

THE PRESCRIBER **C-LETTER**

New Agents for Gout

Two agents, Krystexxa (pegloticase) and Colcrys (colchicine), were recently approved by the Food and Drug Administration for the management of gout. Pegloticase is approved for the treatment of chronic gout that is refractory to conventional therapy, while Colcrys, the branded version of generic colchicine, is approved for prophylaxis and treatment of gout flares in adults. Guidelines for the treatment of gout published by the British Society for Rheumatology recommend a fastacting non-steroidal anti-inflammatory agent (NSAID) as the drug of choice in an acute attack when a patient has no contraindications. Colchicine can be an effective alternative to NSAIDs, but may have a slower onset of action. For patients with more than one attack in a year, long-term uric-acidlowering therapy for uncomplicated gout should be initiated with allopurinol and dose-adjusted to target a serum uric acid level of <300 µmol/L. Colchicine should also be prescribed in combination with allopurinol or other uricosuric agents and continued for up to six months.

Due to the availability of effective, less costly alternatives, MassHealth has determined that Colcrys and Krystexxa will require prior authorization.

The prior authorization process for Krystexxa and Colcrys were implemented on **May 2, 2011**, and **May 16, 2011**, respectively. The prior authorization status of the individual products is outlined below.

Drugs that require PA	Cost/Month
Colcrys (colchicine)	\$149.53
Krystexxa (pegloticase)	\$4,830.00
Uloric (febuxostat)	\$156.73 - \$159.02
Drugs available without PA	Cost/Month
Benuryl # (probenecid)	\$29.65 - \$31.19
Col-Benemid #, Col-Probenecid #	\$49.60
(colchicine/probenecid)	
Zyloprim # (allopurinol)	\$3.67 - \$7.77

This is a brand-name drug with an FDA "A"-rated generic equivalent. PA is required for the brand, unless a particular form of that drug does not have an FDA "A"-rated generic.

Butrans (buprenorphine) Transdermal

The Butrans (buprenorphine) transdermal system is Food and Drug Administration approved for the management of moderate-to-severe chronic pain in patients requiring a continuous around-the-clock opioid analgesic for an extended period of time. Butrans is a Schedule III controlled substance that is available as a 5 mcg/hour, 10 mcg/hour, or 20 mcg/ hour patch, all of which should be worn for seven days. Buprenorphine exerts its analgesic effect as a partial agonist at mu opioid receptor. For conversion from other opioids to Butrans, the patient's current around-the-clock opioids should be tapered for up to seven days to no more than 30 mg of morphine or equivalent per day before beginning treatment with Butrans. Patients currently receiving less than 30 mg of oral morphine equivalent should start with the 5 mcg/hour Butrans patch, while patients taking 30 mg to 80 mg of oral morphine equivalent can be started on the 10 mcg/hour patch. Caution should be used when prescribing Butrans to opioidexperienced patients, as Butrans may not provide adequate analgesia for patients requiring greater than 80 mg/day of oral morphine equivalents. A description of the potential for abuse is included in the product's black box warning. In an attempt to utilize less-costly alternatives for effective pain management, MassHealth has determined that Butrans will require prior authorization.

The prior authorization process for Butrans was implemented on **May 2, 2011**. The prior authorization status of the individual products is outlined below.

No PA required:

• Codeine (<360 mg/day), hydromorphone (<60 mg/day), morphine immediate and extended-release (<360mg/day), and oxycodone immediate-release (<240 mg/day)

PA required (long acting agents):

- Avinza (morphine extended-release)
- Dolophine (methadone)
- Duragesic (transdermal fentanyl)
- Exalgo (hydromorphone extended-release)
- Kadian (morphine sustained-release)
- MS Contin (morphine controlled-release)
- Opana (oxymorphone extended-release)
- Oxycontin (oxycodone controlled-release)

