PRESBYTERIAN

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

Pharmacy and Therapeutics (P&T) Committee Provider Update

THIRD QUARTER 2019

P&T Committee Decisions Effective September 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 **July 17, 2019**, and we would like to share with you 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				
Symjepi™ (epinephrine) 0.3 milligram pre-filled syringe	Alpha-/Beta- Agonist	F	T1	T2
Avycaz® (ceftazidime/avibactam) 2.5 gram single-dose vial	Antibiotic	MB	MB	MB
Fetzima® (levomilnacipran ER) 20, 40, 80 and 120 milligram capsules	Antidepressant	F, PA, QL	NF	NF
Sarafem® (fluoxetine) 10 and 20 milligram tablets	Antidepressant	F, PA, QL	NF	NF
protriptyline 5 and 10 milligram tablets	Antidepressant	F, PA, QL	NF	NF
trimipramine 25, 50 and 100 milligram capsules	Antidepressant	F, PA, QL	NF	NF
Trintellix® (vortioxetine) 5, 10 and 20 milligram tablets	Antidepressant	F, PA, QL	NF	NF
Marplan® (isocarboxazid) 10 milligram tablets	Antidepressant	F, PA, QL	NF	NF
Spravato™ (esketamine) 28 milligram/spray (two sprays per device)	Antidepressant, Adjunct	MB, PA, SP	MB, PA, SP	MB, PA, SP

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, mg = milligrams

Centennial, Commercial, Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care	Commercial	Metal Level Plans
Symbyax® (olanzapine/fluoxetine) 3/25, 6/25, 6/50, 12/25 and 12/50 milligram capsules	Antidepressant, Atypical Antipsychotic	F, PA, QL	NF	NF
Balversa™ (erdafitinib) 3, 4 and 5 milligram tablets	Antineoplastic	F, PA	T4, PA, SP	T5, PA, SP
Abilify Maintena® (aripiprazole injection) Vial: 300 and 400 milligrams Syringe: 300 and 400 milligrams	Atypical Antipsychotic	PA, AL, QL, SP	NF	NF
Aristada Initio™ (aripiprazole lauroxil) 675 milligram pre-filled syringe	Atypical Antipsychotic	PA, AL, QL, SP	NF	NF
Perseris® (risperidone) 90 and 120 milligram prefilled syringe	Atypical Antipsychotic	PA, AL, QL, SP	NF	NF
Zyprexa® Relprevv (olanzapine) 210, 300 and 405 milligram vials for reconstitution	Atypical Antipsychotic	PA, AL, QL, SP	NF	NF
New Generics – Unless otherwise noted, when a generic product becomes available, the brand-name product will be removed from the formularies.				
solifenacin (generic for Vesicare®) 5 and 10 milligram tablets	Anticholinergic, Overactive Bladder	NF	T3, ST, QL	T4, ST, QL
fulvestrant (generic for Faslodex®) 250/5 milliliter injection	Antineoplastic, Estrogen Receptor Antagonist	MB	MB	MB
penicillamine (generic for Cuprimine®) 250 milligram capsules	Chelating Agent	NF	NF	T5, PA, QL
norethindrone acetate/ ethinyl estradiol/ Fe (generic for Aurovela-24 Fe) 1 milligram/20 microgram/75 milligram tablets	Contraceptive	F	T1	T2
norethindrone acetate/ ethinyl estradiol/ Fe (generic for Tarina-24 Fe) 1 milligram/20 microgram/75 milligram tablets	Contraceptive	F	T1	T2
desogestrel/ethinyl estradiol (generic for Simliya) 0.15-0.02/0.01 milligram tablets	Contraceptive	F	T1	T2
norgestimate/ethinyl estradiol (generic for Tri-Lo-Mili™) 0.18/0.215/0.25/25 microgram tablets	Contraceptive	F	T1	T2
ambrisentan (generic for Letairis®) 5 and 10 milligram tablets	Endothelin Receptor Antagonist	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
mesalamine (generic for Delzicol®) 400 milligram capsules	Gastrointestinal Anti-Inflammatory	ST	T3, ST	T4, ST
loteprednol etabonate (generic for Lotemax®) 0.5% ophthalmic suspension	Ophthalmic Corticosteroid	ST	T3, ST	T4, ST
erlotinib (generic for Tarceva®) 25mg, 100mg, 150mg)	Anti-neoplastics	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL,SP
valrubicin (generic for Valstar®) 40mg/mL	Antibacterial	MB	MB	MB
insulin lispro (generic for Humalog®) 100 units/mL	Diabetes Agent	NF	NF	T4, ST, QL

