

TREATMENT POLICY #05

SUBJECT: Criteria for Using Methadone for Medication-Assisted Treatment and Recovery

ISSUED: September 1, 2003, revised August 5, 2005, October 3, 2007, July 31, 2011, October 1, 2011, and August 24, 2012

EFFECTIVE: October 1, 2012

PURPOSE:

The purpose of this policy is to clarify the process for the use of methadone in medication-assisted treatment and recovery for opioid dependence.

SCOPE:

This policy applies to all regional substance abuse PIHPs and their provider network of opioid treatment programs (OTPs). Medicaid-specific services are also identified in this document. The state administrative rules and federal regulations are not replaced or reduced by these criteria.

BACKGROUND:Methadone Use in Medication-Assisted Treatment and Recovery

Methadone is an opioid medication used in the treatment and recovery of opioid dependence to prevent withdrawal symptoms and opioid cravings, while blocking the euphoric effects of opioid drugs. In doing so, methadone stabilizes the individual so that other components of the treatment and recovery experience, such as counseling and case management, are maximized in order to enable the individual to reacquire life skills and recovery. Methadone is not a medication for the treatment and recovery from non-opioid drugs.

The Medicaid Provider Manual lists the medical necessity requirements that shall be used to determine the need for methadone as an adjunct treatment and recovery service. The Medicaid-covered substance use disorder benefit for methadone services includes the provision and administration of methadone, nursing services, physician encounters, physical examinations, lab tests (including initial blood work, toxicology screening, and pregnancy tests) and physician-ordered tuberculosis (TB) skin tests. The medical necessity requirements and services also apply to all non-Medicaid covered individuals.

Consistent with good public health efforts among high-risk populations, and after consultation with the local health department, an OTP may offer Hepatitis A and B, as well as other adult immunizations recommended

by the health department, or they should refer the individual to an appropriate health care provider. Smoking cessation classes or referrals to local community resources may also be made available.

The American Society of Addiction Medicine (ASAM) level of care (LOC) indicated for individuals receiving methadone is usually outpatient. The severity of the opioid dependency and the medical need for methadone should not be diminished because medication-assisted treatment has been classified as outpatient. Counseling services should be conducted by the OTP that is providing the methadone whenever possible and appropriate. When the ASAM LOC is not outpatient or when a specialized service is needed, separate service locations for methadone dosing and other substance use disorder services are acceptable, as long as coordinated care is present and documented in the individual's record.

If methadone is to be self-administered off-site of the OTP, off-site dosing must be in compliance with the current Michigan Department of Health & Human Services (MDHHS) *Treatment Policy #4: Off-Site Dosing Requirements for Medication-Assisted Treatment*. This includes Sunday and holiday doses for those individuals not deemed to be responsible for managing take-home doses.

All six dimensions of the ASAM patient placement criteria must be addressed:

1. Acute intoxication and/or withdrawal potential.
2. Biomedical conditions and complications.
3. Emotional/behavioral conditions and complications (e.g., psychiatric conditions, psychological or emotional/behavioral complications of known or unknown origin, poor impulse control, changes in mental status, or transient neuropsychiatric complications).
4. Treatment acceptance/resistance.
5. Relapse/continued use potential.
6. Recovery/living environment.

In using these dimensions, the strengths and supports, or recovery capital, of the individual will be a major factor in assisting with the design of the individualized treatment and recovery plan.

In many situations, case management or care coordination services may be needed by individuals to further support the recovery process. These services can link the individual to other recovery supports within the community such as medical care, mental health services, educational or vocational assistance, housing, food, parenting, legal assistance, and self-help groups. Documentation of such referrals and follow up must be in the treatment plan(s) and progress notes within the individual's chart. If it is determined that case management or care coordination is not appropriate for the individual, the rationale must be documented in the individual's chart. The acupuncture detoxification five-point protocol is suggested as a means of assisting the individual with symptom management of anxiety and restorative sleep.

