OPIOID TREATMENT PROGRAM
(MAINTENANCE THERAPY)

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BENEFIT CONSIDERATIONS

Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

COVERAGE RATIONALE

In accordance with federal regulations, national guidelines, and clinical evidence, maintenance therapy in an Opioid Treatment Program is proven and medically necessary when the following criteria are met:

- Member has been diagnosed with an opioid use disorder, according to the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and one of the following is applicable:
  - Member has been dependent on opioids for at least one year; OR
  - Member has been released from a correctional facility within the past 6 months; OR
  - Member has received treatment in an OTP within the past 2 years; OR
  - A physician certifies that the member is pregnant; OR
  - The member is under age 18, has had at least 2 unsuccessful short-term detoxifications or drug-free treatment within the past 12 months, and the member’s parent/guardian consents to OTP.

- The treating provider is qualified under section 303(g) of the Controlled Substances Act to dispense opioid drugs in the treatment of opioid use disorders.

- The OTP has a current, valid certification and accreditation from an accreditation body approved by SAMHSA under Federal Regulation 42 CFR Part 8.

- In accordance with Federal Regulation 42 CFR Part 8, the OTP provides adequate medical, counseling, vocational, educational, and other assessment and treatment services, including adequate substance abuse counseling to each patient as clinically necessary.
  - These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP.
  - The program sponsor must be able to document that these services are fully and reasonably available to patients.
  - OTPs should include professional staff trained to screen for the presence of co-occurring disorders, develop appropriate referrals to services for these disorders, and provide coordination of care (Center for Substance Abuse Treatment 2005).
  - Staff members responsible for establishing linkages with other healthcare organizations and practitioners should be knowledgeable about pharmacotherapy treatment and actively seek...
patient consent to talk with other providers, including the patient’s primary care physician (SAMHSA 2015).

In accordance with federal regulations, national guidelines, and clinical evidence, maintenance therapy in an Opioid Treatment Program is unproven and not medically necessary when the above criteria are not met.

The requested service or procedure must be reviewed against the language in the member’s benefit document. When the requested service or procedure is limited or excluded from the member’s benefit document, or is otherwise defined differently, it is the terms of the member’s benefit document that prevails.

**UTILIZATION MANAGEMENT CRITERIA**

*Prior authorization may be required for Medication Assisted Treatment.*

Before using this section, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

**Opioid Treatment Program Admission Criteria**

- The proven criteria from the **coverage rationale** section of this document are met, unless otherwise mandated by regulation or customer contract.
- Medical complications, if present, can be safely managed. Examples include:
  - The member has no known contraindications to methadone or buprenorphine treatment.
  - The member does not have a co-occurring dependence on high doses of benzodiazepines or other central nervous system depressants, including alcohol.
- The member is not in imminent or current risk of harm to self, others, and/or property.
- The member is willing to participate in a highly structured program with required daily attendance.
- The member is at high risk of relapse without opioid pharmacotherapy, close outpatient monitoring, therapy, and structured support within a programmatic milieu that promotes treatment progress and recovery.

**Evaluation and Treatment Planning:**

- OTPs must require each patient undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP (SAMHSA 2016)
  - The full medical examination, including the results of the serology and other tests, must be documented in the patient’s record within 14 days following admission (SAMHSA 2016).
  - States may have additional requirements, such as laboratory tests, and OTPs must comply with these requirements (SAMHSA 2014).
- It is recommended that the following types of information be collected, documented, or communicated to patients (SAMHSA 2014):
  - Treatment history;
  - Orientation to medication-assisted treatment (MAT);
  - Age of applicant;
  - Recovery environment;
  - Suicide and other emergency risks;
  - Substances of abuse;
  - Prescription drug and over-the-counter medication use;
  - Method and level of opioid use;
  - Pattern of daily preoccupation with opioids;
  - Compulsive behaviors;
  - Patient motivation and reasons for seeking treatment;
  - Patient personal recovery resources;
  - Scheduling the next appointment.
SAMHSA regulations require that patients accepted for treatment at a OTP be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment (SAMHSA 2016).