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Centennial, Commercial, Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care	Commercial	Metal Level Plans
Other Changes				
Pristiq® (desvenlafaxine ER) 25, 50 and 100 milligram tablets *Add to Centennial Care formulary.*	Antidepressant	F, PA, QL	NF	T4, PA
nefazodone 50, 100, 150, 200 and 250 milligram tablets *Add to Centennial Care formulary.*	Antidepressant	F, PA, QL	NF	T4
pimozide 1 and 2 milligram tablets *Add to Centennial Care formulary.*	Antidepressant	F, PA, QL	T3	T4
Exelon® (rivastigmine) 1.5, 3, 4.5 and 6 milligram oral capsules *Add to Centennial Care formulary.*	Antidepressant	F, PA, QL	T3	T4
Provigil® (modafinil) 100 and 200 milligram tablets *Prior authorization criteria updated.*	Central Nervous System Stimulant	PA, QL	T1, PA, QL	T2, PA, QL
Nuvigil® (armodafinil) 50, 150, 200 and 250 milligram *Prior authorization criteria updated.*	Central Nervous System Stimulant	PA, QL	T1, PA, QL	T2, PA, QL
Xarelto® (rivaroxaban) 10, 15 and 20 milligram tablets *Updating prior authorization requirement for Centennial Care plan for the 10, 15 and 20 milligram tablets.*	Direct Oral Anticoagulant (DOAC)	F, PA, QL	T2, QL	T3, QL
Divigel® (estradiol) 0.75 milligram/0.75 gram; 0.1% topical gel *Adding 0.1% strength to Commercial and Metal plans.*	Estrogen Derivative	NF	T2	T3
Trulicity® (dulaglutide) 0.75 milligram/0.5 milliliter; 1.5 milligram/0.5 milliliter solution *Decrease tiering for Commercial and Metal plans.*	Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist	F, PA, QL	T2, ST, QL	T3, ST, QL
Amicar® (aminocaproic acid) 500 and 1000 milligram tablets *Added to Centennial Care plan.*	Hemostatic Agent	F	T4	T5
Amicar® (aminocaproic acid) 0.25 gram/milliliter oral solution *Adding prior authorization criteria to only allow for members less than 12 years of age or unable to swallow tablets or capsules.*	Hemostatic Agent	PA, AL	T4, PA, AL	T5, PA, AL
Pulmicort™ nebulizing solution (budesonide) 0.25 milligram/2 milliliter, 0.5 milligram/2 milliliter, 1 milligram/2 milliliter solution *Remove age maximum on 0.25, 0.5 milligram nebulizing solutions on Centennial Care, Commercial, and Metal plans. One milligram nebulizing solution is still non-formulary on all plans.*	Inhaled Corticosteroid	**0.25 milligram, 0.5 milligram**: QL **1 milligram**: NF	**0.25 milligram, 0.5 milligram**: T1, QL **1 milligram**: NF	**0.25 milligram, 0.5 milligram**: T2, QL **1 milligram**: NF

