Pharmacy and Therapeutics (P&T) Committee Provider Update

THIRD QUARTER 2016

PRESBYTERIAN

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

P&T Committee Decisions effective September 1, 2016

Dear Healthcare Practitioner: 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. The P&T Committee met on **July 20, 2016**, and we would like to share with you the decisions made at the meeting that affect our formularies and pharmacy benefits.

Drug Name	Centennial Care	Commercial and HIX	Medicare*
Formulary Additions			
Descovy® (emtricitabine/tenofovir alafenamide) 200 mg/25 mg tablets *Added to all formularies. Quantity limit on Centennial Care, Commercial and HIX formularies.*	QL (1 tablet/day)	Tier 4, QL (1 tablet/day)	Tier 5
Evomela™ (mephalan) 50 mg lyophilized powder for reconstitution in a single-dose vial *Added to the formularies with prior authorization.*	MB, PA	MB, PA	NF
Tecentriq™ (atezolisumab) 1200 mg/20 mL solution in a single-use vial *Added to all formularies with prior authorization.*	MB, PA	MB, PA	Tier 5, PA
Tivicay® (dolutegravir) 10 mg and 25 mg tablets *Added to the formularies with a quantity limit.*	QL (1 tablet/day)	10 mg- Tier 3, QL 25 mg- Tier 4, QL (1 tablet/day)	NF
Xarelto® (rivaroxaban) 10 mg, 15 mg, and 20 mg tablets *Added to the formularies. Prior authorization required for Centennial Care.*	PA	Tier 2	Tier 3

HIX = Health Insurance Exchange, MB = Medical Benefit, NF = Non-Formulary, PA= Prior Authorization Required, QL= Quantity Limits Apply, SP = Specialty Pharmacy Mandated, ST = Step Therapy Required
*Medicare formulary changes may be pending approval from Centers for Medicare & Medicaid Services (CMS)

Drug Name	Centennial Care	Commercial and HIX	Medicare*
Formulary Coverage Changes			
Aloxi® (palonosetron) 0.25 mg/5 mL injection *Specialty pharmacy mandate removed.*	MB, PA, QL (5 mL /5 days)	MB, PA, QL (5 mL/5 days)	Tier 4, PA
azelastine nasal 1% (generic for Astelin®) 137 mcg/spray *Changed prior authorization requirement to a step therapy requirement on the Centennial Care formulary.*	ST	Tier 1	Tier 2
Brilinta® (ticagrelor) 60 mg and 90 mg tablets *The 60 mg tablets have been added to the Centennial Care, Commercial and HIX formularies. The prior authorization requirement for Brilinta has been removed from Commercial and HIX formularies.*	PA, QL (60 tablets/30 days)	Tier 2, QL (60 tablets/30 days)	90 mg tablets= Tier 3, QL, PA (60 tablets/30 days)
ciclopirox 8% topical solution (generic for Penlac®) *Quantity limit updated.*	QL (6.6 mL/30 days)	Tier 1, QL (6.6 mL/30 days)	Tier 2
Eliquis® (apixiban) 2.5 mg and 5 mg tablets *Removed from Centennial Care, Commercial and HIX formularies.*	NF	NF	Tier 4, PA, QL (2 tablets/day)
Flumist® Quadrivalent (influenza vaccine live, intranasal) 0.2 mL intranasal spray *This product will not be covered during the 2016-2017 flu season based on CDC Advisory Committee on Immunization Practices (ACIP)'s recommendations.*	NF	NF	NF
testosterone 50 mg/5 gram gel packets (Testim®) *Removed from Centennial Care, Commercial, and HIX formularies.*	NF	NF	NF
Zovirax® (acyclovir) 5% cream and ointment *Removed from Centennial Care, Commercial, and HIX formularies.*	NF	NF	Tier 3 (cream) Tier 4 (ointment)
New Generics (brand products will removed from the formularies with the availability of generics)			
armodafinil (generic for Nuvigil®) 50 mg, 150 mg, 200 mg, and 250 mg tablets	PA, QL	Tier 3, PA, QL	Tier 3, PA, QL
dicyclomine (generic for Bentyl™) 20 mg/2 mL injection for intramuscular use	MB	MB	Tier 2
dofetilide (generic for Tikosyn®) 0.125 mg, 0.25 mg, and 0.5 mg capsules	NF	Tier 3	Tier 3
ibuprofen lysine (generic for NeoProfen®) 10 mg/mL preservative free solution for IV use	MB	MB	MB
pantoprazole (Protonix® I.V.) 40 mg for IV solution	MB	MB	Tier 2

