PRESBYTERIAN

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

Pharmacy and Therapeutics Update

Formulary and pharmacy benefit updates for Presbyterian Healthcare Services professionals, providers and staff

FOURTH QUARTER 2021

Pharmacy and Therapeutics (P&T) Committee Decisions Effective Jan. 1, 2022

The Presbyterian Health Plan, Inc., and Presbyterian Insurance Company, Inc., (Presbyterian) Pharmacy and Therapeutics (P&T) Committee meets quarterly to promote the appropriate use of drugs to maintain the Presbyterian formularies and support our network of practitioners. The P&T Committee met on **Oct. 20, 2021**, and we would like to share the decisions made at the meeting that affect our formularies and pharmacy benefits.

Centennial, Commercial and Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care*	Commercial*	Metal Level Plans*
Formulary Additions				
Darzalex Faspro® (daratumumab and hyaluronidase-fihj) 1,800mg daratumumab and 30,000 units hyaluronidase per 15mL (120mg and 2,000 units/mL) solution in a single-dose vial	Antineoplastic Agent	MB, PA	MB, PA	MB, PA
New Generics – Unless otherwise noted, when a generic product becomes available, the brand-name product will be removed from the formularies.				
varenicline (generic for **Chantix®**) 0.5mg and 1mg tablets	Smoking Cessation Aid	F, PPACA	PPACA, QL	PPACA, QL, ST
ferumoxytol (generic for **Feraheme®**) 510mg/17mL single-dose vial	Iron Product	MB, PA	MB, PA	MB, PA
difluprednate (generic for **Durezol®**) 0.5% emulsion	Ophthalmic Corticosteroid	NF	NF	T4, QL, ST
enalapril (generic for **Epaned®**) 1mg/mL suspension	Ace Inhibitor	F, PA	T4, PA, AL	T5, PA, AL
sunitinib (generic for **Sutent®**) 12.5mg, 25mg, 37.5mg, 50mg tablets	Antineoplastic Agent	F, PA, SP	T4, PA, SP	T5, 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

Centennial, Commercial and Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care*	Commercial*	Metal Level Plans*
Other Changes				
Mavenclad® (cladribine) 10mg tablets *Updated prior authorization criteria.*	Multiple Sclerosis Agent	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
Mayzent® (siponimod) 0.25mg and 2mg tablets *Updated prior authorization criteria.*	Multiple Sclerosis Agent	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
Nuedexta® (dextromethorphan/quinidine) 20mg/10mg tablet *Updated prior authorization criteria.*	NMDA Antagonists	F, PA, QL	T4, PA, QL	T5, PA, QL
buprenorphine (generic for **Subutex®**) 2mg and 8mg sublingual tablets *Removed prior authorization requirement for Centennial Care formulary. Effective 9/1/2021.*	Opioid Analgesics, Opioid Partial Agonist	F, QL	T3, PA, QL	T4, PA, QL
Vyvanse® (lisdexamfetamine) 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg capsules and chewable tablets *Removed from Commercial and Exchange formularies.*	Stimulant	F, PA, QL	NF	NF
Wakix® (pitolisant) 4.45mg and 17.8mg tablets *Updated prior authorization criteria.*	Histamine H3 Antagonist/Inverse Agonist	F, PA, QL, AL	T4, PA, QL, AL	T5, PA, QL, AL
Zubsolv® (buprenorphine/naloxone) 0.7mg/0.18mg, 1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg sublingual tablets *Removed prior authorization requirement for Centennial Care formulary. Effective 9/1/2021.*	Opioid Analgesics, Opioid Partial Agonist	F, QL	NF	NF

