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**Subject: Updated opioid high dose limits**

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**Key points:**

- **Opioid misuse and abuse is a major public health concern in Massachusetts and across the United States.**
- **After careful review of recent medical literature, MassHealth intends to update its opioid high dose limits.**
- **Further adjustments to opioid high dose limits may be implemented in the future.**

Dear Prescriber,

Over the past several decades, and especially more recently, opioid misuse and abuse has become a major public health concern in the United States. In 2010, deaths in the United States related to opioid overdose accounted for almost 60% of overdose deaths where a drug was specified, up from 30% in 1999.<sup>1</sup> In Massachusetts, opioid-related fatal overdoses have exceeded motor vehicle-related injury deaths in every year since 2005.<sup>2</sup>

MassHealth currently requires prior authorization (PA) to exceed certain dose limits for most opioid formulations. The dose limits were developed based on analysis of opioid utilization within the MassHealth population, and have been augmented by other PA requirements under conditions specified in the MassHealth Drug List, such as for certain duplicate long-acting and duplicate short-acting opioid therapies.

As part of the continuous monitoring of drug utilization within the MassHealth population, and in light of opioid misuse concerns, the MassHealth Pharmacy Program has conducted an analysis of updated opioid utilization, as well as recent published medical literature. Although there is no one single definition of “high dose” opioid therapy, 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.<sup>3-5</sup>

Given this information, **MassHealth intends to implement lower dose limits for opioids beginning in March 2014.** PA will be required for doses exceeding these limits, which are available for your reference in **Table 1** on the following page. Please note that most long-acting opioids are also subject to quantity limits, which are also included in Table 1. While every effort has been made to approximate equivalent doses for these agents based on morphine equivalents, some exceptions have been made based on maximum daily doses and dosing frequencies listed in prescribing information as well as operational considerations (e.g., available tablet strengths).

<sup>1</sup> Department of Health and Human Services. Addressing prescription drug abuse in the United States. 2013 [cited 2013 Oct 17]. Available from: <http://www.asam.org/docs/default-source/advocacy/addressing-prescription-drug-abuse-in-the-united-states>.

<sup>2</sup> Massachusetts Department of Public Health Bureau of Substance Abuse Services. Opioid overdose prevention strategies in Massachusetts. 2012 [cited 2013 Oct 17]. Available from: <http://www.mass.gov/eohhs/docs/dph/substance-abuse/opioid-overdose-prevention-strategies.pdf>.

<sup>3</sup> Chou R, Ballantyne JC, Fanciullo GJ, Fine PG, 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. *J Pain*. 2009;10(2):147-59.

<sup>4</sup> 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.

<sup>5</sup> Washington State Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain. 2010 [cited 2013 Oct 17]. Available from: [www.agencymeddirectors.wa.gov](http://www.agencymeddirectors.wa.gov).

**Table 1. Updated opioid high dose and quantity limits effective March 2014**

Long-acting				Short-acting		
Drug	Dose Limits		Quantity Limit	Drug	Dose Limits	
	Current Dose Limit	New Dose Limit			Current Dose Limit	New Dose Limit
Avinza <sup>®</sup> (morphine extended-release)*	> 360 mg/day	> 240 mg/day	> 1 capsule/day	Codeine <sup>‡</sup>	> 360 mg/day	Unchanged
Dolophine <sup>®</sup> , Methadose <sup>®</sup> (methadone) <sup>† ‡</sup>	> 120 mg/day	> 60 mg/day	N/A	Demerol <sup>®</sup> (meperidine)* <sup>‡</sup>	> 750 mg/day	Removed**
Duragesic <sup>®</sup> (transdermal fentanyl)* <sup>‡</sup>	> 200 µg/hr	> 75 µg/hr	> 10 patches/month	Dilaudid <sup>®</sup> (hydromorphone) <sup>† ‡</sup>	> 60 mg/day	> 64 mg/day <sup>§</sup>
Exalgo <sup>®</sup> (hydromorphone extended-release)*	> 60 mg/day	> 64 mg/day <sup>§</sup>	> 4 tablets/day	Morphine immediate-release <sup>† ‡</sup>	> 360 mg/day	> 240 mg/day
Kadian <sup>®</sup> (morphine extended-release)* <sup>‡</sup>	> 360 mg/day	> 240 mg/day	> 1 capsule/day	Opana <sup>®</sup> (oxymorphone immediate-release)* <sup>† ‡</sup>	> 120 mg/day	> 80 mg/day
Levo-Dromoran <sup>®</sup> (levorphanol) <sup>‡</sup>	> 32 mg/day	> 8 mg/day	> 4 tablets/day	Oxycodone immediate-release <sup>‡</sup>	> 240 mg/day	> 160 mg/day
MS Contin <sup>®</sup> , Oramorph SR <sup>®</sup> (morphine controlled-release) <sup>‡</sup>	> 360 mg/day	> 240 mg/day	N/A			
Opana <sup>®</sup> ER (oxymorphone extended-release)* <sup>‡</sup>	> 120 mg/day	> 80 mg/day	> 2 tablets/day			
OxyContin <sup>®</sup> (oxycodone controlled-release)*	> 240 mg/day	> 160 mg/day	> 3 tablets/day			

\*Both brand and generic (if available) require PA, even within dose and quantity limits; PA criteria available at [www.mass.gov/masshealth/pharmacy](http://www.mass.gov/masshealth/pharmacy)

†Dose limits apply to both oral and injectable formulation

‡Available generically

§Increased limit due to available tablet strengths

\*\*PA required for all doses

In evaluating PA requests for doses above these new limits, MassHealth will continue to use the same criteria that are currently in place for evaluating high dose opioid requests. If applicable, such requests must first meet PA criteria unique to the requested drug. Requests exceeding quantity limits must include supporting documentation indicating that the requested dose cannot be obtained within the established quantity limits.

The MassHealth Drug List, including Therapeutic Class Table 8 outlining the coverage status and PA criteria for all opioids, will be updated to reflect these changes. The MassHealth Drug List can be found on the MassHealth Pharmacy website at [www.mass.gov/masshealth/pharmacy](http://www.mass.gov/masshealth/pharmacy).

The issue of opioid misuse is truly a multidisciplinary one that requires the efforts of patients, health care providers, and other stakeholders to address. We will continue to evaluate this class of medication and may implement further adjustments to our opioid high dose limits in the future, if it is clinically appropriate to do so. We appreciate your continued support and dedication to providing high quality care to MassHealth members.

Sincerely,



Paul L. Jeffrey, PharmD  
 Director of Pharmacy  
 MassHealth