

Pharmacy Policy

Opioids

Policy Number: 9.210

Version Number: 2.0

Version Effective Date: 6/01/2021

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

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

Prior Authorization Policy

Products Affected:

- fentanyl 12.5mcg, 25mcg, 50mcg, 75mcg, 100mcg transdermal patch
- hydromorphone HCl 8mg, 12mg, 16mg 32 mg ER 24 Hr Tablet
- Hysingla ER (hydrocodone 100mg, 120mg ER Tablet)
- levorphanol 2mg Tablet
- methadone tablet
- methadone concentrate 10mg/mL
- methdose tab soluble 40mg
- morphine sulfate 60mg, 100mg, 200mg ER tablet
- Nucynta 100mg, 150mg, 200mg, 250mg ER tablet
- Oxycontin 10mg, 20mg, 30mg, 40mg, 60mg, 80mg ER tablet
- oxymorphone 30mg, 40mg ER tablet

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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><u>Fentanyl transdermal patch</u></p> <ol style="list-style-type: none"> 1.The member has a documented diagnosis of pain severe enough requiring continuous around the clock therapy with an opioid analgesic AND 2.The member is not opioid-naïve AND 3. The patient can safely take the requested dose based on their current opioid use history. <p><u>Methadone and Methadose:</u></p> <ol style="list-style-type: none"> 1.The member has a documented 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: <ol style="list-style-type: none"> a). An inadequate response to at least a 2-week trial of, intolerance or contraindication to morphine ER and oxycodone 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. <p>The plan may authorize coverage opioids, where a single dosage form or FDA labeled daily dose exceeds 90 MME/day and requests over specific quantity limits when all the following criteria are met:</p> <ol style="list-style-type: none"> 1. A diagnosis of sickle cell disease pain, cancer pain or member is in hospice care; OR 2. All of the following: <ol style="list-style-type: none"> 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 a trial or failure of the opioid at a lower MME dose; AND

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	<ul style="list-style-type: none"> 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 and 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	Maximum of 1 year.

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Coverage for select long-acting opioids where a single dosage form or FDA approved daily dose exceeds 90 MME will require prior authorization, and be limited as follows:

Appendix A - Limitations: MME dosing Equivalents

Drug	Limitation	Morphine dose equivalent
Fentanyl Transdermal Patch 12.5mcg, 25mcg, 50mcg, 75mcg 100 mcg/hr	50mcg/day	2.4 (mcg/hr)
Hydromorphone ER 32 mg tablet (generic Exalgo)	1 tab/day	4
Hysingla ER 100 and 120 mg (hydrocodone ER tablet)	1 tab/day	1
Methadone (conversion factor increases at higher doses)		
1-20mg/day; 5mg tab	4 tabs/day	4
1-20mg/day; 10 mg tab	2 tabs/day	4
21-40 mg/day		8
41-60 mg/day		10
≥ 61-80mg/day		12
Morphine sulfate ER tablets 60, 100, 200 mg (generic MS Contin)	3 tablets/day	1
Nucynta (tapentadol) ER	2 tabs/day	0.4
OxyContin ER 12HR Tab 40, 60,80mg	2 tabs/day	1.5
Oxymorphone ER 30 , 40mg	2 tabs/day	3

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.

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9. Product Information. Lazanda[®], fentanyl nasal spray. Archimedes Pharma US Inc. Bedminster, NJ. 2011
10. Product Information. Nucynta[™], tapentadol immediate –release oral tablets. Ortho-McNeill-Janssen Pharmaceuticals, Inc. 2008.
11. Product Information. Opana[®] ER, oxymorphone hydrochloride extended-release tablets. Endo Pharmaceuticals, Chadds Fors, Pennsylvania 19317. June 2007.
12. Product Information. Opana[®], oxymorphone hydrochloride tablets. Endo Pharmaceuticals, Chadds Ford, Pennsylvania 19317. June 2007.
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14. Product Information. Hysingla[®] ER, hydrocodone bitartrate extended release, crush resistant. Purdue Pharma L.P., Stamford, CT. November 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](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](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

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Policy Revisions History

9/10/2020	9.107 Opioid Policy retired, new policy created. P&T Annual Review. Removed from policy Arymo ER fentanyl buccal lozenge, Hydromorphone extended release (Exalgo), Morphabond, morphine sulfate ER 24HR capsule (Kadian or Avinza), Opana ER, Oxaydo, Xtampa ER and Zohydro per 2021 QHP formulary. Addition of sickle cell disease pain to acceptable diagnoses for dosing over MME. Additional criteria for dosing over 90mme/day, addition of fentanyl patch and methadone criteria, and addition of required monitoring criteria.	1/1/2021	P&T Committee
1/4/2021	Added Nucynta 250mg ER to policy	1/4/2021	P&T Committee
2/11/2021	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

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,

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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.

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