

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
OFFICE OF DRUG CONTROL POLICY**

TREATMENT POLICY - 05

Subject: Enrollment Criteria For Methadone Maintenance And Detoxification Program

Issued: September 1, 2003, revised August 2005, revised October 3, 2007

Effective: September 1, 2003, revision effective October 1, 2005, revision effective January 1, 2008

PURPOSE:

The purpose of this policy is to clarify the process for the use of methadone as a medication for the treatment of opioid dependence.

SCOPE:

This policy applies to the Substance Abuse Coordinating Agencies (CAs) and their provider network. Medicaid specific services are so identified in the document.

BACKGROUND:

Methadone Services as an Approved Pharmacological Support

Methadone is a medication with three major effects: prevention of withdrawal symptoms, prevention of opioid cravings, and blocking the euphoric effects of opioid drugs.

Methadone is designed to address these physiological problems as an adjunct to counseling and/or other substance abuse treatment.

The Michigan Medicaid medical necessity requirement shall be used for all funded clients to determine medical necessity for methadone as an adjunct to substance abuse treatment. The Medicaid-covered methadone services that apply equally to all other funded clients are the provision and administration of methadone, nursing services, physician encounters, physical examinations lab tests (including toxicology screening) and physician ordered TB skin tests.

The American Society of Addiction Medicine (ASAM) Level of Care (LOC) indicated for clients receiving methadone is usually outpatient. Outpatient services should be conducted by the opioid treatment program (OTP) that is providing the methadone. When the ASAM LOC is not outpatient or when a specialized service, such as a women's specific program, is needed, separate service locations for OTP methadone dosing and other substance abuse treatment are acceptable.

In cases, such as in rural areas, where the logistics of travel make it optimal for the client to receive counseling services and toxicology screens at a local outpatient program, this may be done as long as the OTP dispensing the methadone and the other provider coordinate the client's care. If methadone is to be dispensed offsite of the OTP, off-site dosing must be in compliance with the current Michigan Department of Community Health, Office of Drug Control Policy (MDCH/ODCP) Treatment Policy #4: *Off-Site Dosing Requirements for Medication-Assisted Treatment*.

Clarification of Substance Dependence Treatment with Methadone in Clients with Prior or Existing Pain Issues

All persons assessed for substance abuse/dependence treatment must be assessed using the ASAM patient placement criteria and the current Diagnostic and Statistical Manual (DSM). In the case of opioid addiction, pseudo-addiction should also be ruled out. Tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. The "Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain" should be consulted to assist in determining when substance abuse treatment is appropriate.

OTPs are substance dependence treatment programs; they are not pain clinics nor should OTPs treat pain. In some cases, primary care and other doctors may misunderstand the scope of the OTP and refer clients to the OTP for pain control. Methadone use solely for pain control, and not for treatment of addiction to opioid drugs, is managed by the client's primary care physician (PCP) or Managed Care Organization. This does not preclude the treatment by an OTP of a client who needs substance abuse treatment for opioid dependency and who is also a pain patient.

Clients receiving methadone for the treatment of opioid addiction may need pain medication in conjunction with their addiction treatment. Opioid analgesics as prescribed for pain by the clients' PCP can be used; they are not a reason to detox the client to a drug-free state. The methadone used in treating the opioid addiction does not replace the need for the pain medication. On-going coordination between the OTP physician and the prescribing practitioner is required.

REQUIREMENTS:

Administrative Rules of Substance Abuse Programs in Michigan

Methadone Treatment and Other Chemotherapies, Rule 325.14401-325.14423

Certification of Opioid Treatment Programs

42 CFR Part 8.12

Michigan Medicaid Provider Manual

An OTP using methadone for the treatment of opioid dependency must be:

- 1) Licensed by the state as a methadone provider.
- 2) Accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Accreditation (COA) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- 3) Certified by the Substance Abuse and Mental Health Services Administration as an OTP.
- 4) Licensed by the Drug Enforcement Administration (DEA).

Compliance with state administrative rules and federal regulations is required as well. These requirements are not listed in this document and are not replaced or reduced by these enrollment criteria.

PROCEDURE:

Enrollment Criteria

Decisions to enroll a client for methadone maintenance must be medically necessary as defined by a LOC determination using all six dimensions of the ASAM Patient Placement Criteria; and have an initial diagnostic impression of opioid dependency of one-year duration based on the current Diagnostic and Statistical Manual (DSM) criteria.

A client under 18 years of age is required to have had at least two documented unsuccessful attempts at short-term detoxification and/or drug-free treatment within a 12-month period to be eligible for maintenance treatment with the exception of a pregnant woman for which detox is not recommended. No client under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the State Methadone Authority consents in writing to such treatment. See 42CFR Subpart 8.12 (e) (2).

