



THE PRESCRIBER e-LETTER

Pulmonary Hypertension Agents

There are three classes of drugs that are FDA approved for the treatment of World Health Organization (WHO) Group 1 Pulmonary Arterial Hypertension (PAH): prostanoids, endothelin receptor antagonists (ERAs), and phosphodiesterase 5 (PDE5) inhibitors.

The consensus guidelines published by the American College of Chest Physicians and the guidelines from the American College of Cardiology Foundation (ACCF) in conjunction with the American Heart Association (AHA) recommend oral therapy with either PDE5 inhibitors or ERAs as first-line agents in patients who are considered lower risk and are not candidates for calcium-channel blockers. These guidelines also recommend intravenous therapy with a prostanoid, epoprostenol, or treprostinil as a first-line agent in patients at higher risk with poor prognostic indexes. Epoprostenol is the preferred treatment for the most severely ill patients and is the only therapy shown to prolong survival.

MassHealth has reviewed the PAH agents with respect to appropriate use of generic alternatives. Due to the availability of a generic epoprostenol (Flolan) and ACCF and AHA recommendations that epoprostenol can be used as a first-line agent in patients at higher risk with poor prognostic indexes, MassHealth has determined that all PAH agents with the exception of generic epoprostenol (Flolan) will require prior authorization.

The prior-authorization requirement for PAH agents became effective on **November 15, 2010**. The prior-authorization status of the individual products is outlined below.

Requires PA	Avg. cost/therapy*
ambrisentan (Letairis)	\$5,701.50
bosentan (Tracleer)	\$6,016.50
iloprost inhalation (Ventavis)	\$5,859.00
sildenafil intravenous (Revatio)	\$8,819.69
sildenafil oral (Revatio)	\$1,351.80
tadalafil (Adcirca)	\$1,122.07
treprostinil inhalation (Tyvaso)	\$11,833.50–13,266.75
treprostinil injection (Remodulin)	\$1,237.95– \$8,665.65
Available without PA	
epoprostenol (Flolan)#	\$2,286.08–\$3,639.68

This is a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the branded Flolan. For weight-based dosing regimens, the cost of therapy was calculated using a 70 kg patient.

Thiazolidinedione Update

Actos and Avandia are oral thiazolidinedione (TZD) anti-diabetic agents indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). The consensus algorithms for the treatment of T2DM developed by the American Diabetes Association (ADA)/European Association for the Study of Diabetes (EASD) and the American College of Endocrinology/American Association of Clinical Endocrinologists (ACE/AACE) recommend metformin as the cornerstone of therapy. However, the two guidelines differ in their recommendations with regard to the next step in patients not adequately controlled on metformin. ACE/AACE guidelines prefer incretin mimetics and TZDs over sulfonylureas due to increased risk of hypoglycemia. Conversely, the ADA/EASD guidelines consider therapy with incretin mimetics and TZDs to be less well validated than sulfonylureas and recommend their use only in selected clinical settings, when hypoglycemia is particularly undesirable. Both Actos and Avandia carry a black box warning about the risk of congestive heart failure exacerbation and are contraindicated in patients with established New York Heart Association (NYHA) Class III or IV heart failure.

MassHealth has reviewed the thiazolidinedione anti-diabetic agents with respect to safety, efficacy, and appropriate use. Due to the availability of less costly alternatives, ADA/EASD and ACE/AACE recommendations that sulfonylureas can be used as a second-line agent in addition to metformin, and the potential for serious cardiac complications in patients with preexisting heart failure, MassHealth has determined that Actos and Avandia will require prior authorization.

The prior authorization requirement for Actos and Avandia became effective on **January 1, 2011**.

Drug	Availability	Avg. monthly price*
pioglitazone (Actos)	Tablet: 15 mg, 30 mg, 45 mg	\$144.40–\$239.41
rosiglitazone (Avandia)	Tablet: 2 mg, 4 mg, 8 mg	\$82.53–\$223.25