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
alcaftadine ophthalmic solution (Lastacaft)	Addition; requires PA	Lastacaft is indicated for the treatment of allergic conjunctivitis. There are more cost-effective alternatives available for the management of the same clinical condition including ketotifen, which is available without PA.
aliskiren/amlodipine/ hydrochlorothiazide (Amturnide)	Addition; requires PA	Amturnide is a combination product indicated for the treatment of hypertension. All of the product's components are available individually, two of which are generic. There are more cost-effective alternative combination products available for the management of the same clinical condition, which are available without PA.
baclofen injection (Gablofen)	Addition; does not require PA	Gablofen is indicated for use in the management of severe spasticity in adult and pediatric patients aged 4 and older.
benzoyl peroxide 9.8% foam (Benzefoam Ultra)	Addition; requires PA	Benzefoam Ultra is indicated for the treatment of acne vulgaris. There are more cost-effective alternatives available for the management of the same clinical condition including generic single- entity topical anti-acne products and oral isotretinoin, which are available without PA for members aged 21 years and younger.
buprenorphine transdermal (Butrans)	Addition; requires PA	Butrans is indicated for the management of moderate-to-severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic. There are more generic, cost-effective alternatives available for the management of the same clinical conditions including morphine sulfate, oxycodone, and hydromorphone, which are available without PA if the dosing limits have not been exceeded.
carglumic acid (Carbaglu)	Addition; requires PA	Carbaglu is indicated for the adjunctive treatment of acute hyperammonemia and the maintenance treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthetase (NAGS).
ceftaroline (Teflaro)	Addition; requires PA	Teflaro is a 5 th -generation cephalosporin indicated for the treatment of acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia. There are more cost-effective alternatives available for the management of the same clinical condition depending on the type of infection being treated, which are available without PA.
clonidine extended- release (Kapvay)	Addition; requires PA	Kapvay is indicated for the treatment of attention deficit hyperactivity disorder in patients 6 to17 years of age. There are more cost-effective alternatives available for the management of the same clinical conditions including generic immediate-release clonidine and guanfacine tablets, which are available without PA.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
clonidine extended-release (Nexiclon ER)	Addition; requires PA	Nexiclon ER is indicated for the treatment of hypertension. There are more cost-effective alternatives available for the management of the same clinical conditions including generic clonidine and guanfacine immediate-release tablets, methyldopa, and reserpine, which are available without PA.
colchicine (Colcrys)	Change in PA status; requires PA	Colcrys, a branded colchicine product, is indicated for the prophylaxis and treatment of gout flares. Colcrys is the only colchicine product available on the market. There are more cost-effective alternatives available for the management of the same clinical condition including probenecid, allopurinol, and NSAIDs, which are available without PA.
cyclosporine (Restasis)	Change in PA status; requires PA	Restasis is indicated to increase tear production that is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. There are more generic, cost-effective alternatives available for the management of the same clinical conditions including ophthalmic NSAIDs and ophthalmic corticosteroids, which are available without PA.
denosumab (Xgeva)	Addition; requires PA	Xgeva is indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumors. There are more cost-effective alternatives available for the management of the same clinical condition including pamidronate and Zometa, which are available without PA.
dextromethorphan/ quinidine (Nuedexta)	Addition; requires PA	Nuedexta is indicated for the treatment of pseudobulbar affect. There are more cost-effective alternatives available for the management of the same clinical condition including SSRIs and TCAs, which are available without PA.
ethinyl estradiol/ drospirenone/levomefolate (Safyral)	Addition; does not require PA	Safyral is indicated for use by women in the prevention of pregnancy and to raise folate levels in women who choose to use an oral contraceptive for contraception.
ethinyl estradiol 5 mcg/ norethindrone 1 mg (Jinteli)	Addition; does not require PA	Jinteli is indicated in women with an intact uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause.
