



THE PRESCRIBER e-LETTER



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Opioids

Opioids are approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe pain associated with a number of etiologies and has been commonly used in the postoperative and malignant pain settings. Opioids are classified as controlled substances by the FDA due to their known potential for abuse.

There is limited literature available defining what constitutes “high dose” opioids. The maximum dose varies by patient, and is generally identified by the amount needed to relieve the pain without producing intolerable side effects. However, a review of clinical studies and guidance indicates that the highest daily dose of morphine allowed in randomized opioid trials was 240 mg/day, and the highest average dose was 120 mg/day.¹⁻³

Some references suggest that consultative assistance for opioid management and prudent prescribing may be appropriate at 120 mg of morphine equivalent doses/day, and the consulting specialist should advise the prescribing provider on a pain management plan. The dose of 120 mg/day is based, in part, on literature asserting that overdose risk is elevated in chronic non-cancer pain patients receiving medically prescribed opioids; it suggests that there is a ninefold increase in overdose risk in patients receiving 100 mg or more per day of morphine equivalents. High-dose opioid therapy can be ineffective and may be associated with poorer functional outcomes than lower doses.

MassHealth is frequently evaluating opioid utilization to determine the appropriateness of current and future opioid dose limits.

The updated prior-authorization process for opioid analgesics was implemented on **March 7, 2016**. The prior-authorization restrictions of the individual products are outlined below:

Drug	PA for dose limits
Astramorph-PF (morphine, injection)	> 120 mg/day
Dilaudid # (hydromorphone)	> 32 mg/day

Opioids (cont.)

Drug	PA for dose limits
Dolophine (methadone oral)	All quantities for new starts; > 30 mg/day high-dose PA restriction regardless of stability
Duragesic # (fentanyl 12, 25, 50 mcg/hr transdermal system)	> 50 mcg/hr and PA > 10 patches/month
Duragesic (fentanyl 75, 100 mcg/hr transdermal system)	All quantities
Duramorph (morphine, injection)	> 120 mg/day
hydrocodone/acetaminophen	> 80 mg/day
levorphanol tablet	> 4 mg/day
Methadose (methadone oral)	All quantities for new starts; > 30 mg/day high-dose PA restriction regardless of stability
morphine immediate-release	> 120 mg/day
MS Contin # (morphine controlled-release tablet)	> 120 mg/day
oxycodone/acetaminophen	> 80 mg/day
oxycodone/aspirin	> 4 grams of aspirin/day
Percocet # (oxycodone/acetaminophen)	> 80 mg/day
Roxicodone # (oxycodone immediate-release)	> 80 mg/day
Vicoprofen # (hydrocodone 7.5 mg/ibuprofen)	> 80 mg/day

This designates a brand-name drug with FDA “A”-rated generic equivalents. Prior authorization is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

References

1. Chou R, Ballantyne J, Fanciullo G, Fine P, Miaskowski C. Research Gaps on Use of Opioids for Chronic Noncancer Pain: Findings From a Review of the Evidence for an American Pain Society and American Academy of Pain Medicine Clinical Practice Guideline. *The Journal of Pain*. 2009;10(2):147-159.
2. Manchikanti L, Abdi S, Atluri S, Balog CC, Benyamin RM, Boswell MV, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2 – guidance. *Pain Physician*. 2012;15:S67-S116.
3. Washington State Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain. 2010 [cited 2014 Jan 28]. Available from: www.agencymeddirectors.wa.gov.