*Cost based on once daily administration

The Prescriber e-Letter is an update designed to enhance the transparency and efficiency of the MassHealth drug prior-authorization (PA) process and the MassHealth Drug List. Each issue **highlights** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
nonsteroidal anti-inflammatory agents	Change in PA status; requires PA <ul style="list-style-type: none"> • diclofenac potassium (Cataflam) • meclofenamate • naproxen (Naprosyn) suspension (>12 years) • naproxen EC (Naprosyn EC) • piroxicam (Feldene) • tolmetin (Tolectin) 	Branded Cataflam, Naprosyn suspension, Naprosyn EC, Feldene, Tolectin, and generic meclofenamate require prior authorization. There are more cost-effective alternatives available for the management of the same clinical condition including generic diclofenac sodium, ibuprofen, and naproxen, which are available without PA.
acyclovir cream (Zovirax)	Change in PA status; requires PA >12 years and PA >5 grams/month	Zovirax cream is indicated for the treatment of recurrent herpes labialis in patients 12 years and older. There are more cost-effective alternatives available for the management of the same clinical condition including Denavir (penciclovir) cream, which is available without PA.
acyclovir/hydrocortisone (Xerese)	Addition; requires PA	Xerese is indicated for the treatment of recurrent herpes labialis in patients 12 years and older. There are more cost-effective alternatives available for the management of the same clinical condition including Denavir (penciclovir) cream, which is available without PA.
amylase/lipase/protease (Pancrease MT, Pancrecarb, Ultrase)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services.
aztreonam (Cayston)	Addition; does not require PA	Cayston is indicated to improve respiratory symptoms in patients with cystic fibrosis known to have <i>Pseudomonas aeruginosa</i> in the lungs.
cabazitaxel (Jevtana)	Addition; does not require PA	Jevtana is indicated in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel.
chenodiol (Chenodal)	Addition; requires PA	Chenodal is indicated for patients with radiolucent gallstones when surgery is not an option due to increased surgical risk. There are more cost-effective alternatives available for the management of the same clinical condition including ursodiol products, which are available without PA.
clindamycin/tretinoin (Veltin)	Addition; requires PA	Veltin is indicated for the topical treatment of acne vulgaris in patients 12 years or older. There are more cost-effective alternatives available for the management of the same clinical condition including generic clindamycin and tretinoin, which are available without PA in patients <21 years of age.
clobetasol/coal tar (Clobeta Plus Kit)	Addition; requires PA	Clobeta Plus Kit is indicated for the treatment of psoriasis. There are more cost-effective alternatives available for the management of the same clinical condition such as topical corticosteroids including augmented betamethasone, clobetasol propionate, diflorasone diacetate, and halobetasol, which are available without PA.
clonidine (Catapres-TTS Patch)	Change in PA status; requires PA	Catapres-TTS Patch requires prior authorization. There are more cost-effective alternatives available for the management of the same clinical condition including generic clonidine tablets, which are available without PA.
denosumab (Prolia)	Addition; requires PA	Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. There are more cost-effective alternatives available for the management of the same clinical condition including generic alendronate tablet, which is available without PA.
diclofenac powder for solution (Cambia)	Addition; requires PA	Cambia is indicated for the acute treatment of migraine attacks in adults 18 years of age or older. There are more cost-effective alternatives available for the management of the same clinical condition including other formulations including generic acetaminophen and non-steroidal anti-inflammatory products, which are available without PA.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
donepezil, orally disintegrating tablet (Aricept ODT)	Change in PA status; does not require PA	Aricept ODT is indicated for the treatment of Alzheimer-associated dementia.
dutasteride/tamsulosin (Jalyn)	Addition; requires PA	Jalyn is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH). There are more cost-effective alternatives available for the management of the same clinical condition including generic doxazosin, tamsulosin, and terazosin, which are available without PA.
everolimus (Afinitor) 2.5 mg	Addition; requires PA >30 units/month	Due to comparable pricing between 2.5 mg, 5 mg, and 10 mg tablets, prior authorization is required for quantities of >30 units/30 days of the 2.5 mg and 5 mg tablets to promote dose consolidation.
everolimus (Zortress)	Addition; does not require PA	Zortress is indicated for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.
gatifloxacin (Zymaxid)	Addition; requires PA	Zymaxid is indicated for the treatment of bacterial conjunctivitis. There are more cost-effective alternatives available for the management of the same clinical condition including generic ophthalmic antibiotics, which are available without PA.
glipizide/metformin	Change in PA status; does not require PA	Generic glipizide/metformin combination is now considered a least costly alternative (LCA) and is available without PA.
glyburide/metformin	Change in PA status; does not require PA	Generic glyburide/metformin combination is now considered a least costly alternative (LCA) and is available without PA.
influenza virus vaccine (Afluria)	Addition; does not require PA	Afluria is an influenza virus vaccine indicated for the prevention of influenza virus infection in persons aged 6 months or older. On August 5, 2010, the Advisory Committee on Immunization Practices (ACIP) recommended against its use in children 6 months to 8 years of age due to the increased incidence of fever and febrile seizures.
influenza virus vaccine (Agriflu)	Addition; does not require PA	Agriflu is an influenza virus vaccine indicated for the prevention of influenza virus infection in persons 18 years of age or older.
lacosamide solution (Vimpat)	Addition; requires PA	Vimpat oral solution is indicated for adjunctive therapy in partial-onset seizures in patients aged 17 years or older. There are more cost-effective alternatives available for the management of the same clinical condition including generic carbamazepine suspension, gabapentin solution, lamotrigine tablet, topiramate, valproic acid, and divalproex, which are available without PA.
