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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

SECOND QUARTER 2021

Pharmacy and Therapeutics (P&T) Committee Decisions Effective June 1, 2021

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 **April 21, 2021**, and we would like to share the decisions 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				
Selzentry® (maraviroc) 25mg/75mg tablets; 20mg/mL oral solution	Antiretroviral	F, QL	T2, QL	T3, QL
Xeljanz® (tofacitinb citrate) 1mg/ml oral solution	Janus Kinase Inhibitor, Antirheumatic	PA, QL, AL, SP	T4, PA, QL, AL, SP	T5, PA, QL, AL, SP
Xtandi® (enzalutamide) 40mg/80mg tablets	Antineoplastic Agent, Antiandrogen	F, PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
Iclevia (levonorgestrel/ethinyl estradiol) 0.15mg/0.03mg tablets	Oral Contraceptive	$0	$0	$0
Veklury® (remdesivir) 100mg vial	Antiviral	MB	MB	MB
Xtandi® (enzalutamide) 80mg tablets	Antineoplastic	PA, QL, SP	T4, PA, QL, SP	T5, PA, QL, SP
atropine 1% ophthalmic ointment	Ophthalmic Mydriatic	F	T1	T2
Avsola® (infliximab-axxq) 100mg vial	Biologic Disease Modifying Antirheumatic	MB, PA	MB, PA	MB, PA
Glucagon® **Emergency Kit** (manufactured by Fresenius) 1mg kit	Hypoglycemia Antidote	F	T2	T3
Humira® (adalimumab) 80mg/0.8ml pen injector kit	Biologic Disease Modifying Antirheumatic	PA, SP, QL	T4, PA, SP, QL	T5, PA, SP, QL

*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

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Centennial, Commercial and Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care*	Commercial*	Metal Level Plans*
Formulary Additions (continued)				
clobetasol propionate (generic for Temovate®) 0.05% cream	Topical Corticosteroid	F, QL	T1, QL	T2, QL
Omnipod Dash® insulin pump Insulin pods	Insulin Pump	PA, QL	T3, PA, QL	T4, PA, QL
New Generics – Unless otherwise noted, when a generic product becomes available, the brand-name product will be removed from the formularies.				
lubiprostone (authorized brand alternative for **Amitiza®**) 8mcg/24mcg capsules	Chloride Channel Activator	F, PA, QL	T2, ST, QL	T3, ST, QL
brinzolamide (generic for **Azopt®**) 1% ophthalmic suspension	Antiglaucoma Agent	F	T3	T4
glucagon (RDNA) for injection (generic for Glucagon® Emergency Kit) 1mg kit	Hypoglycemia Antidote	F	T3	T4
loteprednol etabonate (generic for **Lotemax Gel®**) 0.5% ophthalmic gel	Ophthalmic Corticosteroid	F, ST	T3, ST	T4, ST
Lyleq (generic for **Ortho Micron®**) 0.35mg tablets	Oral Contraceptive	$0	$0	$0
Nymyo (generic for **Ortho-Cyclen®**) 0.25mg/35mcg	Oral Contraceptive	$0	$0	$0
Tri-Nymyo (generic for **Ortho-Tri-Cyclen®**) 0.25mg/35mcg	Oral Contraceptive	$0	$0	$0
Zafemy (generic for **Xulane®**) 150-35mcg/24-hour patch	Contraceptive	$0	$0	$0
Other Changes				
Brilinta® (ticagrelor) 60mg/90mg tablets *Updated prior authorization criteria for Centennial Care formulary.*	Antiplatelet Agent	F, PA, QL	T2, QL	T3, QL
Kalydeco® (ivacaftor) 150mg tablets; 25mg/50mg/75mg packets *Updated prior authorization criteria.*	Cystic Fibrosis Treatment	F, PA, SP, QL	T4, PA, SP, QL	T5, PA, SP, QL
Xolair® (omalizumab) 75mg/0.5-mL and 150mg/mL prefilled syringe; 150mg single dose vial *Updated prior authorization criteria.*	Asthma treatment	MB, PA, SP	MB, PA, SP	MB, PA, SP
cimetidine HCl 300mg/5mL oral solution *Adjusted tiers for commercial and exchange formularies.*	Histamine Antagonist	F	T1	T2
Humatin® (paromomycin sulfate) 250mg capsules *Adjusted tiers for commercial and exchange formularies.*	Amebicide	NF	T3	T4

