BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Opioids

Policy Number: 9.210
Version Number: 2.0
Version Effective Date: 6/01/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth – MCO ☒ MassHealth – ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Arymo ER (morphine extended-release [abuse deterrent])**
- **Embeda (morphine-naltrexone)**
- **fentanyl buccal lozenge**
- **hydromorphone extended release (Exalgo)**
- **Hysingla ER (hydrocodone ER crush resistant)**
- **methadone**
- **Morphabond ER (morphine extended release [abuse deterrent])**
- **morphine sulfate ER 24HR capsule (Kadian or Avinza)**
- **Nucynta (tapentadol IR)**
- **Nucynta ER (tapentadol ER)**
- **Opana ER (oxymorphone ER [abuse deterrent])**
- **Oxaydo (oxycodone immediate release [abuse deterrent])**

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

- **Oxycontin (oxycodone extended release)**
- **oxymorphone ER**
- **oxymorphone IR**
- **Xtampza ER (oxycodone extended release [abuse deterrent])**
- **Zohydro ER (hydrocodone ER [abuse deterrent])**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Methadone for the use of opioid dependence
Required Medical Information	**For all immediate release opioids**: 1. The member has a diagnosis of moderate to severe pain AND 2. An inadequate response to at least a 2-week trial of, intolerance or contraindication to immediate-release versions of morphine and oxycodone at the maximum tolerated dose **For Oxycontin® (oxycodone extended release):** The member has a diagnosis of moderate to severe pain AND 1. Inability to use morphine ER tablet (Ms Contin®) due to one of the following reasons: a. An allergic reaction b. Inadequate pain control or dose limiting side-effects with use of up to 90mg equivalent of morphine per day. **For all other extended release opioids:** 1. The member has a diagnosis of moderate to severe pain AND 2. Inability to use morphine ER tablet (Ms Contin®) and Oxycontin® [PA required] due to one of the following reasons: a. An allergic reaction b. Inadequate pain control or dose limiting side-effects with use of up to 90mg equivalent of morphine per day **Methadone:** 1. The member has a diagnosis of moderate to severe pain requiring continuous therapy with an opioid analgesic AND 2. The member is not opioid-naïve AND 3. The member meets one of the following: a). Has had an inadequate response to at least a 2-week trial of, intolerance or contraindication to morphine ER and Oxycontin ER at the maximum tolerated dose OR

b). The provider submits clinical rationale for the use of oral methadone over these preferred long-acting opioid analgesics AND

4. Attestation by provider that that a baseline ECG was done and shows a normal QTc interval AND

5. The Member signed a pain management agreement/contract. AND

6. Prescriber has reviewed the state on line controlled drug data base within the last 4 weeks.

For requests for duplicative therapy:

1. A diagnosis of sickle cell disease pain, cancer pain or member is in hospice care; **OR.**
2. All of the following :

    a. A diagnosis of non-cancer chronic pain; **OR**

    b. Persistent pain despite use of low dose opioids, non-opioids drugs, non-drug therapies and management of underlying medical conditions; ***AND***

    c. Prescriber is switching from one short acting opioid to another short acting opioid or from one long acting opioid to another long acting opioid due to lack of response (duplicate therapy rejection only); **AND**

    d. Prescriber has reviewed the state on line controlled drug data base within the last 4 weeks.

<u>Dosing above quantity limits and daily dose exceeding 90MME/day:</u>
The plan may authorize coverage of opioid medications where a single dosage form or FDA labeled daily dose exceeds 90 MME/day or exceeds specific quantity limits when the following criteria are met:

1. A diagnosis of sickle cell disease pain, cancer pain or member is in hospice care; **OR**

2. All of the following:

    a. A diagnosis of non-cancer chronic pain; AND

    b. Persistent pain despite use of preferred low dose opioids, non-opioids drugs, non-drug therapies and management of underlying medical conditions; AND

    c. Member has had adequate trial or failure of opioid at a lower MME dose; **AND**

    d. Member is an appropriate candidate for chronic opioid therapy **AND**

    e. If prior authorization is required for the medication all criteria has been met. **AND**

    f. Medication is prescribed by, or in collaboration/consultation with a pain

	specialist, addiction medicine specialist, hematologist or oncologist and member has signed a pain agreement; **AND** g. Prescriber will continue to monitor for signs of severe respiratory depression, as well as misuse, abuse and addiction during therapy **AND** h. Prescriber has reviewed the state's on line controlled drug data base within the last 4 weeks. **AND** i. Prescriber has prescribed and/or dispensed naloxone to the Member within the last year. **AND** j. The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.
Age Restriction	Age appropriate dosing per package insert/FDA approved dosing.
Prescriber Restriction	Prescribed by OR in collaboration/consultation with pain specialist, addiction medicine specialist, or oncologist for dosing over 90MME/day only.
Coverage Duration	Duplicative therapy approvals – Maximum of 3 months. All other approvals maximum of 1 year.
Quantity Limit	
Other criteria	None