Clarification of Substance-Dependence Treatment and Recovery with Methadone in Individuals with Prior or Existing Pain Issues

All persons assessed for a substance use disorder must be assessed using the ASAM patient placement criteria and the current Diagnostic and Statistical Manual of Mental Disorders (DSM). In the case of opioid addiction, pseudo-addiction must also be ruled out. Tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. In some cases, primary care and other doctors may misunderstand the scope of the OTP and refer individuals to the OTP for pain control. The "Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain," should be consulted to assist in determining when substance use disorder treatment is appropriate, as well as the publication, *Responsible Opioid Prescribing: A Michigan Physician's Guide* by Scott M. Fishman, MD. This publication was distributed to all controlled substance prescribers in Michigan by the Michigan Department of Health &

Human Services, Bureau of Health Professions, in September of 2009. OTPs are not pain clinics, and cannot address the underlying medical condition causing the pain. The OTP and CA are encouraged to work with the local medical community to minimize inappropriate referrals to OTPs for pain.

Individuals receiving methadone as treatment for an opioid addiction may need pain medication in conjunction with this adjunct therapy. The use of non-opioid analgesics and other non-medication therapy is recommended whenever possible. Opioid analgesics as prescribed for pain by the individual's primary care physician (or dentist, podiatrist) can be used; they are not a reason to initiate detoxification to a drug-free state, nor does their use make the individual ineligible for using methadone for the treatment of opioid addiction. The methadone used in treating opioid addiction does not replace the need for pain medication. It is recommended that individuals inform their prescribing practitioners that they are on methadone, as well as any other medications. On-going coordination (or documentation of efforts if prescribing practitioners do not respond) between the OTP physician and the prescribing practitioner is required for continued services at the OTP and for any off-site dosing including Sunday and holidays.

REQUIREMENTS:

These codes, regulations, and manuals must be followed:

- *Methadone Treatment and Other Chemotherapy*, Michigan Administrative Code, Rule 325.14401-325.14423
- *Certification of Opioid Treatment Programs*, U.S. Code of Federal Regulations, 42 CFR Part 8
- *Michigan Medicaid Provider Manual*

An OTP using methadone for the treatment and recovery 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 (TJC), formerly JCAHO.
3. Certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) as an OTP.
4. Registered by the Drug Enforcement Administration (DEA).

PROCEDURE:Admission Criteria

Decisions to admit an individual for methadone maintenance must be based on medical necessity criteria, satisfy the LOC determination using the six dimensions of the ASAM Patient Placement Criteria, and have an initial diagnostic impression of opioid dependency for at least one year based on current DSM criteria. It is important to note that each individual, as a whole, must be considered when determining LOC, as methadone maintenance therapy may not be the best answer for every individual. For exceptions, see “Special Circumstances for Pregnant Women and Adolescents” on page six (6). Consistent with the LOC determination, individuals requesting methadone must be presented with all appropriate options for substance use disorder treatment, such as:

- Medical Detoxification.
- Sub-acute Detoxification.
- Residential Care.
- Buprenorphine/Naloxone.
- Non-Medication-Assisted Outpatient.

In addition to these levels of care, each CA is expected to have providers available that can also offer case management services, treatment for co-occurring disorders, early intervention, and peer recovery and recovery support services. Acupuncture detoxification may be used in all levels of care. These additional service options can be provided to opioid dependent individuals who do not meet the criteria for adjunct methadone treatment. Individuals should be encouraged to participate in treatment early in their addiction before methadone is necessary.

Admission procedures require a physical examination. This examination must include a medical assessment to confirm the current DSM diagnosis of opioid dependency of at least one year, as was identified during the screening process. The physician may refer the individual for further medical assessment as indicated.

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

1. Daily attendance at the clinic is necessary for dosing, including Sundays and holidays if criteria for take home medication are not met.
2. Compliance with the individualized treatment and recovery plan, which includes referrals and follow-up as needed.
3. Monthly random toxicology testing.
4. Coordination of care with all prescribing practitioners (physicians, dentists, and any other health care provider) over the past year.