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Centennial, Commercial, Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care	Commercial	Metal Level Plans
Other Changes (continued)				
Airduo Respiclick® (fluticasone/ salmeterol) 55/14 microgram/actuation, 113/14 microgram/actuation, 232/14 microgram/actuation inhalers *Remove step therapy through inhaled corticosteroid or anticholinergic requirement from Commercial and Metal plans.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	ST	T2	T3
Symbicort® (Budesonide/ formoterol fumarate dehydrate) 80/4.5 microgram/actuation; 160/4.5 microgram/actuation inhalers *Remove step therapy through inhaled corticosteroid or anticholinergic requirement from Commercial and Metal plans.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	ST, QL	T2, QL	T3, QL
fluticasone/salmeterol (authorized generic for Advair) 100/50 microgram/dose, 250/50 microgram/dose, 500/50 microgram/ dose inhalers *Step therapy updated to require claims for generic Airduo® AND Symbicort® in the past 150 days.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	PA, QL, AL	T3, ST, QL	T4, ST, QL
Dulera® (mometasone/ formoterol) 100/5 microgram/actuation; 200/5 microgram/actuation inhalers *Step therapy updated to require claims for generic Airduo® AND Symbicort® in the past 150 days.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	PA, QL, AL	T3, ST, QL	T4, ST, QL
Wixela™ (fluticasone/salmeterol) 100/50 microgram/dose, 250/50 microgram/dose, 500/50 microgram/ dose inhalers *Step therapy updated to require claims for generic Airduo® AND Symbicort® in the past 150 days.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	PA, QL, AL	T3, ST, QL	T4, ST, QL
Nutritional Supplements all covered products *Update prior authorization criteria for Centennial Care plan.*	Nutritional Supplement	F, PA	BE	BE
loteprednol etabonate (generic for Lotemax®) 0.5% ophthalmic suspension *Tier increased on Commercial and Metal plans.*	Ophthalmic Corticosteroid	ST	T3, ST	T4, ST
Sublocade™ (buprenorphine for injection) 100 milligram/0.5 milliliter; 300 milligram/0.5 milliliter *Prior authorization requirement removed for Centennial Care.*	Opioid Partial Agonist	F, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
Xenazine® (tetrabenazine) 12.5 and 25 milligram oral tablet *Prior authorization criteria updated*	VMAT2 Inhibitor	PA, SP, QL	T4, PA, QL, SP	T5, PA, QL, SP

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Medicare Formulary Updates

Drug Name	Therapeutic Class	Coverage
New Generics		
pyridostigmine (generic for Mestinon®) 60 milligram/5 milliliter oral solution	Acetylcholinesterase Inhibitor	T5
praziquantel (generic for Biltricide®) 600 milligram tablet	Anthelmintic	T3
ranolazine (generic for Ranexa®) 500 milligram ER and 1000 milligram ER tablets	Antianginal Agent	T3, QL
cefixime (generic for Suprax) 400 milligram oral capsule	Antibiotic	T3
solifenacin (generic for Vesicare®) 5 and 10 milligram tablets	Anticholinergic Agent	T4, ST, QL
vigabatrin (generic for Sabril®) 500 milligram tablet	Anticonvulsant	T5
pentamidine (generic for Pentam®) 300 milligram intravenous injection	Antifungal, Antiprotozoal	T4
erlotinib (generic for Tarceva®) 25, 100 and 150 milligram oral tablets	Antineoplastic	T5, PA, SP, QL
toremifene (generic for Fareston®) 60 milligram oral tablet	Antineoplastic Agent, Estrogen Receptor Antagonist	T5, QL
acycylovir cream (generic for Zovirax®) 5% topical cream	Antiviral, topical	T5, QL
penicillamine (generic for Cuprimine®) 250 milligram oral capsules	Chelating Agent	T5
drospirenone/ethinyl estradiol (generic for Yaz®) 3 milligram/0.02 milligram/1 milligram oral tablet	Contraception	T3
Jasmiel™ (generic: ethinyl estradiol and drospirenone) 0.02 milligram/3 milligram tablets	Contraceptive	T3
ambrisentan (generic for Letairis®) 5 and 10 milligram tablet	Endothelin Receptor Antagonist, Pulmonary Arterial Hypertension	T5, SP, QL
bosentan (generic for Tracleer®) 62.5 and 125 milligram oral tablets	Endothelin Receptor Antagonist, Pulmonary Arterial Hypertension	T5, SP, QL
mesalamine (generic for Delzicol®) 400 milligram capsules	Gastrointestinal Anti-Inflammatory	T4, ST
sirolimus (generic for Rapamune®) 1 milligram/milliliter oral solution	Immunosuppressant Agent	T5, PA
deferasirox (generic for Exjade®) 125, 250 and 500 milligram tablets	Iron Chelating Agent	T5
loteprednol (generic for Lotemax®) 0.5% ophthalmic suspension	Ophthalmic Corticosteroid	T4, ST
buprenorphine/naloxone (generic for Suboxone®) 2 milligram/0.5 milligram, 4 milligram/1 milligram, 8 milligram/2 milligram oral strips	Opioid Partial Agonist	T4, QL
polyethylene glycol (generic for Pegylax®) 17 grams per dose	Osmotic Laxative	T2
Alyq™ (authorized generic, tadalafil) 20 milligram oral tablet	Phosphodiesterase Inhibitor, Pulmonary Arterial Hypertension	T5, PA, QL