- The initial assessment must include preparation of a treatment plan that includes the patient’s short-term goals and the tasks the patient must perform to complete the short-term goals; the patient’s requirements for education, vocational rehabilitation, and employment and the medical, psychosocial, economic, legal, or other supportive services that a patient needs (SAMHSA 2016).
- The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect the patient’s personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services (SAMHSA 2016).

**Induction Phase:**
- Initially, methadone is given daily under observation, when there are no signs and symptoms of opioid use or the use of sedatives, tranquilizers, tricyclic antidepressants, benzodiazepines, alcohol, or CNS depressants (SAMHSA 2014).
- For each new patient enrolled in a program, a typical first dose of methadone is 20 to 30mg, and should not exceed 30mg. If withdrawal symptoms persist after 2 to 4 hours, the initial dose can be supplemented with another 5 to 10mg. The total first-day dose of methadone allowed by Federal regulations is 40mg, unless a program physician documents in the patient’s record that 40mg did not suppress opioid abstinence symptoms (SAMHSA 2016; SAMHSA 2014).

**Opioid Treatment Program Continued Service Criteria**

**Stabilization Phase:**
- During the stabilization phase, the provider monitors the member’s response to treatment and level of motivation (SAMHSA 2014).
- Strong evidence supports the use of daily methadone doses in the range of 80mg or more for most patients, but considerable variability exists in patient responses. Some do well on dosages below 80 to 120mg per day, and others require significantly higher dosages (SAMHSA 2014).
  - OTPs should exercise additional caution with higher dosages (SAMHSA 2014).

**Maintenance Phase:**
- The maintenance stage begins when a patient is responding optimally to medication treatment and routine dosage adjustments are no longer needed (SAMHSA 2014).
- Patients at this stage have stopped abusing opioids and other substances (SAMHSA 2014).
- During the maintenance stage, patients often remain on the same dosage for many months (SAMHSA 2014).

**Methadone Maintenance to Buprenorphine Taper or Maintenance Protocol (SAMHSA 2004):**
- The use of buprenorphine to taper off of methadone maintenance or to transition to maintenance with buprenorphine/naloxone should only be considered for patients who have evidence of sustained medical and psychosocial stability; requests to transition to buprenorphine should be entertained with caution – the decision should be made in conjunction and in coordination with the patient’s OTP.
- The steps to achieve either withdrawal with the use of buprenorphine, or to transition to buprenorphine maintenance include the following:
  - There is evidence of medical and psychosocial stability;
  - There is a compelling reason to discontinue the use of methadone (e.g., impending incarceration, conditions of employment);
  - If there is a compelling reason, methadone should be tapered to < 30mg per day, and buprenorphine monotherapy protocol should be followed as described in the Office-Based Opioid Treatment Behavioral Clinical Policy, available at: [www.providerexpress.com > Clinical Resources > Guidelines/Policies & Manuals > Behavioral Clinical Policies](https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locator.html)
  - If the decision is to discontinue buprenorphine after a transition from methadone, the buprenorphine taper protocol should be followed as described in the Office-Based Opioid Treatment Behavioral Clinical Policy, available at: [www.providerexpress.com > Clinical Resources > Guidelines/Policies & Manuals > Behavioral Clinical Policies](https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locator.html)