It is the responsibility of the OTP, as part of the informed consent process, to ensure that individuals are aware of the benefits and hazards of methadone treatment. It is also the OTP’s responsibility to obtain consent to contact other OTPs within 200 miles to monitor for enrollments in other programs (42 CFR §2.34).

OTPs must request that individuals provide a complete list of all prescribed medications. Legally prescribed medication, including controlled substances, must not be considered as illicit substances when the OTP has documentation that it was prescribed for the individual. Copies of the prescription label, pharmacy receipt, pharmacy print out, or a Michigan Automated Prescription System (MAPS) report must be included in the individual’s chart or kept in a “prescribed medication log” that must be easily accessible for review.

Michigan law allows for individuals with the appropriate physician approval and documentation to use medical marijuana. Although there are no prescribers of medical marijuana in Michigan, individuals are authorized by a physician to use marijuana per Michigan law. For enrolled individuals, there must be a copy of the MDHHS registration card for medical marijuana issued in the individual's name in the chart or the "prescribed medication log." Following these steps will help to ensure that an individual who is using medical marijuana per Michigan law will not be discriminated against in regards to program admission and exceptions for dosing.

If an individual is unwilling to provide prescription or medical marijuana information, the OTP must include a statement to this effect, signed by the individual, in the chart. These individuals will not be eligible for off-site dosing, including Sunday and holiday doses. OTPs must advise individuals to include methadone when providing a list of medications to their healthcare providers. The OTP physician may elect not to admit the individual for methadone treatment if the coordination of care with health care providers and/or prescribing physicians is not agreed to by the client.

Off-site dosing, including Sundays and holidays, is not allowed without coordination of care (or documentation of efforts made by the OTP for coordination) by the OTP physician, the prescriber of the identified controlled substance (opioids, benzodiazepines, muscle relaxants), and the physician who approved the use of medical marijuana. This coordination must be documented in either the nurse's or the doctor's notes. The documentation must be individualized, identifying the individual, the diagnosis, and the length of time the individual is expected to be on the medication. A MAPS report must be completed at admission. A MAPS report should be completed before off-site doses, including Sundays and holidays, are allowed and must be completed when coordination of care with other physicians could not be accomplished.

If respiratory depressants are prescribed for any medical condition, including a dental or podiatry condition, the prescribing practitioners should be encouraged to prescribe a medication which is the least likely to cause danger to the individual when used with methadone. Individuals who have coordinated care with prescribing practitioners, and are receiving medical care or mental health services, will be allowed dosing off site, if all other criteria are met. If the OTP is closed for dosing on Sundays or holidays, arrangements shall be made to dose the individual at another OTP if the individual is not deemed responsible for off-site dosing.

Special Circumstance for Pregnant Women and Adolescents

Pregnant women

Pregnant women requesting treatment are considered a priority for admission and must be screened and referred for services within 24 hours. Pregnant individuals 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 treatment is found to be justified. For pregnant individuals, evidence of current physiological dependence is not necessary. Pregnant opioid dependent individuals must be referred for prenatal care and other pregnancy-related services and supports, as necessary.

OTPs must obtain informed consent from pregnant women and all women admitted to methadone treatment that may become pregnant, stating that they will not knowingly put themselves and their fetus in jeopardy by leaving the OTP against medical advice. Because methadone and opiate withdrawal are not recommended during pregnancy, due to the increased risk to the fetus, the OTP shall not discharge pregnant women without making documented attempts to facilitate a referral for continued treatment with another provider.

Pregnant adolescents

For an individual under 18 years-of-age, a parent, legal guardian, or responsible adult designated by the relevant state authority, must provide consent for treatment in writing (Attachment A). In Michigan, the "relevant state authority" to provide consent is children's protective services (CPS) through the Department of Human Services [Public Act 238 722.621]. A copy of this signed, informed consent statement must be placed in the individual's medical record. This signed consent is in addition to the general consent that is signed by all individuals receiving methadone, and must be filed in the medical record.