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Medicare Formulary Updates

Drug Name	Therapeutic Class	Coverage
Formulary Additions		
Balversa™ (erdafitinib) 3, 4 and 5 milligram tablets	Antineoplastic	T5, PA, QL
Versacloz® (clozapine) 50 milligram/milliliter oral suspension	Antipsychotic	T5
Dovato® (dolutegravir/lamivudine) 50 milligram/300 milligram oral tablet	Antiretroviral, Integrase Inhibitor (Anti-HIV); Antiretroviral, Reverse Transcriptase Inhibitor, Nucleoside (Anti-HIV)	T5
Aristada Initio™ (aripiprazole lauroxil) 675 milligram prefilled syringe	Atypical Antipsychotic, Long-Acting Injectable	T5
Proair® (albuterol) 90 microgram/actuation, authorized generic	Beta$_2$ Agonist	T4, ST
Proventil® (albuterol) 90 microgram/actuation, authorized generic	Beta$_2$ Agonist	T4, ST
Ventolin® (albuterol) 90 microgram/actuation, authorized generic	Beta$_2$ Agonist	T4
Aurovela™ Fe (ethinyl estradiol/norethindrone/ferrous fumarate) 0.02 milligram/1 milligram/75 milligram tablet	Contraception	T3
Prograf® (tacrolimus) 0.2 and 1 milligram granules for oral suspension	Immunosuppressant Agent	T3, PA
Tresiba® (insulin degludec) 100 unit/ml 10 milliliter vial	Insulin, Long-Acting	T3, QL
Other Changes		
nitrofurantoin suspension 5 milligram/milliliter oral suspension *Remove prior authorization requirement, remove quantity limit.*	Antibiotic	T2
nitrofurantoin, macrocrystals 25, 50, 100 milligram oral capsule *Remove prior authorization requirement, remove quantity limit.*	Antibiotic	T2
nitrofurantoin monohydrate 75 milligram oral capsule *Remove prior authorization requirement, remove quantity limit.*	Antibiotic	T2
Symbicort® (budesonide/formoterol fumarate) 80/4.5 microgram per actuation, 160/4.5 microgram per actuation *Remove step therapy.*	Inhaled Corticosteroid/Long-Acting Beta$_2$ Agonist	T3
Emadine (emedastine difumarate) 0.05% ophthalmic solution *Remove step therapy.*	Ocular Histamine H$_1$ Antagonist	T4
Adcirca® (tadalafil) 20 milligram tablets *Remove quantity limit.*	Phosphodiesterase Inhibitor, Pulmonary Arterial Hypertension	T5, PA