**Opioid Treatment Program Discharge Planning and Criteria**
Tapering and Readjustment (SAMHSA 2014):
- Withdrawal from maintenance medication should be attempted when desired by a stable member who has a record of abstinence and has responded positively to OTP treatment.
- Relapse prevention techniques should be incorporated into treatment and other support services before, during, and after dosage reduction.
- As medication is tapered, intensified services should be provided, including counseling and monitoring of the member's behavioral and emotional symptoms.
- When tapering or when the end of treatment is indicated, the following occurs:
  - The provider gradually tapers the dose in 5-10% increments every 1-2 weeks; tapering may cause discomfort.
  - The member continues to participate in psychosocial interventions;
  - The provider, in conjunction with the member, schedules follow-up appointments with the OTP. Typically, follow-up appointments occur every 1-3 months.
- Involuntary discharge may be indicated when the member is violent or threatening, dealing drugs, repeatedly loitering, incarcerated, or is not compliant with treatment (SAMHSA 2014). Examples of interventions used to avoid involuntary discharge include:
  - Clarification of the program’s rules;
  - Adjusting the dose of methadone;
  - Intensifying counseling;
  - Facilitating treatment of co-occurring conditions;
  - Enlisting the assistance of the member’s family or other natural resources;
- OTPs should consider assisting with transfer arrangements for long-term methadone-maintained members to an office-based provider in the community for ongoing care.

Continuing Care Phase (SAMHSA 2014):
- Continuing care is the phase that follows successful tapering and readjustment.
- Treatment at this stage comprises ongoing medical follow-up by a primary care physician, occasional check-ins with an OTP counselor, and participation in recovery groups.
- OTPs should establish links with medical providers and programs skilled in treating problems that go beyond the direct services of the OTPs.

DESCRIPTION OF SERVICES

Opioid treatment programs (OTPs) provide medication-assisted treatment (MAT) for individuals diagnosed with an opioid use disorder. MAT is the use of medications, in combination with counseling and behavioral therapies, in the treatment of substance use disorders. OTPs also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs, potential criminal activity, and/or the spread of infectious disease (SAMHSA 2015).

Maintenance therapy in an OTP utilizes daily administrations of methadone or buprenorphine formulations for members with an opioid use disorder to pharmacologically occupy opiate receptors in the brain, extinguish drug craving, and establish a maintenance state (American Society of Addiction Medicine Treatment Criteria, 2013).

OTPs must be accredited by a SAMHSA-approved accrediting body and certified by SAMHSA. The Division of Pharmacologic Therapies (DPT) part of the SAMHSA Center for Substance Abuse Treatment (CSAT) oversees accreditation standards and certification processes for OTPs (SAMHSA 2015).

Federal law requires patients who receive treatment in an OTP to receive medical, counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication (SAMHSA 2016; SAMHSA 2015).

CLINICAL EVIDENCE

Summary of Clinical Evidence
Research supports the perspective that opioid addiction can be treated effectively with medications when they are administered under conditions consistent with their pharmacological efficacy and when treatment includes necessary supportive services, such as psychosocial counseling, treatment for co-occurring disorders, medical services, and vocational rehabilitation (SAMHSA 2014). The clinical evidence in randomized controlled trials, meta-analyses, and systematic reviews demonstrates that maintenance treatment with either methadone or buprenorphine, delivered within an accredited and certified opioid treatment program, can be effective and safe. Clinical trials frequently
incorporate psychosocial services into pharmacological treatment delivery, a practice which is strongly recommended by national guidelines and mandated by federal regulations.

**Clinical Trials**

Hser and colleagues (2016) compared long-term outcomes among opioid-dependent participants randomized to buprenorphine or methadone at one of seven participating opioid treatment programs in the United States between 2006 and 2009. A total of 1080 opioid-dependent participants were followed-up with; these individuals had previously been randomized to receive either open-label buprenorphine/naloxone or methadone for up to 24 weeks. Of those followed-up with, a total of 795 participants completed in-person interviews (74% follow-up rate). Primary outcomes were mortality and opioid use. The follow-up found that mortality was not different between the two conditions, and that opioid use was higher among participants randomized to buprenorphine relative to methadone (43% vs. 32%). The authors conclude that there are few differences in long-term outcomes between buprenorphine and methadone treatment for opioid dependence, and that treatment with each medication is associated with a strong reduction in opioid use.