Non-Pregnant adolescents

An individual 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. No individual under 18 years-of-age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority/CPS consents, in writing, to such treatment (Attachment A). This is sufficient consent to allow for persons 16 and 17 years-of-age to enter methadone treatment [*Administrative Rules for Substance Abuse Services, Rule 325.14409(5)*]. However, persons 15 years-of-age and under must also have permission for admission by the state opioid treatment authority (SOTA), as well as the Drug Enforcement Administration (DEA). A copy of this signed informed consent statement must be placed in the individual's medical record. This signed consent is in addition to the general consent that is signed by all individuals receiving methadone, and must be filed in their medical record [42CFR Subpart 8.12 (e) (2)].

Treatment and Continued Recovery Using Methadone

Individual needs and rate of progress vary from person-to-person and, as such, treatment and recovery must be individualized and treatment and recovery plans must be based on the needs and goals of the individual (*Treatment Policy #06: Individualized Treatment Planning*). Referrals for medical care, mental health issues, vocational and educational needs, spiritual guidance, and housing are required, as needed, based on the information gathered as part of the assessment and other documentation completed by the individual. The use of case managers, care coordinators, and recovery coaches is recommended for individuals whenever possible (*Treatment Policy #8: Substance Abuse Case Management Requirements*). Increasing the individual's recovery capital through these supports, will assist the recovery process and help the individual to become stable and more productive within the community.

Compliance with dosing requirements or attendance at counseling sessions alone is not sufficient to continue enrollment. Reviews to determine continued eligibility for methadone dosing and counseling services must occur at least every four months by the OTP physician during the first two years of service. An assessment of the ability to pay for services and a determination for Medicaid coverage must be conducted at that time, as well. If it is determined by the OTP physician that the individual requires methadone treatment beyond the first two years, the justification of the medical necessity for methadone only needs to occur annually. However, financial review and eligibility for Medicaid is required to continue at a minimum of every six months.

An individual may continue with services if all of the following criteria are present:

- a. Applicable ASAM criteria are met.
- b. The individual provides evidence of willingness to participate in treatment.
- c. There is evidence of progress.
- d. There is documentation of medical necessity.
- e. The need for continuation of services is documented in writing by the OTP physician.

Individuals, who continue to have a medical need for methadone, as documented in their medical record by the OTP physician, are not considered discharged from services; nor are individuals who have been tapered from methadone, but still need counseling services.

All substances of abuse, including alcohol, must be addressed in the treatment and recovery plan. Treatment and recovery plans and progress notes are expected to reflect the clinical status of the individual along with progress, or lack of progress in treatment. In addition, items such as the initiation of compliance contracts, extra counseling sessions, or specialized groups provided, and off-site dosing privileges that have been initiated, rescinded, or reduced should also be reflected in progress notes. Referrals and follow-up to those referrals must be documented. The funding authority may, at its discretion, require its approval of initial and/or continuing treatment and recovery plans.

For individuals who are struggling to meet the objectives in his/her individual treatment and recovery plans, OTP medical and clinical staff must review, with the individual, the course of treatment and recovery and make adjustments to the services being provided. Examples of such adjustments may be changing the methadone dosage (including split dosing), increasing the length or number of counseling sessions,

incorporating specialized group sessions, using compliance contracts, initiating case management services, providing adjunctive acupuncture treatment, and referring the individual for screening to another LOC.

Medical Maintenance Phase of Treatment

As individuals progress through recovery, there may be a time when the maximum therapeutic benefit of counseling has been achieved. At this point, it may be appropriate for the individual to enter the medical maintenance (methadone only) phase of treatment and recovery if it has been determined that ongoing use of the medication is medically necessary and appropriate for the individual. To assist the OTP in making this decision, *TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs* offers the following criteria to consider when making the decision to move to medical maintenance:

- Two years of continuous treatment.
- Abstinence from illicit drugs and from abuse of prescription drugs for the period indicated by federal and state regulations (at least two years for a full 30-day maintenance dosage).
- No alcohol use problem.
- Stable living conditions in an environment free of substance use.
- Stable and legal source of income.
- Involvement in productive activities (e.g., employment, school, volunteer work).
- No criminal or legal involvement for at least three years and no current parole or probation status.
- Adequate social support system and absence of significant un-stabilized co-occurring disorders.