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Medicare Formulary Updates

Drug Name	Therapeutic Class	Coverage
Formulary Deletions		
Mestinon® (pyridostigmine) 12 milligram/milliliter oral syrup	Acetylcholinesterase Inhibitor	Alternative: pyridostigmine oral solution 12 milligram/milliliter (T5)
Biltricide® (praziquantel) 600 milligram tablets	Anthelmintic	Alternative: praziquantel 600 milligram tablets (T3)
Ranexa® (ranolazine ER) 500 and 1000 milligram tablets	Antianginal Agent	Alternative: ranolazine ER 500 milligram tablets and 1000 milligram tablets (T3 QL)
Sabril® (vigabatrin) 500 milligram tablets	Anticonvulsant	Alternative: vigabatrin 500 milligram tablets, 500 milligram oral packets (T5)
Fareston® (toremifene) 60 milligram tablets	Antineoplastic Agent, Estrogen Receptor Antagonist	Alternative: toremifene 60 milligram (T5, QL)
Rapamune® (sirolimus) 1 milligram/milliliter oral solution	Immunosuppressant Agent	Alternative: sirolimus 1 milligram/milliliter oral solution (T5, PA)
Advair® (fluticasone/salmeterol) 100/50, 250/50 and 500/50 microgram inhalers	Inhaled Corticosteroid/Long-Acting $Beta_2$ Agonist	Alternative: fluticasone/salmeterol 100/50, 250/50 and 500/50 microgram inhalers (T4 ST)
Suboxone® (buprenorphine/naloxone) 2 milligram/0.5 milligram, 4 milligram/1milligram and 8 milligram/2 milligram oral strips	Opiod Partial Agonist	Alternative: buprenorphine/naloxone 2 milligram/0.5 milligram, 4 milligram/1 milligram and 8 milligram/2 milligram oral strips (T4, QL)
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You can find Presbyterian formularies and updates, including restrictions (e.g., quantity limits, step therapy and prior authorization criteria) and preferences, online at https://www.phs.org/providers/formularies/Pages/default.aspx.

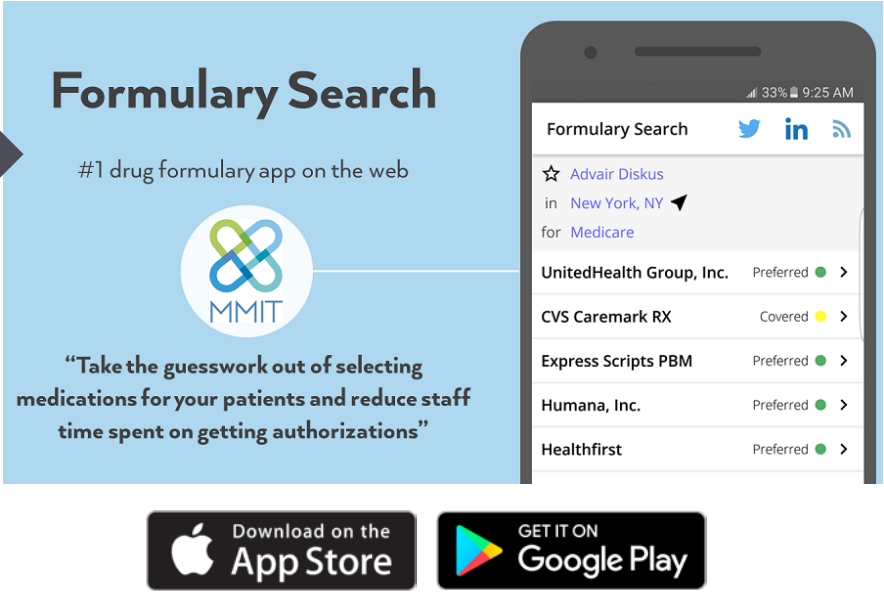
Current and past issues of the Pharmacy & Therapeutics (P&T) Committee Provider Updates are available online at https://www.phs.org/providers/contact-us/news-and-communications/Pages/default.aspx.

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

The Universal Practitioner and Provider Manual and the Centennial Care Practitioner and Provider Manual 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 Operations relationship executive.

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.



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.

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 health plan. Presbyterian formularies may be accessed in the following ways:

- 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 also 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 passwords are 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, you may call Presbyterian's Pharmacy Services Help Desk at (505) 923-5500, or toll-free at 1-888-923-5757. The Help Desk's business hours are Monday through Friday, from 8 a.m. to 5 p.m. You may also email the ASKRX 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 within one business day.