Consistent with the LOC determination, clients requesting methadone must be provided with all appropriate options for substance abuse/dependence treatment such as OTP with various providers and non-OTP options such as methadone-free outpatient, intensive outpatient or residential.

Admission procedures require a physical examination. This examination must include a medical assessment to confirm the current DSM diagnostic impression of opioid dependency of at least one year that was secured during the screening process. The physician also has the option to determine that the client would be best served by initially attempting substance abuse/dependence treatment without methadone. The physician may refer the client for

further medical assessment as indicated.

Clients must be informed that all of the following are required:

- 1) Daily attendance at the clinic is necessary for dosing (with the possible exception of Sundays and holidays),
- 2) compliance with the individualized treatment plan, and
- 3) toxicology testing.

It is the responsibility of the OTP, as part of the informed consent process, to ensure that clients are aware of the benefits and hazards of methadone treatment.

OTPs must request that clients provide a complete list of all prescribed medications. Legally prescribed drugs including controlled substances must not be considered as illicit substances provided the OTP has documentation the drug(s) was prescribed for the client. At a minimum, there must be a copy of the prescription label or receipt and it must be included in the client's chart.

The importance of disclosing the names, for the purposes of coordination of care, of all prescribing physicians, treating physicians, dentists, and any other health care provider over the past year must be explained to the client by OTP personnel. OTPs must also make a good faith effort to obtain the necessary releases. If a client is unwilling to provide this information, the OTP must include a statement to this effect, signed by the client, in the client's file. OTPs must advise clients to include methadone when providing a list of medications to their healthcare providers. Any lack of coordination between the OTP physician and the prescribing practitioners must be taken into consideration when determining the client's eligibility for off-site dosing as well as continuing to receive methadone services.

Treatment and Continued Enrollment

Client needs and rate of progress vary from person to person and, as such, treatment must be individualized and treatment plans based on the needs and goals of the client.

Maintenance treatment shall be discontinued within two years after such treatment has begun, unless, based on the recorded clinical judgment of the staff physician, justification is provided to continue maintenance beyond the 2-year limitation.

Compliance with dosing requirements or attendance at counseling sessions alone is not sufficient to continue enrollment. Reviews to determine continued eligibility for OTP counseling and methadone dosing services must occur at least every four months.

Treatment plans must be individualized, reflect all dimensions of the ASAM Patient Placement Criteria and be developed with the full and active participation of the client. All substances of abuse, including alcohol, must be included in the treatment plan. Treatment plans and notes are expected to reflect the clinical status of the client, such as compliance contracts initiated, extra sessions or specialized groups provided, and off-site dosing privileges rescinded or reduced. If the client's treatment plan identifies a need for counseling services and includes the provision of these services, then signed and dated progress reports by the counselor must be included in the clinical record. The funding authority may, at its discretion, require its approval of initial and/or continuing treatment plans.

Required Procedures for Pregnant Women

Pregnant women requesting or seeking treatment are considered urgent requests and must be screened and referred within 24 hours. Pregnant clients who have a documented history of opioid addiction, regardless of age or length of opioid dependency, may be admitted to an OTP provided the pregnancy is certified by the OTP physician; and he/she finds treatment to be justified. For pregnant clients, evidence of current physiological dependence is not necessary. Pregnant opioid dependent clients must be referred for prenatal care and other services and supports, as may be necessary.

OTPs must obtain informed consent from pregnant women, or any women admitted to methadone treatment that may become pregnant, stating that they will not knowingly put themselves and their fetus in jeopardy by voluntarily leaving the OTP against medical advice. For a client under 18 years of age, a parent, legal guardian, or responsible adult designated by the State Methadone Authority must consent in writing. A copy of the signed informed consent statement must be placed in the client's clinical record. This signed consent is in addition to the general consent that is signed by all clients receiving methadone and filed in their clinical records.

Because methadone and opiate withdrawal are not recommended during pregnancy due to increased risk to the fetus, the OTP shall not discharge pregnant women without making documented attempts to facilitate referral for continued treatment with another provider. Documented attempts through referral and follow-up must also be made to assure or maintain prenatal care.

Discharge/Termination Criteria

For clients who are struggling to meet the objectives in his/her individual treatment plans, OTP medical and clinical staff must review, with the client, the course of treatment and make adjustments. Examples of such adjustments are changing the methadone dosage, increasing the length or number of counseling sessions, incorporating specialized cocaine or anxiety specific group sessions, use of compliance contracts, and referring the client for screening for another LOC.

Clients must be discharged from methadone services when treatment is completed. In addition, clients may be terminated from services if there is clinical and/or behavioral noncompliance.