Hser and colleagues (2014) examined patient and medication characteristics associated with retention and continued illicit opioid use in methadone (MET) versus buprenorphine/naloxone (BUP) treatment for opioid dependence. The secondary analysis included a total of 1,267 opioid-dependent individuals participating at one of nine opioid treatment programs and randomized to receive open-label BUP or MET for a period of 24 weeks. Outcome measures included urine drug screens during treatment, treatment completion, and days in treatment during the 24 week trial. Results found treatment completion rates of 74% for MET and 46% for BUP. Completion rates increased with higher doses (60mg/day MET and 30-32mg/day BUP). Of those remaining in treatment, positive opioid urine results were significantly lower among BUP participants during the first nine weeks of treatment. The authors conclude that the provision of methadone appears to be associated with better retention than buprenorphine, while buprenorphine is associated with lower continued use of illicit opioids.

Soyka and colleagues (2008) conducted a 6-month, randomized, flexible-dose study to compare the effects of methadone and buprenorphine on retention rate and substance use in opioid-dependent patients. A total of 140 patients who had been without opioid substitution therapy in the 4 weeks prior to the study were included. Mean daily dosages after the induction phase were 44-50mg for methadone and 9-12mg for buprenorphine. All patients also received standardized psychosocial interventions. Results from the study found an overall retention rate of 52%, with no significant difference between treatment groups. Substance use decreased significantly over time in both groups, with the buprenorphine group being non-significantly lower. The authors conclude that these results give further evidence that substitution treatment is safe and effective for drug dependence, with methadone and buprenorphine being equally effective. They note that further research is necessary to address patient profiles and outcome under different substitution regimes.

Gibson and colleagues (2008) conducted a ten-year longitudinal follow-up to examine the predictors of mortality of methadone versus buprenorphine maintenance treatment. A total of 405 heroin-dependent participants, aged 18 years and above who consented to participate in a previous randomized study (Mattick et al 2003) were included. The analysis found an overall mortality rate of 8.84 deaths per 1000 person-years of follow-up. There was no differential mortality among methadone versus buprenorphine participants. The authors conclude that increased exposure to opioid maintenance treatment reduces the risk of death in opioid-dependent people, with no differential reduction between buprenorphine and methadone. They note that previous studies suggesting differential effects may have been affected by patient selection bias.

Mattick and colleagues (2003) conducted a randomized double-blind trial to assess the efficacy of buprenorphine compared with methadone maintenance therapy for opioid dependence. A total of 405 opioid-dependent patients seeking treatment were randomized to receive either buprenorphine or methadone over a 13-week period, using a flexible dosage regime. During weeks 1–6, patients were dosed daily; from weeks 7-13, buprenorphine patients received double their week 6 dose on alternate days. Primary outcomes were retention in treatment and illicit opioid use as determined by urinalysis. The study found no significant difference in completion rates at 13 weeks. Methadone was found to be superior to buprenorphine in time to termination over the entire period, but not separately for single-day or alternate-day dosing phases. There were no significant differences in morphine-positive urines or self-reported illicit drug use. The authors conclude that buprenorphine did not differ from methadone in its ability to suppress heroin use, but retained approximately 10% fewer patients. They note that for the majority of patients, buprenorphine can be administered on alternate days.

**Systematic Reviews/Meta- Analyses**

Connery (2015) conducted a review of the evidence for medication-assisted treatment (MAT) of opioid use disorder. All randomized controlled trials (RCTs) with English abstracts on medication management of opioid use disorder were
searched, yielding 502 total abstracts. The review found the evidence to strongly support the use of agonist therapies to reduce opioid use and retain patients in treatment, with methadone maintenance remaining the gold standard of care. The combination of buprenorphine/naloxone also demonstrated significant efficacy and favorable safety and tolerability. The author notes that no research has examined MAT in nondependent opioid use disorder.