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
Alzheimer's agents	Change in PA status; does not require PA within QL	Based on the availability of new FDA "A"-rated generics for Namenda solution, Namenda tablets, and Exelon patches, MassHealth has determined that generic memantine solution for quantities ≤ 360 mL/month, generic memantine tablets for quantities ≤ 60 tablets/month, and generic rivastigmine patches for quantities ≤ 30 patches/month, respectively, will not require a PA.
Nonsteroidal anti-inflammatory drugs	Change in PA status; requires PA Diflunisal Fenoprofen 600 mg Salsalate	Given the significant increase in the cost of generic diflunisal, fenoprofen 600 mg, and salsalate, these agents will require PA due to the availability of less costly alternatives, including naproxen, diclofenac sodium, flurbiprofen, indomethacin, ketoprofen, ketorolac, and ibuprofen.
Aripiprazole solution	Change in PA status; does not require PA within QL or within age restriction	Based on the availability of new FDA "A"-rated generic for Abilify solution, MassHealth has determined that generic aripiprazole solution for members > 6 years or ≤ 18 years of age or for quantities ≤ 750 mL/month will not require a PA.
Aspirin/extended-release dipyridamole	Change in PA status; does not require PA	Based on the availability of new FDA "A"-rated generic for Aggrenox, MassHealth has determined that generic aspirin/extended-release dipyridamole will not require a PA.
Budesonide inhalation suspension	Change in PA status; does not require PA	Based on the availability of new FDA "A"-rated generic for Pulmicort, MassHealth has determined that generic budesonide inhalation suspension will not require a PA.
Buprenorphine injection (Buprenex)	Change in PA status; requires PA	Given the significant cost difference between buprenorphine tablets and buprenorphine injection, MassHealth has determined that buprenorphine injection Buprenex will require a PA.
Opioid agonist/antagonist	Change in PA status; does not require PA within QL Buprenorphine/naloxone film (Suboxone)	Given the significant cost difference between Suboxone film and generic buprenorphine/naloxone tablets, MassHealth has determined that buprenorphine/naloxone film (Suboxone) ≤ 16 mg/day, > 16 mg/day and ≤ 24 mg/day for ≤ 180 days, (> 24 mg/day and ≤ 32 mg/day for ≤ 90 days, and ≤ 32 mg/day will not require a PA.
	Change in PA status; requires PA Buprenorphine/naloxone tablet (Subutex)	Given the significant cost difference between the usual dose of Suboxone film and generic buprenorphine/naloxone tablets, MassHealth has determined that generic buprenorphine/naloxone tablets will require a PA. Buprenorphine/naloxone film (Suboxone) ≤ 16 mg/day, > 16 mg/day and ≤ 24 mg/day for ≤ 180 days, (> 24 mg/day and ≤ 32 mg/day for ≤ 90 days, and ≤ 32 mg/day will not require a PA.
Clindamycin foam (Evoclin)	Change in PA status; requires PA	Given the significant cost difference between Evoclin and other less costly alternatives, MassHealth has determined that Evoclin will require a PA.
Filgrastim (Neupogen)	Change in PA status; does not require PA	Based on the significant cost difference between Neupogen and the other granulocyte colony stimulating factor agents, and that Neupogen is the reference product within the class, MassHealth has determined that Neupogen will not require a PA.
Glatiramer	Change in PA status; does not require PA	Based on the availability of new FDA "A"-rated generic for Copaxone, MassHealth has determined that generic glatiramer will not require a PA.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
Montelukast	Change in PA status; does not require PA	Based on the availability of new FDA “A”-rated generic for Singulair, and given the significant reduction in cost for generic montelukast tablets, MassHealth has determined that generic montelukast tablets will be available without a PA.
Pimozide	Change in PA status; does not require PA within age restriction	Based on the availability of new FDA “A”-rated generic for Orap, MassHealth has determined that generic pimozide for members > 6 years will not require a PA.
Pyrimethamine (Daraprim)	Change in PA status; requires PA	Given a recent increase in the cost of Daraprim tablets, MassHealth has determined that this agent will require a PA.
Rizatriptan orally disintegrating tablet (Maxalt MLT)#	Change in PA status; does not require PA within QL	Given the similar efficacy between triptans and the significant cost difference between rizatriptan orally disintegrating tablets versus the other agents, MassHealth has determined that generic rizatriptan orally disintegrating tablets will be available without a PA for up to 18 units per month.