lisdexamfetamine (Vyvanse)	Change in PA status; requires PA > 60 units/month	Vyvanse is indicated for the treatment of Attention Deficit Hyperactivity Disorder in patients 6 to 17 years old and requires quantity limits to prevent inappropriate overutilization
melatonin tablet and solution	Addition; requires PA >18 years	There are no medications, with the exception of chloral hydrate, that are FDA-approved for the treatment of sleep disorders or insomnia in children. Therefore, MassHealth has determined that melatonin will be available to the pediatric population up to 18 years of age without PA.
metformin (Riomet)	Change in PA status; requires PA >12 years	Riomet solution requires PA for members older than 12 years. There are more cost-effective alternatives available for the management of the same clinical condition including generic metformin, which is available without PA.
methylphenidate (Methylin)	Change in PA status; requires PA >900 ml/month	MassHealth has updated quantity limits on Methylin 5 mg/5 ml oral solution to prevent inappropriate overutilization.
methylphenidate transdermal system (Daytrana)	Change in PA status; requires PA <6 years or >17 years and PA >30 patches/month	Daytrana is indicated for the treatment of Attention Deficit Hyperactivity Disorder in patients 6 to 17 years old and requires PA and quantity limits to ensure treatment is clinically appropriate.
miconazole (Oravig)	Addition; requires PA	Oravig is indicated for the local treatment of oropharyngeal candidiasis (OPC) in adults. There are more cost-effective alternatives available for the management of the same clinical condition including generic nystatin and clotrimazole, which are available without PA.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
mometasone/formoterol (Dulera)	Addition; requires PA	Dulera is indicated for the treatment of asthma in patients 12 years of age or older. There are more cost-effective alternatives available for the management of the same clinical condition including single-agent inhaled corticosteroids, which are available without PA.
naproxen/esomeprazole (Vimovo)	Addition; requires PA <60 years	Vimovo is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. There are more cost-effective alternatives available for the management of the same clinical condition including generic naproxen and omeprazole 20 mg capsule, which are available without PA.
olmesartan/amlodipine/hydrochlorothiazide (Tribenzor)	Addition; requires PA	Tribenzor is indicated for the treatment of hypertension. There are more cost-effective alternatives available for the management of the same clinical condition including generic ACE inhibitors, amlodipine, and hydrochlorothiazide, which are available without PA.
omeprazole/sodium bicarbonate	Addition; requires PA	Omeprazole/sodium bicarbonate combination is indicated for short-term treatment of active duodenal ulcer, active benign gastric ulcer, erosive esophagitis, and treatment of symptoms associated with GERD. There are more cost-effective alternatives available for the management of the same clinical condition including generic omeprazole 10 mg and 20 mg capsules, which are available without PA.
ondansetron oral soluble film (Zuplenz)	Addition; requires PA	Zuplenz is indicated for the prevention of nausea and vomiting associated with cancer chemotherapy, radiotherapy, and post operation. There are more cost-effective alternatives available for the management of the same clinical condition including generic ondansetron 4 mg and 8 mg tablet and orally disintegrating 4 mg tablet formulations, which are available without PA for quantities <15 units/month.
ondansetron solution (Zofran)	Change in PA status; requires PA	Generic and branded Zofran solution require PA for all quantities. There are more cost-effective alternatives available for the management of the same clinical condition including generic ondansetron 4 mg and 8 mg tablet and orally disintegrating 4 mg tablet formulations, which are available without PA for quantities <15 units/month.
ondansetron, orally disintegrating tablet (Zofran ODT 4 mg)	Change in PA status; requires PA >15 units/month	Zofran 4 mg orally disintegrating tablet will no longer require prior authorization for ≤15 units/month.
palonosetron (Aloxi)	Change in PA status; requires PA	Aloxi requires prior authorization. There are more cost-effective alternatives available for the management of the same clinical condition including generic ondansetron 4 mg and 8 mg tablet and orally disintegrating 4 mg tablet formulations, which are available without PA for quantities <15 units/month.
pitavastatin (Livalo)	Addition; requires PA	Livalo is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol, LDL-C, apolipoprotein B, and triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. There are more cost-effective alternatives available for the management of the same clinical condition including lovastatin, pravastatin, and simvastatin, which are available without PA.
romidepsin (Istodax)	Addition; requires PA	Istodax is indicated for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy. There are more cost-effective alternatives available for the management of the same clinical condition including Zolinza, Actimmune, Intron A, and Targretin, which are available without PA.
sacrosidase (Sucraid)	Change in PA status; requires PA	Sucraid is an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency. Sucraid requires PA to ensure treatment is clinically appropriate.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
scopolamine (Transderm Scop)	Change in PA status; requires PA	Transderm Scop requires prior authorization. There are more cost-effective alternatives available for the management of the same clinical condition including generic meclizine, which is available without PA along with generic ondansetron 4 mg and 8 mg tablet and orally disintegrating 4 mg tablet formulations, which are available without PA for quantities <15 units/month.
tranexamic acid (Lysteda)	Addition; does not require PA	Lysteda is indicated for the treatment of cyclic heavy menstrual bleeding.
trazodone ER (Oleptro)	Addition; requires PA	Oleptro is indicated for the treatment of major depressive disorder in adults. There are more cost-effective alternatives available for the management of the same clinical condition including generic SSRIs, SNRIs, TCAs, bupropion, and trazodone (excluding 300 mg tablet), which are available without PA.
Please send any suggestions or comments to: PrescriberEletter@state.ma.us .		