Methadone

Procedure Code: S0109
Service Unit: 5mg
Service Limits: 20 unit limit per calendar day

Assessing a Patient for Opioid Treatment Program Initiation

There are a number of important areas on which to concentrate with regard to a patient history for this population of patients:

1. Ensure the patient has a DSM-5 diagnosis of moderate to severe opioid use disorder.
2. Complete a medical history which should include:
   A. Potential risks for methadone toxicity prior to opioid treatment program initiation (benzodiazepine) use, age, etc.,
   B. Patterns of use of all major drug classes (including tobacco, alcohol and caffeine),
   C. Previous addiction treatment history and response,
   D. High risk behavior such as needle sharing and exchanging sex for drugs,
   E. Legal History,
   F. Psychiatric history and current mental status including suicidal ideation,
   G. Social-Economic situation including, employment, housing, supports, child custody, and partner’s drug-use history, and
   H. Details regarding chronic or recurrent pain.

This information should be included when using H0031, 90791 and 90792 for assessment and evaluations. See Chapter 503 Behavioral Health Rehabilitation Services Manual, for more detailed requirements pertaining to these codes.

Induction Phase

The physician should base the initial methadone dose on the patient’s underlying risk for methadone toxicity. Sedating drugs, including over-the-counter medications such as diphenhydramine, prescribed medications such as antipsychotics, sedating antidepressants and therapeutic doses of benzodiazepines, or drugs of abuse, such as medical grade marijuana, can increase the risk of methadone toxicity and lead to an overdose. The physician prescribing methadone should look for benzodiazepine use in the initial drug screen.

Opioid tolerance is difficult to establish by history, so it is safer to initiate methadone therapy at a lower dose. Lowered tolerance is likely in patients who report non-daily opioid use, daily use of codeine, or daily use of oral opioids at moderate doses. Typically, patients who use opioids intranasally have a lower tolerance than patients who inject opioids. Tolerance is lower in patients who have been abstinent for more than a few days, e.g., patients who have been recently discharged from a correctional facility, detox center or treatment center.
**Patient Factors to Determine Initial Dose Parameters**

1. Recent abstinence from opioids - 10 mg or less
2. Higher risk for methadone toxicity - 20 mg or less
3. No risk factors and recent abstinence - 30 mg or less

**Early Stabilization Phase (0-2 weeks)**

Dosage increases during the early stabilization phase should take place only after an in-person opioid treatment program physician assessment and for patients who are experiencing cravings, ongoing opioid use, and/or several opioid withdrawal symptoms. Physicians should assess patients at least once a week during this phase.

During the early stabilization phase, patients should be on the same dose for at least 3 consecutive days with no missed doses before an increase. If two consecutive doses are missed during the early stabilization phase, the physician should cancel the prescription until the patient can be reassessed. The patient must be reassessed in person by the physician and restarted at 30 mg or less.

**Dosing Adjustments During Early and Late Stabilization Phases**

1. Recent abstinence from opioids - 5 mg or less every 5 days or more
2. Higher risk for methadone toxicity - 5-10 mg every 3-5 days
3. No risk factors and recent abstinence - 10-15 mg every 3-5 days

**Late Stabilization Phase (2-6 Weeks)**

Dose increases during the late stabilization phase should be the same as during the early stabilization phase until a dose of 80 mg is reached. Dose increases during the late stabilization phase should take place with an in-person opioid treatment program clinician assessment for patients who are experiencing cravings, ongoing opioid use, and/or signs of multiple opioid withdrawal symptoms. Opioid treatment program clinic staff should assess patients at least once weekly during this phase.

**Maintenance Phase (6+ Weeks)**

The physician can reach the maintenance dose for the majority of their patients within two to eight weeks of initiating methadone. However, all patients must be treated on an individualized basis and some may not reach their optimal dose until up to 12 weeks. The optimal dose range for most opioid treatment program patients is 60-120 mg. During the maintenance phase (when the dose is 80 mg or more), the physician should increase the dose by no more than 5-10 mg every five to seven days. Dose increases during the maintenance phase should take place with an in-person opioid treatment program physician assessment for patients who are experiencing cravings, ongoing opioid use, and/or several opioid withdrawal symptoms. Opioid treatment program clinical staff should assess patients once weekly when ongoing dose adjustments are occurring and less frequently thereafter as required.
Missed Doses During Late Stabilization and/or Maintenance Phase Standards

If three or more consecutive doses are missed during the late stabilization and/or maintenance phases, the physician should cancel the prescription until the patient can be reassessed by the physician. The patient must be reassessed in person by the physician. After three consecutive days missed, the dose should be decreased to 30 mg or 50% of the current dose. After four or more consecutive days missed, the dose should be decreased to 30 mg or less.

Doses Below 60 mg

There is evidence that methadone doses of 60–100 mg are more effective than doses below 60 mg for reducing heroin use and retaining patients in treatment. However, maintenance doses below 60 mg are justified for patients who have no unauthorized opioid use, report no significant withdrawal symptoms or cravings, are at high-risk for methadone toxicity, or are on a tapering protocol.