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Centennial, Commercial and Metal Formulary Updates

Drug Name	Therapeutic Class	Centennial Care*	Commercial*	Metal Level Plans*
Other Changes (continued)				
methylphenidate (generic for **Ritalin**®) 5mg/10mg/20mg tablets *Updated age limit for all formularies.*	Stimulant	F, PA, QL, AL	T1, PA, QL, AL	T2, PA, QL, AL
methylphenidate (generic for **Methylin**®) 5mg/5mL and 10mg/5mL oral solution *Updated age limit for all formularies.*	Stimulant	F, PA, QL, AL	T1, PA, QL, AL	T2, PA, QL, AL
Pataday® (olopatadine HCl) 0.1%, 0.2% and 0.7%, ophthalmic solution *Removed all strengths for all formularies.*	Ocular Antihistamine	NF	NF	NF
Trelstar Mixject® (triptorelin) 3.75mg/11.25mg/22.5mg injection *Added prior authorization criteria, removed gender edit.*	Gonadotropin Releasing Hormone Agonist	MB, PA	MB, PA	MB, PA

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Medicare Formulary Changes

Drug Name	Coverage*	Date Submitted for Update
Formulary Additions		
Accutane® (isotretinoin) 10mg/20mg/30mg/40mg oral capsules	T4	April 1, 2021
Dificid® (fidoxomicin) 40mg/ml reconstituted oral suspension	T5	April 1, 2021
fenofibrate (generic for **Tricor**®) 48mg/145mg oral tablet	T2	April 1, 2021
leucovorin 15mg oral tablet	T2	April 1, 2021
pilocarpine (generic for **Salagen**®) 7.5mg oral tablet	T2	April 1, 2021
Sulfatrim® **pediatric** (trimethoprim/sulfamethoxazole) 200-40mg/5ml oral suspension	T2	April 1, 2021
Formulary Deletions		
Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate) 600mg/200mg/300mg oral tablet	NF	March 1, 2021
Monurol® (fosfomycin) 3g powder for oral solution	NF	March 1, 2021
Truvada® (tenofovir disoproxil fumarate/emtricitabine) 200mg/300mg oral tablet	NF	March 1, 2021
Tykerb® (lapatinib) 250mg oral tablet	NF	March 1, 2021
Zytiga® (abiraterone) 500mg oral tablet	NF	March 1, 2021
Banzel® (rufinamide) 40mg/ml oral suspension	NF	March 1, 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

