding the specification. Per Mylan, intravenous administration of a solution containing particulates could lead to local irritation, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction, including pulmonary embolism. To date, Mylan has not received any reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter.
7. **Voluntary Recall on Losartan/HCTZ tablets manufactured by Macleods [02/21/2019]:** Products are being recalled due to the detection of trace amounts of an unexpected impurity, N-nitrosodiethylamine (NDEA).
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication.
8. **Voluntary Recall on Gamunex-C injection manufactured by Camber Pharmaceuticals [02/28/2019]:** This medication was recalled due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Gamunex-C.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to providers who may have written orders for Gamunex.
9. **Safety Communication on Uloric (febuxostat) – An increased risk of death with Uloric (febuxostat) use compared to allopurinol [02/21/2019]:** This conclusion was based on an 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. As a result of the findings, a boxed warning for cardiovascular (CV) death was added to the Uloric drug label and to a new patient Medication Guide. The indication for Uloric was also updated to include chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated doses of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia. Patients should tell their healthcare professional if they have a history of heart problems or stroke and discuss the benefits and risks of using Uloric. Patients should seek emergency medical attention right away if they experience the following symptoms while taking Uloric: chest pain, shortness of breath, rapid or irregular heartbeat, numbness or weakness on one side of the body, dizziness, trouble talking, sudden severe headache. Healthcare professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol. Patients taking Uloric should be monitored for CV signs and symptoms. In addition, patients should be counseled about the CV risk with Uloric and they should be advised to seek medical attention immediately if they experience the symptoms listed above.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter.
10. **Safety Communication for Xeljanz (tofacitinib) - Increased risk of pulmonary embolism and death when Xeljanz 10mg twice daily was used in patients with rheumatoid arthritis (RA) [02/25/2019]:** Patients treated with Xeljanz 10mg twice daily had a statistically and clinically important difference in the occurrence of pulmonary embolism vs. patients treated with a tumor necrosis factor inhibitor (TNFi). An increase in overall mortality was also observed with the Xeljanz 10mg twice daily group vs. the Xeljanz 5mg twice daily and TNFi treatment arms. The manufacturer, Pfizer, has taken steps to transition these study patients who are on Xeljanz 10mg twice daily to Xeljanz 5mg twice daily. Patients should be monitored for signs and symptoms of pulmonary embolism, and patients should be advised to seek immediate medical attention if they experience them. Patients should not change or stop their Xeljanz therapy without first discussing with their healthcare provider, as doing so may worsen their condition. Patients should seek immediate medical attention if they experience symptoms of pulmonary embolism or other unusual symptoms including sudden shortness or breach, chest/back pain, coughing up blood, excessive sweating, or clammy/bluish colored skin.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter.

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11. **Voluntary Recall on Losartan tablets manufactured by Camber Pharmaceuticals [02/28/2019]:** Products are being recalled due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a potential human carcinogen. To date, Camber has not received any reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication lots.
12. **Voluntary Recall on Losartan and Losartan/HCTZ tablets manufactured by AvKare Pharmaceuticals [03/04/2019]:** Products are being recalled due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a potential human carcinogen. To date, no reports of adverse events related to this recall. **Presbyterian Health Plan Response:** Inform providers in the P&T newsletter. Letters were sent to notify members who had prescription claims with potentially affected medication lots.
13. **Voluntary Recall of drospirenone and ethinyl estradiol [03/04/2019]:** Some packages may contain defective blisters with incorrect tablet arrangements and/or an empty blister pocket. As a result of this packaging error, where a patient does not take a tablet due to a missing tablet or that a patient takes a placebo instead of an active tablet, loss of efficacy is possible due to variation in the dosage consumed. To date, no case has been reported for pregnancy and adverse event to Apotex.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to members who had prescription claims with potentially affected medication lots.
14. **Voluntary Recall on Valsartan tablets manufactured by American Health Packaging [03/07/2019]:** These products are being recalled due to the detection of trace amounts of N-Nitrosodiethylamine (NDEA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a potential human carcinogen. To date, there have been no reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to notify members who had prescription claims with potentially affected medication lots.
15. **Voluntary Recall on Losartan packaged by Legacy Pharmaceutical Packaging [03/15/2019]:** Products are being recalled due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a potential human carcinogen. The manufacturers of this re-packaged product are Torrent and Camber Pharmaceuticals, who had earlier voluntary recalls. To date, there have been no reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to notify members who had prescription claims with potentially affected medication lots.
16. V**oluntary Recall on Losartan tablets packaged by Preferred Pharmaceuticals [03/28/2019]:** Products are being recalled due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a potential human carcinogen. The manufacturer of this re-packaged product is Torrent Pharmaceuticals, which had earlier voluntary recalls. To date, there have been no reports of adverse events related to this recall.
Presbyterian Health Plan Response: Inform providers in the P&T newsletter. Letters were sent to notify members who had prescription claims with potentially affected medication lots.