Doses Above 100 mg

Opioids such as methadone have several side effects that may be dose related, including sedation, overdose leading to death, sleep apnea and sexual dysfunction. High methadone doses are also associated with a prolonged QT interval which can cause Torsades de Pointes, a ventricular arrhythmia.

Assessment, Monitoring, and Management of High Doses

A trial of tapering is indicated for patients who report sedation when on high doses. Clinical experience suggests that tapering by an overall decrease of 20-40 mg is tolerated well, and patients often report that they feel more alert and energetic.

Ongoing Withdrawal Symptoms in Patients on High Doses

Patients with ongoing withdrawal symptoms despite high methadone doses require ongoing assessment by the physician. Possible causes include the rapid metabolism of methadone. The use of medications that increase the metabolism of methadone such as phenytoin, chronic alcohol use, or the ongoing use of cocaine (a methadone inducer) in large doses may result in the patient complaining of the need for a dose increase. Although controversial, peak and trough levels might be useful in patients who continue to report withdrawal symptoms despite doses of 100 mg or higher.

Additional reasons for ongoing withdrawal symptoms may include the increased tolerance caused by ongoing opioid use and then opioid cessation or dose diversion (consuming partial amounts of the take home dose and selling the rest).

“Pseudonormalization” can occur after a methadone dose increase and some patients experience very mild mood elevation. They develop tolerance to this effect after a few weeks, prompting them to seek another dose increase. Insomnia, anxiety, fatigue and other psychiatric symptoms are such a prominent feature of opioid withdrawal that patients may incorrectly attribute these symptoms to withdrawal.
Managing Missed Doses

Missed doses may indicate a variety of problems, including relapse to alcohol or other drug use. Therefore, the physician should reassess the patient’s clinical stability. Dosing personnel should report missed doses to the opiate treatment program physician in a timely fashion. A clinically significant loss of tolerance to opioids may occur within as little as three days without methadone; therefore, the opioid treatment clinician should reduce the methadone dose in patients who have missed three consecutive days. The dose can be rapidly increased once the response to the lower dose is assessed.

<table>
<thead>
<tr>
<th>Treatment Phase</th>
<th>Missed Doses</th>
<th>Action</th>
<th>Dose Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Stabilization</td>
<td>24 hours</td>
<td>No dose increase</td>
<td>Dose Change</td>
</tr>
<tr>
<td>Early Stabilization</td>
<td>48 hours</td>
<td>Reevaluate patient</td>
<td>Start from initial dose</td>
</tr>
<tr>
<td>Late Stabilization/Maintenance</td>
<td>1-2 days</td>
<td>If patient not intoxicated, continue current dose.</td>
<td>No change</td>
</tr>
<tr>
<td>Late Stabilization/Maintenance</td>
<td>3 days</td>
<td>Reassess Patient Urine Drug Screen</td>
<td>Restart at 50% of dose, then increase dose to no more than 10 mg daily for a maximum of 3 days</td>
</tr>
<tr>
<td>Late Stabilization/Maintenance</td>
<td>4 or more days</td>
<td>Reassess Patient Urine Drug Screen</td>
<td>Restart at 30 mg or less and titrate per usual</td>
</tr>
</tbody>
</table>

Therapy and Phases

Medicaid Members receiving the medication methadone must meet the minimum therapy requirements to continue this Medication Assisted Treatment (MAT) Program.

Phase 1: During their first 12 months of MAT, a member is required to have at least four hours of therapy per month from their date of intake. A minimum of three of these therapies must be in a group setting. The fourth therapy can be a choice of individual, group, or family as based up the member’s service plan and assessed need.
Phase 2: A member who has completed 12 months of MAT and shown compliance with urine drug screens and therapy requirements is required to have a minimum of one hour of therapy per calendar month. This therapy may be a group, individual or family session based on the member’s service plan.

The physician who is responsible for the member’s MAT is required to move a member from Phase 2 to Phase 1 if there is non-compliance with therapy or urine drug screens.

Urine drug screen requirements: Phase 1 members are required to have two random urine drug screens per calendar month. Phase 2 member are required to have one random drug screen per month.

These requirements are in addition to any requirements that can be found in the Legislative Rule of 69 CSR 11 as governed by OHFLAC

GLOSSARY

Definitions in Chapter 200, Definitions and Acronyms apply to all West Virginia Medicaid services, including those covered by this chapter. Definitions in this glossary are specific to this chapter.

Clinical Staff -- The individuals employed by or associated with a MAT program who provide treatment, care or rehabilitation to program patients or patients’ families

Coordination of Care: Sharing information between relevant parties to plan, arrange, implement, and monitor provision of services to Medicaid Members.

Freedom of Choice: The guaranteed right of a beneficiary to select a participating provider of their choice.

Office of Health Facility Licensure and Certification (OHFLAC): The office designated by the West Virginia Department of Health and Human Resources to determine whether facilities comply with Federal and State licensure and State certification standards.

Physician: As defined in West Virginia Code Annotated §30-3-10, an individual who has been issued a license to practice medicine in the state of WV by the WV Board of Medicine and is in good standing with the board; or an individual licensed by the WV Board of Osteopathy in accordance with West Virginia Code Annotated 30-14-6.