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Medicare Formulary Changes

Drug Name	Coverage*	Date Submitted for Update
Formulary Deletions (continued)		
Kuvan® (sapropterin) 100mg soluble tablet, 100mg/500mg powder packet	NF	March 1, 2021
Symfi® (efavirenz-lamivudine-tenofovir disoproxil fumarate) 600mg/300mg/300mg oral tablet	NF	March 1, 2021
Symfi Lo 400mg/300mg/300mg oral tablet	NF	March 1, 2021
New Products		
Diacomit® (stiripentol) 250mg/500mg powder packet for oral suspension	T5	March 1, 2021
Onureg® (azacitadine) 200mg/300mg oral tablet	T5	March 1, 2021
Orgovyx® (relugolix) 120mg oral tablet	T5	April 1, 2021
New Generics		
asenapine (generic for **Saphris**®) 2.5mg/5mg/10mg sublingual tablet	T4	March 1, 2021
efavirenz/ lamivudine/ tenofovir disoproxil fumarate (generic for **Symfi**®) 600mg/300mg/300mg oral tablet	T5	March 1, 2021
fosfomycin (generic for **Monurol**®) 3g powder for oral solution	T4	March 1, 2021
icosapent ethyl (generic for **Vascepa**®) 1000mg oral capsule	T4	March 1, 2021
lapatinib ditosylate (generic for **Tykerb**®) 250mg tablet	T5	March 1, 2021
rufinamide (generic for **Banzel**®) 40mg/ml oral suspension	T5	March 1, 2021
loteprednol etabonate (generic for **Lotemax**®) 0.5% ophthalmic gel	T4	April 1, 2021
Other Formulary Changes		
Iclusig® (ponatinib) 10mg/30mg oral tablet *New strength.*	T5	April 1, 2021

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Food and Drug Administration (FDA) Alerts
January 11, 2021 to April 12, 2021

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

1. **Recall of metformin ER manufactured by Nostrum [01/25/2021]** - Nostrum announced a voluntary, consumer level recall of one lot of metformin 750mg ER tablets due to contamination with n-nitrosodimethylamine (NDMA). This is an expansion of the recall initially announced on Nov. 2, 2020. Patients who have the recalled metformin ER should continue taking it until a doctor or pharmacist gives them a replacement or a different treatment option. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to prescribing providers and members who had prescription claims for potentially affected lots of medication.

2. **Recall of enoxaparin manufactured by Apotex [02/02/2021]** - Apotex announced a voluntary, consumer level recall of two lots of enoxaparin injection due to a packaging error resulting in some syringe barrels containing 150mg/mL markings (corresponding to 120mg/ 0.8mL strength) instead of 100mg/mL markings (corresponding to 100mg/mL strength) on the syringe barrel and vice versa. Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately. **Presbyterian's Response:** Informed providers in the P&T newsletter and letters were sent out to notify prescribing providers and members who had prescription claims potentially affected lots of medication.

3. **Safety update for Xeljanz and Xeljanz XR [02/04/2021]** - The FDA announced that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. Clinical trials examining safety are now complete and initial results show a higher occurrence of serious heart-related events and cancer in RA patients treated with both doses of Xeljanz vs. patients treated with a TNF inhibitor. The FDA is awaiting additional results from the trial. Patients should not stop taking Xeljanz or Xeljanz XR without first consulting with their healthcare professionals, as doing so may worsen their condition. Healthcare professionals should consider the benefits and risks of Xeljanz or Xeljanz XR when deciding whether to prescribe or continue patients on the medicine. **Presbyterian's Response:** Informed providers in the P&T newsletter.

4. **Recall of Gamunex-C manufactured by Grifols [03/02/2021, 03/23/2021]** - Grifols Therapeutics announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C (immune globulin [human]) injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection. Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately. **Presbyterian's Response:** Informed providers in the P&T newsletter and sent letters to prescribing providers and members who had prescription claims for potentially affected lots of medication.

5. **Recall of spironolactone manufactured by Bryant Ranch Repack [03/09/2021]** - The FDA announced a voluntary, patient-level recall of four lots of Bryant Ranch Repack spironolactone tablets because some prepackaged bottles labeled spironolactone 50mg may contain spironolactone 25mg tablets and prepackaged bottles of spironolactone 25mg may contain spironolactone 50mg tablets. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled spironolactone. Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately. **Presbyterian's Response:** Informed providers in the P&T newsletter.

6. **Recall of acyclovir manufactured by Zydus [03/24/2021]** - Zydus announced a voluntary, user-level recall of four lots of acyclovir 50mg/mL injection after receiving several complaints of crystallization in vials. Administration of crystalized acyclovir injection has a potential for life-threatening adverse consequences including injection site inflammation of a vein and local reactions, damage and/or obstruction of blood vessels, which could induce clots, particularly in the lungs. Passage of the particulate matter into the bloodstream may lead to clots resulting in stroke, heart attack, decreased liver or kidney function or death of tissues or cells. Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately. **Presbyterian's Response:** Informed providers in the P&T newsletter.

