

QUANTITY LIMIT CRITERIA

BRAND NAME
(generic)

METHADOSE 10 MG/ML**
(methadone oral concentrate)

METHADOSE 40 MG DISPERSIBLE TABLET**
(methadone dispersible tablets)

Status: CVS Caremark Criteria
Type: Quantity Limit

***Please note that these methadone products are indicated for detoxification/opioid addiction ONLY. Methadone products indicated for BOTH detoxification/opioid addiction AND pain are targeted on the Opioids ER criteria.*

POLICY

FDA-APPROVED INDICATIONS

Methadose Concentrate

- For detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- For maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Methadose Dispersible

Methadone hydrochloride tablets for oral suspension contain methadone, an opioid agonist indicated for the:

- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction

Code of Federal Regulations, Title 42, Sec 8: Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment.

Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment:

During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction [pursuant to 21 CFR 1306.07(c)], to facilitate the treatment of the primary admitting diagnosis). During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility [pursuant to 21 CFR 1306.07(b)].

Methadone (Oral Concentrate, Dispersible Tablets) Limit Policy 11-2017

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LIMIT CRITERIA

These limits accumulate together across all drugs and strengths up to the highest quantity listed depending on the order that the claims are processed.

Drug	1 Month Limit*	3 Month Limit*
Methadose 10 mg/mL (methadone oral concentrate)	30 mL/25 days**	30 mL/75 days**
Methadose 40 mg (methadone dispersible tablet)	9 tablets/25 days**	9 tablets/75 days**

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

*** The 1 month, 3 month, retail, and mail limits will be the same.*

REFERENCES

1. Methadose Concentrate [package insert]. Hazelwood, MO: Mallinckrodt Inc.; February 2017.
2. Methadose Dispersible [package insert]. Hazelwood, MO: Mallinckrodt Inc.; April 2017.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2017.
4. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2017.
5. Medication-Assisted Treatment for Substance Use Disorders. *Follow Directions: How to Use Methadone Safely*. Division of Pharmacologic Therapies Website. <http://store.samhsa.gov/shin/content/SMA09-4409/SMA09-4409.pdf>. Accessed October 2017.
6. DEA Methadone Fact Sheet. http://www.justice.gov/dea/druginfo/drug_data_sheets/Methadone.pdf. Accessed October 2017.