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THE PRESCRIBER e-LETTER

Anti-Gout Agents

The British Society for Rheumatology recommends the use of nonsteroidal anti-inflammatory drugs (NSAIDs) as the oral agents of choice for the management of acute gout attacks. There does not appear to be any clinical difference regarding which NSAID is selected. Colchicine and corticosteroids are both considered effective alternatives if NSAIDs are contraindicated. Initiation of urate-lowering therapy (ULT) with allopurinol is recommended after a second gout attack within a one-year period. In conjunction with ULT, guidelines recommend the use of colchicine in combination with allopurinol for up to six months to prevent further gout attacks; NSAIDs are indicated in situations of colchicine intolerance. In addition, due to the potential for toxicity and inability of colchicine to prevent urate accumulation, colchicine is infrequently used for long-term prophylaxis (i.e. for periods greater than six months). The National Institute for Health and Clinical Excellence (NICE) guidelines for the management of hyperuricemia in patients with gout recommend Uloric (febuxostat) as an option only for patients who are intolerant, or have a contraindication, to allopurinol.

The table below details the average cost per claim for the various oral antigout agents. As a result of a recent review of the utilization of these agents within the MassHealth population, the high cost of these agents, and the availability of less costly alternatives, Colcrys, Krystexxa, and Uloric will continue to require prior authorization (PA).

Medication	Average Cost/Claim
Allopurinol	$3.66
Colcrys (colchicine)	$193.41
Krystexxa (pegloticase)	$4,830.00*
Probenecid	$29.37
Probenecid-Colchicine	$27.47
Uloric (febuxostat)	$156.13

* Please note this cost is an estimate, due to lack of utilization within MassHealth the true average cost per claim is not available.

Kalydeco (ivacaftor)

Cystic fibrosis (CF) is the most common fatal autosomal recessive disease among Caucasians. The frequency is approximately 1: 2,000 to 3,000 live births. CF is caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which codes for the CFTR protein. The CFTR protein functions as a channel across the membrane of cells that produce mucus, sweat, saliva, tears, and digestive enzymes. The channel transports chloride ions into and out of cells helping to control the movement of water in tissues; necessary for the production of thin, freely flowing mucus, which provides a protective coating in the airways, digestive system, reproductive system, and other organs and tissues. In addition to chloride, the CFTR gene also transports sodium ions across cell membranes necessary for lung and pancreatic function.

Kalydeco (ivacaftor) treats the underlying pathophysiology in patients who carry the G551D gene mutation of the CFTR gene. This mutation results in improper functioning of the CFTR protein leading to inhibition of normal cellular flow of salt and fluid. Kalydeco is approved in patients ≥ 6 years of age and it has been shown to restore function to the defective protein, thereby improving lung function, lowering sweat chloride levels and assisting with weight gain. Clinical trials with this agent have demonstrated a statistically significant improvement in FEV1, CFTR activity (measured by sweat chloride), and measures of nutritional status (body mass index and weight). Improvements were noticed within 2 weeks and sustained through 48 weeks of treatment.

While it is estimated that only 4% of the 30,000 CF patients in the US have this mutation, this approval marks a major advancement in targeted gene therapy for CF patients. However, due to the high cost and very specific indication for this product, Kalydeco requires PA.

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 will **highlight** 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
aflibercept (EYLEA)	Addition; **does not require PA^** ^This agent is only available through the health-care professional who administers the drug. MassHealth does not pay for this drug to be dispensed through a retail pharmacy.	Aflibercept is FDA approved for the treatment of patients with neovascular (wet) age-related macular degeneration. This agent has been added to the MassHealth Drug List and does not require a PA; however, it is only available through the health-care professional who administers the drug.
axitinib (INLYTA)	Addition; **requires PA**	Axitinib is a kinase inhibitor FDA approved for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy. Due to the high cost of this product, the specific indication, and the availability of less costly alternatives including Afinitor (everolimus), Nexavar (sorafenib), Sutent (sunitinib), and Votrient (pazopanib), axitinib requires PA.
azilsartan/chlorthalidone (Edarbyclor)	Addition; **requires PA**	Azilsartan/chlorthalidone is a combination of an angiotensin II receptor blocker and a thiazide-like diuretic that is FDA approved for the treatment of hypertension in patients inadequately controlled with monotherapy and also in patients who are likely to require multiple drugs to achieve blood pressure goals. Due to the availability of less costly alternatives, including various generic angiotensin converting enzyme inhibitors, diuretics, and angiotensin receptor blockers, azilsartan/chlorthalidone requires PA.
capsaicin high-dose patch (Qutenza)	Change in PA status; **requires PA^** ^This agent is only available through the health-care professional who administers the drug. MassHealth does not pay for this drug to be dispensed through a retail pharmacy.	Capsaicin high-dose patch is FDA approved for the management of neuropathic pain associated with postherpetic neuralgia. It is to be administered by a physician or health-care professional who is under the close supervision of a physician. In order to ensure this agent is used properly it is now only available through the health-care professional who administers the drug and requires a PA.
ciclopirox 0.77% cream, suspension (Loprox)	Deletion; **removed from MassHealth Drug List**	The production of this product has been discontinued by the manufacturer and has been removed from the MassHealth Drug List.
deferiprone (Ferriprox)	Addition; **requires PA**	Deferiprone is an iron chelator that is FDA approved for the treatment of patients with transfusional iron overload as a result of thalassemia syndromes when current therapy is inadequate. Due to the high cost and specific indication of this product, deferiprone requires PA.
diphenoxylate/atropine (Lonox)	Deletion; **removed from MassHealth Drug List**	The production of this product has been discontinued by the manufacturer and has been removed from the MassHealth Drug List.

