

Pharmacy Policy

Opioids

Policy Number: 9.210

Revision Number: R2

Version Effective Date: 1/1/2021

Product Applicability	<input type="checkbox"/> All Plan ⁺ Products
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input checked="" type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

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

Prior Authorization Policy

Products Affected:

- **Arymo ER[®] (morphine sulfate ER)**
- **Duragesic[®] (fentanyl patch)**
- **Embeda (morphine sulfate and naltrexone)**
- **Exalgo[®] (hydromorphone ER)**
- **Hysingla ER[®] (hydrocodone ER)**
- **Kadian[®] (morphine ER)**
- **Levorphanol tab**
- **Methadone tab**
- **MS Contin[®] (morphine sulfate ER)**
- **Morphabond ER[™] (morphine sulfate ER)**
- **Nucynta (tapentadol IR)**
- **Nucynta ER (tapentadol ER)**
- **oxymorphone IR**
- **Oxycontin[®] (oxycodone ER)**
- **Xtampza ER[®] (oxycodone ER)**
- **Zohydro ER[®] (hydrocodone ER)**

⁺ 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.

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	<p>Immediate release opioids:</p> <ol style="list-style-type: none"> 1. 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. <p>Methadone:</p> <ol style="list-style-type: none"> 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 provider submits clinical rationale for the use of oral methadone. 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's on line controlled drug data base within the last 4 weeks. <p>Arymo ER[®], Duragesic[®], Exalgo[®], Hysingla ER[®], Kadian[®], MS Contin[®], Morphabond ER[™], Oxycontin[®], Xtampza ER[®], Zohydro XR</p> <ol style="list-style-type: none"> 1. Diagnosis of moderate to severe pain that requires continuous around the clock pain management. AND: 2. Trial and failure of 2 preferred products on the NH PDL (see Appendix A) AND 3. For Duragesic the member is opioid tolerant. <p>Embeda</p> <ol style="list-style-type: none"> 1. Diagnosis of severe pain requiring around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. <p>Nucynta IR/ER</p> <ol style="list-style-type: none"> 1. Diagnosis of one of the following: <ol style="list-style-type: none"> a). Neuropathic pain associated with diabetic peripheral neuropathy (DPN) severe enough to require daily, around-the-clock, long-term opioid treatment OR b). Severe pain that requires daily, around-the-clock, long-term opioid treatment

* 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.

AND

2. Trial of one of the following preferred products:
 - a). tramadol (generic for Ultram®) **OR**
 - b). tramadol/acetaminophen (generic for Ultracet®) **OR**
 - c). tramadol ER (generic for Ryzolt ER®, Ultram ER®)

For requests for duplicative therapy:

1. A diagnosis of cancer pain or member is in hospice care; **OR**
2. One 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**
3. All the following:
 - a. 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**
 - b. Prescriber has reviewed the state's on line controlled drug data base within the last 4 weeks (where available)

Dosing above quantity limits and daily dose exceeding 100MME/day:

The plan may authorize coverage of opioid medications including **select long-acting opioids** (Appendix B), where a single dosage form or FDA labeled daily dose exceeds 100 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**
4. 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**

* 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.

	<p>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</p> <p>g. Prescriber will continue to monitor for signs of severe respiratory depression, as well as misuse, abuse and addiction during therapy AND</p> <p>h. Prescriber has reviewed the state's on line controlled drug data base within the last 4 weeks. AND</p> <p>i. Prescriber has prescribed and/or dispensed naloxone to the Member within the last year. AND</p> <p>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.</p>
Age Restriction	Age appropriate dosing per package insert and FDA approved dosing.
Prescriber Restriction	Pain specialist, addiction medicine specialist, or oncologist for dosing over 100 MME/day
Coverage Duration	Duplicative Therapy Requests for chronic non-cancer pain: 3 months All other requests: 12 months
Other criteria	None

Appendix A:

Preferred Long Acting Opioid Products:	
Embeda®	morphine sulfate SA (generic MS Contin®)
fentanyl patch (generic for Duragesic®)	oramorph SA (generic for MS Contin®)
hydromorphone ER (generic for Exalgo®)	oxycodone SA
morphine ER capsule (generic for Avinza®, Kadian®)	oxymorphone ER (generic for Opana ER®)

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. 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.
4. FDA Safety Information on Extended Release – Long Acting Opioid Analgesics. Available: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm396503.htm>. Accessed: August 7, 2014.

* 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.

5. Morphabond ER™ (morphine sulfate) [prescribing information]. Basking Ridge, NJ. December 2016.
6. Product Information. Embeda®, morphine sulfate and naltrexone hydrochloride) Extended-Release Capsules for oral use. King Pharmaceuticals, Bristol, TN 37620.
7. Product Information. Exalgo®, hydromorphone HCL extended-release oral tablets. Mallinckrodt, Inc. 2010
8. Product Information. Nucynta™, tapentadol immediate –release oral tablets. Ortho-McNeill-Janssen Pharmaceuticals, Inc. 2008.
9. Product Information. Opana® ER, oxymorphone hydrochloride extended-release tablets. Endo Pharmaceuticals, Chadds Fors, Pennsylvania 19317. June 2007.
10. Product Information. Opana®, oxymorphone hydrochloride tablets. Endo Pharmaceuticals, Chadds Ford, Pennsylvania 19317. June 2007.
11. Product Information. Oxycontin®, oxycodone HCL controlled-release oral tablets. Purdue Pharma L.P. 2009.
12. Product Information. Hysingla® ER, hydrocodone bitartrate extended release, crush resistant. Purdue Pharma L.P., Stamford, CT. November 2014
13. Product Information. Zohydro ER™, hydrocodone bitartrate extended-release capsule. Zogenix, Inc. San Diego, CA. October, 2013.
14. 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.
15. 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.
16. Xtampza™ER (oxycodone-extended release) [prescribing information]. Cincinnati, OH. November 2016
17. Agency Medical Director’s Group (AMDG). Opioid dose calculator
<http://agencymeddirectors.wa.gov/opioiddosing.asp>
18. New Hampshire Medical Society. Examples of opioid informed consent & agreement Practice Resources.
<http://www.nhms.org/content/examples-opioid-informed-consent-agreement>

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

Policy Revisions History

* 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.

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	9.107 Opioid Policy retired, new policy created. Added Prescriber attestation of naloxone prescribing for Members exceeding MED limits.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

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.

* 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.