HIX = Health Insurance Exchange, MB = Medical Benefit, NF = Non-Formulary, PA= Prior Authorization Required, QL= Quantity Limits Apply, SP = Specialty Pharmacy Mandated, ST = Step Therapy Required
*Medicare formulary changes may be pending approval from Centers for Medicare & Medicaid Services (CMS)

Prior Authorization and Step Therapy Criteria Additions/Revisions

- **Azelastine nasal spray 1% (137 mcg/actuation) Step Therapy Criteria for Centennial Care Plans:** The member must have a prescription claim history of a nasal corticosteroid and a non-sedating antihistamine within the past 120 days.
- **Cerebral Stimulant Prior Authorization Criteria for Adults Age 19 and Above:** Multiple Sclerosis fatigue has been added as an indication for approval.
- **Xarelto Prior Authorization Criteria for Centennial Care Plans:** For treatment of atrial fibrillation and for the treatment and prevention of recurrence of deep vein thrombosis and/or pulmonary embolism the member must have tried and failed warfarin or have a medical reason for avoiding the use of warfarin (e.g., poor INR control despite good adherence to warfarin therapy, allergy, intolerance, or contraindication to use, significant barrier to warfarin monitoring).
- **Prior Authorization Criteria for use of Hormonal Interventions in the Treatment of Gender Dysphoria in Children and Adolescents:** New prior authorization requirements will apply to the use of gonadotropin-releasing hormone analogs (e.g., Lupron, Lupron Depot, Lupron Depot-Ped) and cross-sex hormone treatment in children and adolescents when used for the diagnosis of gender dysphoria.

The complete prior authorization criteria requirements and other information regarding Presbyterian formularies can be found online at: https://www.phs.org/providers/formularies/Pages/default.aspx

The Centers for Medicare & Medicaid Services (CMS) Expectations for Formulary-Level Cumulative Opioid Point of Sale Edits

Starting January 1, 2017, CMS expects Medicare Part D sponsors who adjudicate pharmacy claims to implement cumulative opioid edits at the point of sale (POS) to prospectively prevent opioid overutilization. The parameters proposed by CMS include the following:

- A soft edit rejection that can be overridden by the pharmacist when a prescription claim will result in the beneficiary's active or overlapping opioid prescriptions to reach or exceed a certain daily morphine equivalent dose (MED) threshold (90 mg to 120 mg MED).
- Hard edits for daily cumulative MED threshold at or above 200 mg MED.

You can find additional information regarding this CMS requirement in the 2017 Announcement online at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html. Presbyterian will also send out additional communications to providers regarding these new POS edits in the near future.

FDA Safety Alerts from April 2016 to July 2016

For full information and additional FDA Alerts see the FDA website at: http://www.fda.gov/Safety/MedWatch/

- **Fluconazole (generic for Diflucan) – Drug Safety Communication [04-26-16]:** The FDA is evaluating the results of a Danish study that indicates there is an increased risk of miscarriage with the use of oral fluconazole for yeast infections. The FDA is recommending cautious prescribing of oral fluconazole in pregnancy and will communicate final conclusions and recommendations when the review is complete.
- **Brintellix (vortioxetine) – Drug Safety Communication [05/02/16]:** The FDA has approved a brand name change for the antidepressant Brintellix. The new brand name of the drug is Trintellix and it became available June 3, 2016. The brand name is being changed due to name confusion between Brintellix and the anti-platelet agent Brilinta (ticagrelor). This confusion led to prescribing and dispensing errors.
- **Aripiprazole (Abilify, Abilify Maintena, Aristada) – Drug Safety Communication [05-03-16]:** The FDA is requiring the addition of new warnings to the drug labels of all aripiprazole products regarding the risk of compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex. These uncontrollable urges were reported to have stopped when the medication was discontinued or the dose was reduced. The FDA is recommending that healthcare professionals should make patients and caregivers aware of the risk of these uncontrollable urges, closely monitor for new or worsening uncontrollable urges in patients at higher risk of impulse control and consider reducing the dose or stopping the medication if such urges develop.