Clinical Background Information and References

1. Arymo ER (morphine sulfate) [prescribing information]. Wayne, PA; Egalet US Inc; January 2017
2. Berland D, Rodgers P. Rationale use of opioids for management of chronic nonterminal pain. Am Fam Physician 2012 Aug 1;86(3):252-8.
3. Codeine and Tramadol Can cause Breathing Problems for Children. U.S. Food and Drug Administration, April 20th, 2017. https://www.fda.gov/forconsumers/consumerupdates/ucm315497.htm
4. Dworkin RH, O'Connor AB, Backonja M, Farrar JT, Finnerup NB, Jensen TS, Kalso E, Loeser JD, Miaskowski C, Nurmikko TJ, Portenoy RK, Rice AS, Stacey BR, Treede RD, Turk DC, Wallace MS. Pharmacologic Management of Neuropathic Pain: evidence-based recommendations. Pain 2007 Dec 5;132(3):237-51.
5. FDA Safety Information on Extended Release – Long Acting Opioid Analgesics. Available: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm396503.htm. Accessed: August 7, 2014.
6. Morphabond ER™ (morphine sulfate) [prescribing information]. Basking Ridge, NJ. December 2016.
7. Product Information. Embeda®, morphine sulfate and naltrexone hydrochloride) Extended-Release Capsules for oral use. King Pharmaceuticals, Bristol, TN 37620.
8. Product Information. Exalgo, hydromorphone HCL extended-release oral tablets. Mallinckrodt, Inc. 2010

9. Product Information. Nucynta™, tapentadol immediate –release oral tablets. Ortho-McNeill-Janssen Pharmaceuticals, Inc. 2008.
10. Product Information. Opana® ER, oxymorphone hydrochloride extended-release tablets. Endo Pharmaceuticals, Chadds Fors, Pennsylvania 19317. June 2007.
11. Product Information. Opana®, oxymorphone hydrochloride tablets. Endo Pharmaceuticals, Chadds Ford, Pennsylvania 19317. June 2007.
12. Product Information. Oxycontin®, oxycodone HCL controlled-release oral tablets. Purdue Pharma L.P. 2009.
13. Product Information. Hysingla® ER, hydrocodone bitartrate extended release, crush resistant. Purdue Pharma L.P., Stamford, CT. November 2014
14. Product Information. Xartemis XR™, oxycodone and acetaminophen extended-release tablet. Mallinckrodt Brand Pharmaceuticals, Inc. Hazelwood, MO. March, 2014
15. Product Information. Zohydro ER™, hydrocodone bitartrate extended-release capsule. Zogenix, Inc. San Diego, CA. October, 2013.
16. Taylor, DR. The pharmacology of fentanyl and its impact on the management of pain. Medscape Neurology and Neurosurgery. 2005;7(2). Posted 12/13/2005.
17. Use of Opioids for the treatment of chronic pain. A statement from the American Academy of Pain Medicine. Available at http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf. Accessed July 13, 2015.
18. Xtampza ™ER (oxycodone-extended release) [prescribing information]. Cincinnati, OH. November 2016
19. CDC Guidelines for Prescribing Opioids for Chronic Pain. http:// cdc.gov/drugoverdose/ prescribing/guidelines.html. August 2020.
20. CDC Guidelines for Opioid Overdose and overdose prevention. https:// www.cdc.gov/drugoverdose/ pdf/calculating_total_daily_dose-a.pdf. October 2020

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	P&T Annual Review. Retired Opioid	1/1/2021	P&T Committee

Policy Revisions History			
	Policy 9.107 and created separate policy for each line of business. Addition of diagnosis to all drugs including additional criteria requirements for methadone requiring member be opioid tolerant, Changed MME requirement from 100 to 90mg due to MA state regulations. Addition of criteria for dosing over 90 MME/day, and addition of monitoring criteria. Addition of sickle cell disease pain to acceptable diagnoses for dosing over MME.		
02/11/2021	P & T annual review. No criteria changes. Minor language changes to clarify prescriber restrictions.	6/01/2021	P&T Committee

Next Review Date

February 2022

Other Applicable Policies

9.080 Non Preferred Policy
9.015 Quantity Limitation Policy

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as

the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.