Please send any suggestions or comments to PrescriberELetter@state.ma.us.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
everolimus (Afinitor) 7.5 mg	Addition; **does not require PA**	Everolimus is a kinase inhibitor that is indicated for the treatment of adults with progressive neuroendocrine tumors of pancreatic origin that are unresectable, locally advanced, or metastatic; for the treatment of adults with renal cell carcinoma after failing sunitinib or sorafenib; adults with renal angiomyolipoma and tuberous sclerosis complex that does not require immediate surgery; and patients ≥ 3 years of age with subependymal giant cell astrocytoma associated with tuberous sclerosis who are not considered candidates for surgery. This agent was recently approved in a new 7.5 mg formulation. This new dose does not require PA.
exenatide extended-release (BYDUREON)	Addition; **requires PA**	Exenatide extended-release is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist FDA approved, as an adjunct to diet and exercise, for the treatment of adults type 2 diabetes mellitus. Due to the availability of less costly alternatives, including metformin and sulfonylureas, this agent requires PA.
ivacaftor (Kalydeco)	Addition; **requires PA**	Ivacaftor is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. This agent is FDA approved for the treatment of cystic fibrosis in patients ≥ 6 years of age who have a *G551D* mutation in the CFTR gene. Due to the high cost and very specific indication for this product, ivacaftor requires PA.
linagliptin/metformin (Jentadueto)	Addition; **requires PA**	Linagliptin/metformin is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product that is FDA approved as an adjunct to diet and exercise for adults with type 2 diabetes. Due to the availability of less costly alternatives, including metformin and sulfonylureas, and to ensure appropriate use of this product, this agent requires a PA.
metoprolol extended-release/hydrochlorothiazide (DUTOPROL)	Addition; **requires PA**	Metoprolol extended release/hydrochlorothiazide is a combination of a beta adrenoceptor blocker and a diuretic that is FDA approved for the treatment of hypertension. Due to the availability of less costly alternatives, including various generic angiotensin converting enzyme inhibitors, diuretics, and beta blockers, metoprolol extended release / hydrochlorothiazide requires PA.
nitroglycerin 0.4% ointment (Rectiv)	Addition; **requires PA**	Nitroglycerin 0.4% ointment is a nitrate vasodilator FDA approved for the treatment of moderate to severe pain associated with chronic anal fissures. Due to the availability of a less costly alternative compounded nitroglycerin ointment (0.2%), this agent requires PA.
oxycodone immediate-release 5 mg and 7.5 mg tablets (Oxecta)	Addition; **requires PA**	Oxycodone immediate-release is an opioid agonist FDA approved for the management of acute and chronic moderate to severe pain when the use of an opioid analgesic is appropriate. Due to the availability of generic 5 mg oxycodone tablet, both doses for Oxecta require PA.

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Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
palonosetron (Aloxi)	Change in PA status; **requires PA for quantities > 1 vial/14 days**	Palonosetron is a serotonin subtype 2 (5-HT_3) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately or highly emetogenic chemotherapy as well as for the prevention of postoperative nausea and vomiting. A recent quality assurance analysis demonstrated appropriate utilization within the MassHealth population. As a result, palonosetron now requires PA when requested for more than 1 vial in a 14-day period.
quetiapine	Addition; **requires PA if quantity > 90 units/month**	Quetiapine is the new "A" rated generic to Seroquel. To ensure proper dose consolidation, when applicable, this agent requires a PA if quantities > 90 units/month.
sitagliptin/metformin extended-release (Janumet XR)	Addition; **requires PA**	Sitagliptin/metformin extended-release is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product that is FDA approved as an adjunct to diet and exercise for adults with type 2 diabetes. Due to the availability of less costly alternatives, including metformin and sulfonylureas, and to ensure appropriate use of this product, this agent requires PA.
tenofovir powder (Viread)	Change in PA status; **requires PA if patient ≥ 13 years**	Tenofovir powder is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children ≥ 2 years of age as well as for the treatment of chronic hepatitis B in adults. To allow for an additional dosage form in pediatric patients, this agent only requires PA for patients ≥ 13 years of age.
vismodegib (Erivedge)	Addition; **requires PA**	Vismodegib is a hedgehog pathway inhibitor that is FDA approved for the treatment of adults with metastatic basal cell carcinoma and also for the treatment of locally advanced basal cell carcinoma that has recurred following surgery or in patients who are not candidates for surgery or radiation. Due to the high cost of this agent and the very specific indication, vismodegib requires PA.
ziprasidone capsule	Addition; **requires PA if quantity > 60 units/month**	Ziprasidone is the new "A" rated generic to Geodon. To ensure proper dose consolidation, when applicable, this agent requires PA if quantities > 60 units/month.

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