eribulin (Halaven)	Addition; requires PA	Halaven is indicated for metastatic breast cancer in patients who have received at least two prior chemotherapy regimens that should have included an anthracycline and a taxane.
fentanyl sublingual tablets (Abstral)	Addition; requires PA	Abstral is indicated for the management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. There are more generic, cost-effective alternatives available for the management of the same clinical conditions including morphine sulfate, oxycodone, and hydromorphone, which are available without PA if the dosing limits have not been exceeded.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
glycopyrrolate oral solution (Cuvposa)	Addition; requires PA	Cuvposa is indicated to reduce chronic severe drooling in young patients with neurologic conditions associated with problems of drooling (e.g., cerebral palsy). There are more cost-effective alternatives available for the management of the same clinical conditions including glycopyrrolate tablets, which are available without PA.
hydroxypropyl cellulose ophthalmic insert (Lacrisert)	Change in PA status; requires PA	Lacrisert is indicated for patients with moderate-to-severe dry eye syndromes including keratoconjunctivitis sicca, exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions. There are more cost-effective alternatives available for the management of the same clinical conditions including artificial tear preparations, which are available without PA.
immune globulin injection (Gammunex-C)	Addition; requires PA	Gamunex-C is indicated for the treatment of primary humoral immunodeficiency disease, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy.
interferon alfacon-1 (Infergen)	Change in PA status; requires PA	Infergen is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease.
lurasidone (Latuda)	Addition; requires PA	Latuda is indicated for the treatment of schizophrenia. There are more cost-effective alternatives available for the management of the same clinical condition including generic risperidone and other atypical antipsychotics, which are available without PA, unless the quantity limit is exceeded.
melatonin/pyridoxine	Change in PA status; requires PA > 18 years	Melatonin is considered to be a "dietary supplement" by the United States Food and Drug Administration (FDA) and is not regulated as a "drug." There are more cost-effective alternatives available for the management of the same clinical conditions including benzodiazepine and non-benzodiazepine hypnotics, which are available without PA, unless the quantity limit is exceeded.
moxifloxacin ophthalmic (Moxeza)	Addition; requires PA	Moxeza is indicated for the treatment of bacterial conjunctivitis. There are more generic, cost-effective alternatives available for the management of the same clinical condition including ophthalmic macrolides, fluoroquinolones, aminoglycosides, and sulfonamide-agents, which are available without PA.
pantoprazole (Protonix)	Change in PA status; requires PA > 30 units/month (20 mg tablets) or > 60 units/month (40 mg tablets)	Protonix is indicated for the healing/maintenance of erosive esophagitis or ulcerative GERD or other hypersecretory conditions. Quantity limits will not apply to children <12 years old or members with a diagnosis of abnormal secretion of gastrin, aka Barrett's esophagus, or erosive esophagitis.
pegloticase (Krystexxa)	Addition; requires PA	Krystexxa is indicated for the treatment of chronic gout in adult patient's refractory to conventional treatments. A higher incidence of anaphylaxis and infusion related reactions have been reported with this agent. There are more cost-effective alternatives available for the management of the same clinical conditions including probenecid, colchicine/probenecid, allopurinol, and NSAIDs, which are available without PA.

Drug/Drug Class	Addition/Deletion/Change	Rationale
penciclovir (Denavir)	Change in PA status; requires PA > 1 tube/month	Denavir is indicated for the treatment of recurrent herpes labialis (cold sores) in patients aged 12 and older. There are more cost-effective alternatives available for the management of the same clinical conditions including Valtrex and Zovirax tablets, which are available without PA.
testosterone 2% gel (Fortesta)	Addition; does not require PA	Fortesta is indicated as a replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
ulipristal acetate (ella)	Addition; does not require PA	ella is indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure.
zolpidem oral spray (Zolpimist)	Addition; requires PA	Zolpimist is indicated for the short-term treatment of insomnia. There are more cost-effective alternatives available for the management of the same clinical conditions including benzodiazepine and non-benzodiazepine hypnotics such as zolpidem, which are available without PA, unless the quantity limit is exceeded.

Recent MassHealth Drug List Updates (cont.)