Discontinuation of Services

Individuals must discontinue treatment with methadone when treatment is completed with respect to both the medical necessity for the medication and for counseling services. In addition, individuals may be terminated from services if there is clinical and/or behavioral non-compliance. If an individual is terminated, the OTP must attempt to make a referral for another LOC assessment or for placing the individual at another OTP, and must make an effort to ensure that the individual follows through with the referral. These efforts must be documented in the medical record. The OTP must follow the procedures of the funding authority in coordinating these referrals.

Any action to terminate treatment of a Medicaid recipient requires a notice of action be given to the individual. The individual has a right to appeal this decision; services must continue and dosage levels maintained while the appeal is in process.

The following are reasons for discontinuation/termination:

1. Completion of Treatment – The decision to discharge an individual must be made by the OTP's physician with input from clinical staff and the individual. Completion of treatment is determined when the individual has fully or substantially achieved the goals listed in his/her individualized treatment and recovery plan and when the individual no longer needs methadone as a medication. As part of this process, a reduction of the dosage to a medication-free state (tapering) should be implemented within safe and appropriate medical standards.

2. Administrative Discontinuation – The OTP must work with the individual to explore and implement methods to facilitate compliance. Administrative discontinuation relates to non-compliance with treatment and recovery recommendations, and/or engaging in activities or behaviors that impact the safety of the OTP environment or other individuals who are receiving treatment.

The repeated or continued use of illicit opioids and non-opioid drugs, including alcohol, would be considered non-compliance. OTPs must perform toxicology tests for methadone metabolites, opioids, cannabinoids, benzodiazepines, cocaine, amphetamines, and barbiturates (*Administrative Rules of Substance Abuse Services Programs in Michigan*, R 325.14406). Individuals 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 medication) were detected.

OTPs must test for alcohol use if: 1) prohibited under their individualized treatment and recovery plan; or 2) the individual appears to be using alcohol to a degree that would make dosing unsafe. The following actions are also considered to be non-compliant:

- Repeated failure¹ to submit to toxicology sampling as requested.
- Repeated failure¹ to attend scheduled individual and/or group counseling sessions, or other clinical activities such as psychiatric or psychological appointments.
- Failure to manage medical concerns/conditions, including adherence to physician treatment and recovery services and prescription medications that may interfere with the effectiveness of methadone and may present a physical risk to the individual.
- Repeated failure¹ to follow through on other treatment and recovery plan related referrals.

¹ *Repeated failure should be considered on an individual basis and only after the OTP has taken steps to assist individuals to comply with activities.*

The commission of acts by the individual that jeopardize the safety and well-being of staff and/or other individuals, 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 individuals.
- Threats (verbal or physical) against staff and/or other individuals.
- 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 or within a one block radius of the clinic.
- Sexual harassment of staff and/or other individuals.
- Loitering on the clinic property or within a one-block radius of the clinic.

Administrative discontinuation of services can be carried out by two methods:

1. Immediate Termination – This involves the discontinuation of services at the time of one of the above safety-related incidents or at the time an incident is brought to the attention of the OTP.
2. Enhanced Tapering Discontinuation – This involves an accelerated decrease of the methadone dose (usually by 10 mg or 10% a day). The manner in which methadone is discontinued is at the discretion of the OTP physician to ensure the safety and well-being of the individual.

It may be necessary for the OTP to refer individuals who are being administratively discharged to the local access management system for evaluation for another level of care. Justification for noncompliance termination must be documented in the individual's chart.