Food and Drug Administration (FDA) Alerts from April 1, 2019 to June 30, 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. **Opioids safety update: Changes to prescribing information [04/09/2019] -** The FDA announced that they are requiring changes to the prescribing information for opioids due to reports of serious harm in patients who are physically dependent on opioids suddenly having these medicines discontinued or the dose rapidly decreased. Reports include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. The FDA's Deputy Center Director for Regulatory Programs released an additional announcement regarding the opioid safety update. The opioid label changes will provide expanded guidance to healthcare providers on how to safely decrease the dose in patients who are physically dependent on opioids when the dose is to be decreased or the medicine is to be discontinued. Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. These symptoms can lead patients to seek other sources of opioids, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin and other substances.
   Response by Presbyterian: Inform providers in the P&T newsletter.

2. **Voluntary recall (expansion) on losartan and losartan/HCTZ tablets manufactured by Torrent Pharmaceuticals Limited. [01/03/2019, 01/22/2019, 03/01/2019, 04/18/2019] -** 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 Hetero Labs Limited. Torrent is only recalling lots of losartan-containing products that contain N-Methylnitrosobutyric acid (NMBA) 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.
   Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

3. **Voluntary recall on fentanyl transdermal system manufactured by Alvogen. [04/23/2019]:** A small number of cartons labeled 12 microgram/hour Fentanyl Transdermal System patches contained 50 microgram/hour patches. The 50 microgram/hour patches that were included in cartons labeled 12 microgram/hour are individually labeled as 50 microgram/hour. Application of a 50 microgram/hour patch instead of a prescribed 12 microgram/hour patch could result in serious, life threatening, or fatal respiratory depression.
   Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

4. **Voluntary recall (expansion) on losartan manufactured by Hetero Labs Limited, distributed by AvKare [04/23/2019], Major [04/26/2019] -** These products are being recalled due to the detection of trace amount 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, no reports of adverse events related to this recall. **Response by Presbyterian:** Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

5. **Voluntary recall (expansion) on losartan packaged by Legacy Pharmaceutical Packaging. [03/15/2019, 04/24/2019] -** These products are being recalled due to the detection of trace amount 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, no reports of adverse events related to this recall. **Response by Presbyterian:** Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

6. **Voluntary recall on ceftazidime injection (2 g/50mL duplex) manufactured by B. Braun Medical. [04/25/2019]-** The recalled lot contained elevated high molecular weight polymers (HMWPs). Additional tests for the recalled lot also indicated levels that were out of trend when compared with prior stability data. Elevated levels of HMWP have been shown to cause acute nephrotoxicity in rabbits and mice and phagocytic deposits of foreign material in liver cells of dogs after repeated elevated doses. While the impact of HMWPs in humans is unknown.
   Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

7. **Voluntary recall on losartan 25 and 100 milligram tablets manufactured by Teva Pharmaceuticals USA, Inc., sold to Golden State Medical Supply. [04/26/2019, 06/11/2019] -** These products are being recalled due to the detection of trace amount of an unexpected, impurity N-Nitroso N-Methyl 4-amino butyric acid (NMBA).
   Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

8. **Voluntary recall on bevacizumab (1.25 milligram/0.05 milliliter 31 G syringe) manufactured by AmEx Pharmacy. [04/29/2019] -** The Monoject Syringe of this product may become difficult to express, and when additional force is applied, while the needle is in the eye, may cause injury to the patient. The additional force needed to express the drug product could potentially result in damage to the eye while the needle is in the eye. To date, AmEx Pharmacy has received three reports associated with the lot being recalled as either being difficult to express, two of which, resulted in an Adverse Drug Event. **Response by Presbyterian:** Inform providers in the P&T newsletter.

9. **Insomnia medications: Safety communication and updated labeling [04/30/2019] -** A boxed warning will be added to the drug labels of certain common prescription insomnia medications due to rare but serious injuries occurring because of complex sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These behaviors appear to be more common with eszopiclone (Lunesta®), zaleplon (Sonata®), and zolpidem (e.g., Ambien®, Ambien CR®, Edluar®, Intermezzo®, and Zolpimist™) than other prescription medications used for sleep. The FDA is also requiring an update to the Contraindication section of the drug labels, to avoid use of these medications in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem. This information will also be added to the patient Medication Guides.
   Response by Presbyterian: Inform providers in the P&T newsletter.