As part of the termination process, reduction of the dosage to a medication-free state (tapering) should be expedited within safe and appropriate detoxification medical standards whenever possible.

The OTP must make a referral for the determination of the need for another LOC assessment or for placing the client at another OTP and must follow up on these referrals. The OTP must follow the procedures of the funding authority in making these referrals.

The following are reasons for discharge/termination:

- 1) Completion of treatment. The decision to discharge a client must be made by the OTP's physician with input from clinical staff. Completion of treatment is determined when the client has fully or substantially achieved the goals listed in his/her individualized treatment plan and when the client no longer needs methadone as a medication. The methadone treatment discharge date is defined as the date the client completes detoxification.
- 2) Clinical noncompliance. A client's failure to comply with the individualized treatment plan, despite attempts to address such noncompliance, may result in an administrative discharge for clinical noncompliance. Justification for a clinical noncompliance discharge must be documented in the case file. Reasons for such discharge may include but are not limited to the following:
 - Treatment goals have not been met within two years of commencement of treatment. A client may continue in treatment if all of the following criteria are met: 1) applicable ASAM criteria are met, 2) the client provides evidence of willingness to participate in treatment, 3) there is evidence of progress, 4) there is documentation of medical necessity and 5) continuation of services is recommended by the OTP physician.
 - Repeated or continued use of one or more other drugs and/or alcohol that is prohibited in the client's treatment plan. It may be necessary for the OTP to refer these clients to the local access management system for evaluation for alternate services. OTPs must perform toxicology tests for methadone metabolites, cannabinoids and benzodiazepines in addition to those substances required by *Administrative Rules of Substance Abuse Services Programs in Michigan*, R 325.14406. Clients whose toxicology results do not indicate the presence of methadone metabolites must be considered noncompliant, with the same actions taken as if illicit drugs (including non-prescribed drugs) were detected. Weekly toxicology

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screening is required for all noncompliant clients. OTPs must test for alcohol use if 1) prohibited under their individualized treatment plan; or 2) if the client appears to be using alcohol to a degree that would make dosing unsafe.

- Failure to attend scheduled individual and/or group counseling sessions, or other clinical activities such as psychiatric or psychological appointments.
 - Other noncompliance with the treatment plan—such as repeated failure to follow through on other treatment plan related referrals.
 - Failure to manage medical concerns/conditions, including adherence to physician treatment services and prescription medications, that may interfere with the effectiveness of methadone treatment and/or the continued use of methadone, and may present a physical risk to the client.
 - Failure to submit to toxicology sampling as requested.
- 3) Behavioral noncompliance. The OTP must work with the client to explore and implement methods to facilitate behavioral compliance. When such actions do not result in compliance, the OTP may implement an administrative discharge for behavioral noncompliance.

The commission of acts by the client that jeopardize the safety and well-being of staff and/or other clients, or negatively impact the therapeutic environment, is not acceptable and can result in immediate discharge. Such acts include, but are not limited to, the following:

- Possession of a weapon on OTP property.
- Assaultive behavior against staff and/or other clients.
- Threats (verbal or physical) against staff and/or other clients.
- Diversion of controlled substances, including methadone.
- Diversion and/or adulteration of toxicology samples.
- Possession of a controlled substance with intent to use and/or sell on agency property.
- Sexual harassment of staff and/or other clients.
- Loitering on the clinic property or within a one-block radius of the clinic.

Any action to terminate treatment requires that the Medicaid client receive a notice of "action."

REFERENCES:

American Society of Addiction Medicine (for Buprenorphine information).
<http://www.asam.org>

Certification of Opioid Treatment Programs: United States Code of Federal Regulations, Title 42, Part 8, Washington, D.C. (s003) <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl>

Guidelines for the Accreditation of Opioid Treatment Programs: Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, Substance Abuse and Mental Health Services Administration. Revised July 20, 2007.
<http://www.dpt.samhsa.gov/pdf/OTPAccredGuidelines-2007.pdf>

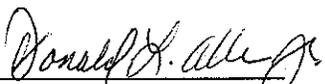
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http://www.michigan.gov/documents/mdch_MI_guidelines_91795_7.pdf

Part 4: *Methadone Treatment and Other Chemotherapy:* Michigan Administrative Code, Rules 325.14401-325.14423, State Office of Administrative Hearings and Rules. Lansing, Michigan. (September 10, 1971).
http://www.michigan.gov/documents/cis_bhs_fhs_sa_part4_37163.pdf

Treatment Policy #4: Off-Site Dosing Requirements for Medication Assisted Treatment. Michigan Department of Community Health, Office of Drug Control Policy, 2006.
http://www.michigan.gov/documents/Treatment_Policy_04_Off-Site-Dosing_1473687.pdf

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