



Effective Date: 07.15 Last Review Date: 07.21 Line of Business: Medicaid



Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

FDA Approved Indication(s)

Methadone is a potent synthetic opiate agonist of the phenylheptylamine class and is structurally unrelated to morphine. Methadone is the most frequently used agent in medically supervised opiate withdrawal and maintenance programs. Methadone is an effective analgesic but is considered a second-line agent in the treatment of severe, chronic pain. Methadone is useful in patients who have developed tolerance to other opiate agonists or have developed intractable side effects due to opiate therapy. Equianalgesic dosing of chronic methadone and other opiate agonists is unclear. Benefits of methadone in the treatment of chronic pain include lack of active metabolites, high bioavailability following oral administration, and low cost.

All edits are based on FDA labeling as published by the manufacturer

Brand

Multiple Medication classes are included in this edit

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Methadone is **medically necessary** for members meeting the following criteria:

Initial Approval Criteria:

methadone oral tablet, dispersible tablet, or oral solution

A. Indication of methadone is for the treatment of long term chronic pain requiring long

term therapy (must meet all);

- 1. Diagnosis of moderate to severe chronic pain;
- 2. Failure of at least TWO non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, anticonvulsants, antidepressants, etc.) at maximum tolerated doses, unless contraindicated;

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- 3. Member must have trialed and failed monotherapy with an immediate release agent;
- 4. Member has tried and failed all preferred long acting opioids

AND

- B. Total daily dose \leq 60mg;
 - OR
- C. Total daily dose > 60mg; and
- D. Member not opiate naïve; and
- E. Member tried methadone with total daily dose \leq 60mg with suboptimal pain relieving effect and therefore this is a dose increase; or
- F. Member has intractable side effects or tolerance to pain relieving effects of other opiate medication and equinanalgesic conversion from other opiate suggests starting dose of methadone > 60mg (Appendix A).

Approval duration: 6 months

Continued Approval (must meet all criteria as applicable):

- A. Indication for methadone continues to be pain management
- B. Member not experiencing severe adverse reactions to methadone

Approval duration: 6 months

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Appendix A: Equinalgesic Conversion Chart²

Opioid agonist	Oral/rectal mg	IV/SC mg	IV to	These are NOT suggested starting doses; these are doses of opioids that produce approximately the same amount of analgesia.		
Morphine	30	10	3	Titration to clinical response is necessary. Recommended doses do not apply to patients with renal or hepatic insufficiency. Elderly patients generally require lower doses, titrated slowly to the desired effect or intolerable side effects. CONVERTING TO/FROM FENTANYL PATCH 1mcg/hr fentanyl transdermal ≈ 2mg total oral morphine/day 25mcgr/fentanyl transdermal ≈ 9 tabs per day of: Oxycodone 5mgAPAP 325mg, Hydrocodone5mg/APAP500 ,Codeine 30mg/APAP		
Oxycodone	20	N/A				
Hydromorphone	7.5	1.5	5			
Codeine	200	120 (IM)				
Hydrocodone	30	N/A	N/A			
Oxymorphone	10	1		(Percocet TM) (Lortab \vec{s}^{TM}) (Tylenol # \vec{s}^{TM})		
Fentanyl ¹	N/A	100mcgr single dose		PREVENTING CROSS TOLERANCE When converting from one opioid to another decrease the equianalgesic dose		
Methadone 2	1-20	1-10	1.5	by 25-50% to allow for incomplete cross-tolerance between different opioids. (may need to titrate rapidly to an analgesic dose within the first 24 hrs).		
Codeine	200	130	1.5	(may need to duate rapidly to all allalgesic dose within the first 24 ms).		
Equianalgesic dos	Δ '	ianalgesic dose		OPIOIDS NOT RECOMMENDED FOR USE Meperidine SHOULD NOT BE USED in older adults or patients with renal failure because of CNS toxic metabolites. Contraindicated with MAOIs. Mixed agonist/ antagonist (pentazocine, butorphanol, nalbuphine): compete		
(route) current opioid(route) Desired opioid		with agonists leading to withdrawal. analgesic ceiling effect. high risk of psychotomimetic adverse effects		
24hr dose(route) 2		thr dose (route) esired opioid		Propoxyphene: no better than placebo, toxic metabolite at high doses. OPIOIDS SPECIAL PRECAUTIONS		
Equianalgesic Dose Conversion Formula				Methadone: Variable pharmacodynamic and pharmacokinetic effects complicate the use of methadone for analgesia. Symptoms of overdose may be delayed 3-7 days after starting or increasing Methadone. Escalate methadone q4-7 days		

References:

- 1. Methadone monograph. Clinical Pharmacology. Accessed June 2015. http://www.clinicalpharmacology-ip.com/Forms/drugoptions.aspx?cpnum=380&n=Methadone&t=0 Accessed 6/09/2015.
- 2. University of Texas Geriatric Equianalgesic Conversion Table.

 http://geriatrics.uthscsa.edu/tools/PAIN%20CARD%20SanchezReilly%20&%20Ross%2020
 08.pdf

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy	7/15	7/15
Reformatted policy to be consistent with pharmacy medical necessity format	10/15	10/15
Added Appendix A, Equinanalgesic Table		
Added detail to long term chronic therapy for initial therapy criteria	9/16	9/16
Added that methadone has step therapy through all other preferred long acting opioids.	7/2017	7/2017
Annual Review – No updates needed	7/2018	7/2018
Annual Review – No updates needed	7/2019	7/17/2019
Annual Review – No updates needed		07/2020
Annual Review – No updates needed		07/2021

Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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