10. **Voluntary recall on ketorolac tromethamine injection (60 milligram/2 milliliter) manufactured by Sagent Pharmaceuticals. [04/30/2019] -** Sagent has initiated this voluntary recall of ketorolac tromethamine Injection, USP to the to the user level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products. Adult patients administered the product intravenously are at most risk of a serious bloodstream infection of sepsis.
    Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

11. **Voluntary recall on mycophenolate mofetil injection manufactured by Par Pharmaceuticals. [05/01/2019] -** One vial of product was observed containing a glass fragment after reconstitution. The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening.
    Response by Presbyterian: Inform providers in the P&T newsletter.

12. **Voluntary recall on losartan potassium (25, 50 and 100 milligram tablets) manufactured by Vivimed. [05/03/2019] -** These products are being recalled due to the detection of trace amount of an unexpected, impurity N-Nitroso N-Methyl 4-amino butyric acid (NMBA). These products are distributed by Heritage Pharmaceuticals, Inc.
    Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

13. **Voluntary recall on Promacta® oral suspension (12.5 milligram) manufactured by Novartis. [05/12/2019] -** The oral suspension lots are being recalled because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site. Peanut is a known food allergen. Potential cross contamination with peanut flour, even in small traces, can lead to hypersensitivity reaction in a population of patients with an unknown or known sensitivity to peanut antigen, including a medically significant anaphylactic reaction, which can be fatal.
    Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

14. **Voluntary recall on amikacin sulfate injection (1 gram/4 milliliter) manufactured by Heritage Pharmaceuticals, Inc. [05/28/2019] -** The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot. Non-sterile injectable products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, organ damage or death.
    Response by Presbyterian: Inform providers in the P&T newsletter.

15. **Voluntary recall on prochlorperazine edisylate injection (10 milligram/2 milliliter) manufactured by Heritage Pharmaceuticals, Inc. [05/28/2019] -** The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot. Non-sterile injectable products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, organ damage or death.
    Response by Presbyterian: Inform providers in the P&T newsletter.

16. **Zytiga® (abiraterone acetate): Updates to the *Warnings and Precautions* section of the drug label [06/03/2019] -** The *Warning and Precaution* subsection regarding hypokalemia, fluid retention, and cardiovascular adverse reactions due to mineralocorticoid excess was updated with information regarding risk of QT prolongation and Torsades de Pointes. In post-marketing experience, QT prolongation and Torsades de Pointes have been observed in patients who develop hypokalemia while taking Zytiga. Patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention should be closely monitored. The Warnings and Precautions section was also updated to include information regarding increased fractures and mortality in combination with radium Ra 223 dichloride and embryo-fetal toxicity.
    Response by Presbyterian: Inform providers in the P&T newsletter.

17. **Voluntary recall on heparin sodium in 5% dextrose manufactured by B. Braun Medical. [06/13/2019] -** The voluntary recall was due to of one lot of heparin sodium in 5% dextrose injection due to a failure in ongoing stability data. During stability testing of batch J7B259, an out of specification result was identified at the 104-week stability interval for the drug anti-factor IIa potency.
    Response by Presbyterian: Inform providers in the P&T newsletter.

18. **Voluntary recall (expansion) on losartan manufactured by Macleods [06/20/2019] -** These products are being recalled due to the detection of trace amount 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.
    Response by Presbyterian: Inform providers in the P&T newsletter and letters were sent out to notify members who had prescription claims potentially affected lots of medication.

19. **Voluntary recall on fluorouracil by Fresenius Kabi USA [06/28/2019] -** The product is being recalled due to glass particulates found in five vials of the remaining inventory of lot 6120341 during an inspection for a quality investigation. The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur.
    Response by Presbyterian: Inform providers in the P&T newsletter.

NOTE: Notification is sent to Presbyterian members regarding class I or II drug recalls or market withdrawals due to a drug safety issue. Notification regarding drug recalls that are lot specific is not required as it is not possible for the health plan to identify members who were dispensed a specific lot of a medication.

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