*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 Changes

Drug Name	Coverage*	Date Submitted for Update
Formulary Additions		
NovoLog Mix® (insulin aspart protamine/insulin aspart) 70/30 relion suspension vial, relion prefilled flexpen	T3, QL, SSM	08/01/2021
Infanrix® (diphtheria and tetanus toxoids/ acellular pertussis) 25-58-10 intramuscular suspension	T3	09/01/2021
Formulary Deletions		
Thiola® (tiopronin) 100mg tablet	NF	08/01/2021
Banzel® (rufinamide) 200mg, 400mg oral tablet	NF	09/01/2021
Kaletra® (lopinavir/ritonavir) 100/25mg, 200/50mg oral tablet	NF	10/01/2021
Intelence® (etravirine) 100mg, 200mg oral tablet	NF	10/01/2021
New Generics		
calcitonin salmon (generic for **Miacalcin®**) 200/ml solution	T3	08/01/2021
etravirine (generic for **Intelence®**) 100mg, 200mg oral tablet	T5, NDS	08/01/2021
lopinavir/ritonavir (generic for **Kaletra®**) 100/25mg, 200/50mg oral tablet	T4	08/01/2021
rufinamide (generic for **Banzel®**) 200mg, 400mg oral tablet	T5, ST, NDS	09/01/2021
norethindrone acetate/ethinyl estradiol/ferrous fumarate (generic for **Larin 1/20 Fe®**) 0.02mg/1mg/ 75mg	T3	09/01/2021
varenicline (generic for **Chantix®**) 0.5mg, 1mg oral tablet	T4	09/01/2021
New Products		
Lumakras® (sotorasib) 120mg oral tablet	T5, PA, QL, LA, PA, NDS	10/01/2021
Other Formulary Changes		
Ayvakit® (avapritinib) 25mg, 50mg oral tablet	T5, PA, QL, LA, SP, NDS	10/01/2021

*Coverage acronym meanings: 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, NDS = Non-Extended Day Supply

Food and Drug Administration (FDA) Alerts June 30, 2021, to Sept. 20, 2021

For a full list of FDA alerts and additional information, see the FDA website at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.

1. **Recall of One Lot of Topotecan Injection 4mg/4mL (1mg/mL) Manufactured by Teva Pharmaceuticals [July 1, 2021]:** Teva Pharmaceuticals announced a voluntary, consumer-level recall of one lot of Topotecan Injection 4mg/4mL (1mg/mL) due to a single glass particle that was observed inside one vial at a pharmacy. Any consumer who has questions or concerns should first consult with their healthcare provider(s). **Presbyterian's Response:** Informed providers in the P&T newsletter.
2. **Recall of CHANTIX® (Varenicline) Tablets manufactured by Pfizer [July 19, 2021]:** Pfizer announced a voluntary, consumer-level recall of two lots of Chantix 0.5mg tablets, two lots of Chantix 1mg tablets, and eight lots of a Chantix kit of 0.5mg/1 mg tablets due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established Acceptable Daily Intake (ADI) level. Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the affected product lots. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to notify prescribing providers and members who had prescription claims for potentially affected lots of medication.
3. **Recall of Atovaquone manufactured by KVK Tech [August 6, 2021]:** KVK Tech, Inc., announced a voluntary, consumer-level recall of two lots of Atovaquone Oral Suspension, USP 750mg/5mL due to customer complaints of unusual grittiness in the product that was most likely caused by prolonged exposure of these product lots to extremely cold weather during shipment, which may result in changes to the effectiveness, appearance, taste and thickness of the liquid. Severely immunocompromised patients who receive less effective Atovaquone Oral Suspension may experience inadequate treatment of serious and life-threatening infections. **Presbyterian's Response:** Informed providers in the P&T newsletter.
4. **Recall Expansion of CHANTIX® (Varenicline) Tablets manufactured by Pfizer [August 16, 2021]:** Pfizer announced a voluntary, consumer-level recall of an additional four lots of Chantix 0.5mg/1mg tablets to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established ADI level. Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the affected product lots. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to notify prescribing providers and members who had prescription claims for potentially affected lots of medication.
5. **Recall of Lidocaine HCl Topical Solution 4% manufactured by Teligent Pharma [August 30, 2021]:** Teligent Pharma, Inc. announced a voluntary recall of one lot of Lidocaine HCl Topical Solution 4%, 50ml in a screw cap glass bottle to the user level because the firm's testing has found it to be extremely potent based on an Out of Specification (OOS) result obtained at the 18-month stability timepoint. Distributors and patients who have the recalled product should contact their place of purchase. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to notify prescribing providers and members who had prescription claims for potentially affected lots of medication.
6. **Recall of Monoject™ Flush Prefilled Saline Syringes manufactured by Cardinal Health [September 2, 2021]:** On Aug. 4, 2021, Cardinal Health (NYSE: CAH) initiated a nationwide recall of approximately 267 million Monoject™ Flush Prefilled Saline Syringes (0.9% Sodium Chloride). The products have been found to reintroduce air into the syringe after the air has been expelled. Patients who have affected product(s) should immediately review their inventory and quarantine and return all affected product. **Presbyterian's Response:** Informed providers in the P&T newsletter.
7. **Recall of Firvanq® (Vancomycin Hydrochloride for Oral Solution) Kit manufactured by Azurity Pharmaceuticals [September 8, 2021]:** Azurity Pharmaceuticals announced a voluntary, consumer-level recall of one lot of Firvanq® Vancomycin 50mg/ml Kit because some products were found to incorrectly contain a First omeprazole (FIRST-PPI) diluent instead of Firvanq diluent bottle. Patients, distributors and retailers that are in possession of Firvanq® from the affected lot should immediately stop using it and return it to the place of purchase. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to notify prescribing providers and members who had prescription claims for potentially affected lots of medication.