FDA Safety Alerts from April 2016 to July 2016 (cont.)

- **Olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbax) – Drug Safety Communication [05-10-16]:** The FDA is warning that the antipsychotic drug olanzapine can cause Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS is a rare but serious skin reaction that can progress to affect other parts of the body. The FDA is requiring the addition of a new warning to the drug labels of all olanzapine products. Patients who are taking an olanzapine-containing product who develop a fever with a rash and swollen lymph glands or swelling of the face should seek medical care right away. Healthcare professionals should immediately stop treatment with olanzapine if DRESS is suspected.*
- **Fluoroquinolone Antibacterial Drugs – Drug Safety Communication [05-12-16]:** An FDA safety review has shown that fluoroquinolones when used systemically (i.e., oral or injectable formulations) are associated with an increased risk of side effects that can affect tendons, muscles, joints, nerves, and the central nervous system. The FDA is advising that these serious side effects outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections. The FDA is recommending that for patients with these conditions, fluoroquinolones should be reserved for patients who do not have alternative treatment options.
- **Canagliflozin (Invokana, Invokamet) – Drug Safety Communication [05-18-16]:** Interim safety results from an ongoing clinical trial have found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medication canagliflozin. The FDA is investigating this new safety issue and will update the public when they have more information.
- **Zecuity (sumatriptan) Migraine Patch – Drug Safety Communication [06-02-16 and 6-13-16]:** On June 2, 2016, the FDA announced it was investigating the risk of serious burns and potential permanent scarring with the use of Zecuity after several reports from patients who had experienced burns or scars on the skin where the patch was placed. On June 13, 2016, the manufacturer of Zecuity, Teva Pharmaceuticals, announced that it decided to temporarily suspend sales, marketing, and distribution to investigate the cause of burns and scars associated with the Zecuity patch. The FDA is recommending that healthcare professionals discontinue prescribing of Zecuity and patients should stop using any remaining patches and contact their prescribers for an alternative migraine medication.
- **Loperamide (generic for Immodium) – Drug Safety Communication [06-07-16]:** The FDA is warning that taking higher than recommended doses of the antidiarrheal loperamide can cause serious heart problems, including abnormal heart rhythms, that can lead to death. A majority of the reported cases of serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria. The maximum approved daily dose for adults is 8 mg per day for OTC use and 16 mg per day for prescription use.
- **Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR) – Drug Safety Communication [06-14-16]:** The FDA has strengthened the existing warning about the risk of acute kidney injury for the Type 2 diabetes medications canagliflozin and dapagliflozin. The FDA is recommending that healthcare professionals consider factors that predispose patients to acute kidney injury prior to the start of one of these medications. Assessment of kidney function should be done prior to start of therapy and monitored periodically thereafter. If acute kidney injury occurs, the drug should be stopped. Use of canagliflozin is not recommended in patients with eGFR <45 mL/min/1.73m2 and dosage reductions are recommended for eGFR 45 mL/min/1.73m2 to 60 mL/min/1.73m2. Dapagliflozin should not be used in patients with eGFR < 60 mL/min/1.73m2.

Contact Us

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 concerns, please contact the pharmacy director, Louanne Cunico, Pharm.D., at **lcunico@phs.org** or (505) 923-8359.

You may also contact the author of this newsletter, Kendra Ward, Pharm.D., at **kward2@phs.org** or (505) 923-6967, Monday through Friday from 8 a.m. to 5 p.m.

Thank you for partnering with us to improve the health of patients, members, and communities we serve.