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Deborah J. Hollis, Director

APPROVED BY: Bureau of Substance Abuse and Addiction Services

An electronic version of the *Consent for an Adolescent to Participate in Opioid Pharmacotherapy Treatment* form (Attachment A) can be found on our website at www.michigan.gov/mdhhs-orosc, choose 'Treatment' and then 'OROSC Policy and Technical Advisory Manual'.

TREATMENT POLICY #05

October 1, 2012

ATTACHMENT A

Consent for an Adolescent to Participate in Opioid Pharmacotherapy Treatment

Name of Patient _____ Date _____

Date of Birth (MM/DD/YY) _____ Patient's Age _____ Pregnant: Yes ___ No ___

Name of Parent or Legal Guardian _____

Name of Practitioner Explaining Procedures _____

Name of Program Medical Director _____

An individual under 18 years of age, who is not pregnant, 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.

No individual 16 or 17 years-of-age may be admitted to maintenance treatment unless a parent or legal guardian consents, in writing, to such treatment. For persons 15 years-of-age and under, a parent or legal guardian consent is required, as well as permission for admission by the state opioid treatment authority (SOTA). A copy of the program's signed informed consent statement must be placed in the individual's clinical chart. This signed consent is in addition to the general consent that is signed by all individuals receiving methadone and shall be filed in their clinical charts.

The parent or legal guardian must sign a release of information for the Opioid Treatment Program (OTP) staff to verify the individual's admission and discharge dates and any other specific information requested by the OTP.

**Verification of Detoxification/Drug-Free Treatment Attempts
(DOES NOT APPLY TO PREGNANT ADOLESCENTS)**

Facility/Counselor Name _____
Street Address _____
City, State, Zip _____
Phone Number _____
Fax Number _____
Dates of Service: From (MM/DD/YY) _____
To (MM/DD/YY) _____
Verified by:

OTP Staff Person Name _____
Title _____ *OTP*
Staff Signature _____
Date _____

Facility/Counselor Name _____
Street Address _____
City, State, Zip _____
Phone Number _____
Fax Number _____
Dates of Service: From (MM/DD/YY) _____
To (MM/DD/YY) _____
Verified by:

OTP Staff Person Name _____
Title _____ *OTP*
Staff Signature _____
Date _____

Consent for an Adolescent to Participate in Opioid Pharmacotherapy

Treatment

– Page 2 –

INFORMED CONSENT STATEMENT

FOR PARENT/GUARDIAN

I hereby authorize and give voluntary consent to _____ Medication-Assisted Treatment Program and its medical personnel to dispense and administer opioid pharmacotherapy (includes methadone or buprenorphine) as part of the treatment of my child's addiction to opioid drugs. Treatment procedures have been explained to me, and I understand that this will involve taking the prescribed opioid drug on the schedule determined by the program physician in accordance with federal and state regulations.

I further authorize provision of the following: diagnostic assessment, individual and group counseling, medication review and monitoring. My child's participation is voluntary. I understand that this program follows person-centered planning guidelines and that my child's treatment plan will be individualized to meet my child's needs and goals, and I will participate in the development of my child's treatment plan.

I understand that it is important for me to inform any medical provider, who may treat my child for any medical problem, that my child is enrolled in an opioid treatment program so that the provider is aware of all the medications my child is taking, can provide the best possible care, and can avoid prescribing medications that might affect the opioid pharmacotherapy or the chances of successful recovery from opioid addiction. If pregnant, my child will receive prenatal care and I will sign releases for coordination of care with that provider.

I understand that I may withdraw my child, from this treatment program and discontinue the use of the medications prescribed at any time. Should I choose this option, I understand my child will be offered a medically supervised tapering process for discontinuation. Withdrawal is not recommended when the individual is pregnant.

Parent/Guardian:

Name _____ Signature _____ Date _____

Witness:

Name _____ Signature _____ Date _____

OTP Physician:

Name _____ Signature _____ Date _____

State Opioid Treatment Authority (Required for minors 15 years-of-age and younger.):

Name __ Signature _____ Date ____