8. **Recall of CHANTIX® (Varenicline) Tablets manufactured by Pfizer [September 16, 2021]:** Pfizer announced a voluntary, consumer-level recall of all lots of Chantix 0.5mg and 1mg tablets due to the presence of nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit. Patients currently taking Chantix should consult with their healthcare provider about alternative treatment options. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to notify prescribing providers and members who had prescription claims for potentially affected lots of medication.

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

ANNOUNCEMENTS

Specialty Pharmacy Split Fill Program

Patients who are new to therapy for select specialty medications often are unable to tolerate these drugs. The patient often ends up discontinuing therapy early or modifying their dosage. To reduce waste and help avoid costs of medication that may go unused, Presbyterian will begin implementing the following Split Fill Program for all Commercial, Metal Level and Centennial Care members:

- Members new to therapy (or who have not had claims history within the past 120 days for the drug) are provided partial, or "split," prescription fills for up to three months. This gives the member an opportunity to try these drugs at a prorated cost share to make sure they can tolerate the drug and any potential side effects before continuing ongoing therapy.
- The Split Fill Program applies to certain specialty drugs. Each drug is evaluated using evidence-based criteria to determine the frequency and duration of a split fill. These decisions are subject to change at any time. Updates are found in the Formulary documents available on the Formularies page of the provider website at the following link: www.phs.org/providers/formularies
- The member receives their split fill and pays the applicable prorated member cost-share (copay/coinsurance) amount for the drug that is dispensed. Once the member can tolerate the medication, the applicable member cost-share amount will apply for each prescription fill received after completion of the program. Please note: All member share costs are determined by the member's pharmacy benefit plan.
- Members must use an in-network specialty pharmacy.
- This change will go into effect on **Sept. 1, 2021**, for all Presbyterian Commercial and Exchange Plans.

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

The Universal Practitioner and Provider Manual and the Centennial Care Practitioner and Provider Manual are also available online at www.phs.org/providermanual and include information about pharmacy benefits, the prior authorization process, generic substitution and requesting non-formulary medications based on medical necessity. Providers may receive a printed copy of both provider manuals at no cost from Presbyterian by contacting their Provider Network Operations relationship executive. Providers may find their relationship executive's contact information at www.phs.org/ContactGuide.

PRESBYTERIAN

Presbyterian Health Plan, Inc.
Provider Network Management
P.O. Box 27489
Albuquerque, NM 87125-7489
www.phs.org

PRESRT STD
U.S. Postage
PAID
Albuquerque, NM
Permit No. 1971

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. Please 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 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:

- Searchable formularies are available on the Formularies page of the provider website at the link previously provided. Providers may search for a drug using this tool by viewing an alphabetical list of drugs, searching by drug name or searching by therapeutic class. Providers may also learn if a covered drug has any restrictions by clicking on the link for the drug.
- Providers can access PDF versions of Presbyterian formularies and updates, including preferences and restrictions (e.g., quantity limits, step therapy and prior authorization criteria), on the Formularies page of the provider website at the link previously provided.

Contact Us

Changes to our formularies are based on requests from our practitioners and 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.

For any questions about the formulary coverage of medications, please call Presbyterian's 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 email ASKRX 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.