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7. **Recall of telmisartan manufactured by Alembic [03/24/2021]** - Alembic announced a voluntary, consumer-level recall of one lot of telmisartan 20mg tablets because of a market complaint received which stated that one bottle labeled as 30-count telmisartan 20mg tablets, incorrectly contained 30 tablets of telmisartan 40mg tablets. Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately. **Presbyterian's Response:**Informed providers in the P&T newsletter and sent letters to prescribing providers and members who had prescription claims for potentially affected lots of medication.
8. **Recall of guanfacine manufactured by Apotex [03/31/2021]** - Apotex announced a voluntary, consumer-level recall of three lots of guanfacine 2mg extended-release tablets because of trace amounts of quetiapine fumarate in one lot. Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately. **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. 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.*

Presbyterian formularies and updates, including restrictions (e.g., quantity limits, step therapy and prior authorization criteria) and preferences are available online at the following link: 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.

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. Providers may receive a printed copy of the Centennial Care Practitioner and Provider Manual at no cost by contacting their Presbyterian Provider Network Management relationship executive. Providers may find their relationship executive's contact information at www.phs.org/ContactGuide.

Formulary Search App

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.

Formulary Search

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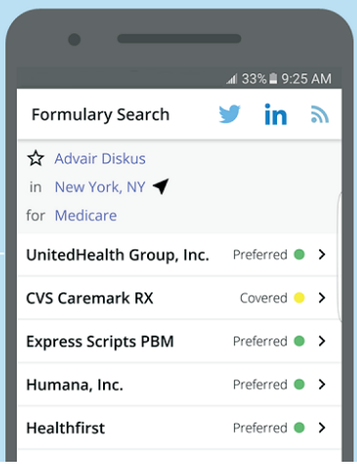
"Take the guesswork out of selecting medications for your patients and reduce staff time spent on getting authorizations"



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ANNOUNCEMENTS

Presbyterian Coverage of Biosimilars

A number of biosimilar products have become available in the United States and multiple biologic products have biosimilar products in development. An approved biosimilar product is a biological product that has been shown to be highly similar to the FDA-approved biological product (i.e., reference product). Minor differences in clinically inactive compounds (e.g., different stabilizer or buffer) between the biosimilar product and reference product are allowed but there cannot be clinically meaningful differences between the biosimilar product and the reference product regarding safety, purity, or potency. As costs for biological drugs continue to rise, the increased availability of biosimilar products will benefit both providers and patients by expanding treatment options and access to these medications at lower costs.

Presbyterian prefers use of biosimilar products prior to the reference product when clinically appropriate. Please see below for a listing of preferred biosimilar products. Please reference Presbyterian formularies and criteria for plan-specific coverage requirements for the agents listed below. This information can be found at https://www.phs.org/providers/formularies/Pages/default.aspx.

Preferred Biosimilar Products

Reference Product	Preferred Biosimilar(s)
Avastin	Zirabev
Herceptin	Ogivri, Trazimera
Neulasta injection	Fulphila, Ziextenzo, Udenyca
Neupogen	Zarxio
Remicade	Renflexis, Avsola
Rituxan	Ruxience, Truxima (rheumatoid arthritis only)

Reference:
FDA. Biosimilar and interchangeable products. Page last updated Oct. 23, 2017. www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biological. (Accessed March 31, 2021).

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 following link: www.phs.org/providers/formularies/Pages/default.aspx. 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 find out 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 restrictions (e.g., quantity limits, step therapy and prior authorization criteria) and preferences, which are available on the Formularies page of the provider website at the link previously provided.
- 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 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 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.

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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.

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