Mattick and colleagues (2014) conducted a systematic review to evaluate buprenorphine maintenance compared to placebo and to methadone maintenance in the management of opioid dependence. This Cochrane Review also examined buprenorphine’s ability to retain people in treatment, suppress illicit drug use, reduce criminal activity, and mortality. A total of 31 trials were identified (total n = 5,430), with the quality of evidence varying from high to moderate quality. Results found that high quality evidence that buprenorphine was superior to placebo medication in retaining participants in treatment at all doses examined. High-quality evidence also found that buprenorphine in flexible doses adjusted to participant need was less effective than methadone in retaining participants. Two reviewed studies found no significant differences between methadone and buprenorphine in terms of adverse events. The authors conclude that methadone is superior to buprenorphine in retaining people in treatment, and methadone equally suppresses illicit opioid use.

Fullerton and colleagues (2014) conducted a review of meta-analyses, systematic reviews, and individual studies of the evidence for methadone maintenance treatment (MMT) effectiveness. The review included seven randomized controlled trials and two quasi-experimental studies of MMT. The review found high level of evidence for the positive impact of MMT on treatment retention and illicit opioid use, particularly at doses greater than 60mg. MMT in pregnancy was associated with improved maternal and fetal outcomes. Potential areas for future research include increased focus on the impact of MMT on secondary outcomes, understanding efficacy and safety tradeoffs of very high doses (> 100mg), and use of MMT in specific subpopulations. Authors recommend that providers, consumers, and family members be educated about the benefits of MMT in helping individuals manage opioid use disorders, and appropriate ways to avoid significant adverse events that can occur with this treatment.

Bao and colleagues (2009) conducted a meta-analysis to estimate the influence of different methadone dose ranges and dosing strategies on retention rates in methadone maintenance treatment (MMT). A literature search identified 18 randomized controlled trials (RCTs), with a total n = 2,831, evaluating methadone dose and retention (defined as percentage of patients remaining in treatment at a specified time point). The meta-analysis found that retention was significantly predicted by effects of methadone dose (above or below 60mg/day), flexible vs. fixed dosing strategy, and duration of follow-up, when the other variables were controlled for. Specifically, retention was greater with methadone doses > 60mg/day and with flexible-dose strategies. The authors conclude that higher doses of methadone and individualization of doses are each independently associated with better retention in MMT.

Mattick and colleagues (2009) conducted a systematic review to evaluate the effects of methadone maintenance treatment (MMT) compared with treatments that did not involve opioid replacement therapy (i.e., detoxification, offer of drug-free rehabilitation, placebo medication, wait-list controls) for opioid dependence. This Cochrane Review found eleven studies that met criteria for inclusion; all were randomized clinical trials (total n = 1969), with two of them double-blinded. The review found that methadone appeared statistically significantly more effective than non-pharmacological approaches in retaining patients in treatment and in the suppression of heroin use as measured by self-report and urine/hair analysis, but not statistically different in criminal activity or mortality. The authors conclude that methadone is an effective maintenance therapy intervention for the treatment of heroin dependence as it retains patients in treatment and decreases heroin use better than treatments that do not utilize opioid replacement therapy.

Connock and colleagues (2007) conducted a systematic review and economic evaluation to assess the clinical effectiveness and cost-effectiveness of buprenorphine maintenance therapy (BMT) and methadone maintenance therapy (MMT) for the management of opioid-dependent individuals. The assessment of clinical effectiveness was based on a review of existing reviews plus an updated search for randomized controlled trials (RCTs). Most of the included systematic reviews and RCTs were of moderate to good quality, and focused on short-term outcomes (up to 1 year) of retention in treatment and level of opiate use (self-report or urinalysis). The review found both flexible-dose MMT and BMT are more clinically effective and more cost-effective than no drug therapy in dependent opiate users. In direct comparison, a flexible dosing strategy with MMT was found to be somewhat more effective in maintaining individuals in treatment than flexible-dose BMT.

Faggiano and colleagues (2003) conducted a systematic review to evaluate the efficacy of different dosages of methadone maintenance treatment (MMT) for opioid dependence in modifying health and social outcomes and in promoting patients’ familial, occupational, and relational functioning. This Cochrane Review included randomized controlled trials (RCTs) and controlled prospective studies (CPS). A total of 21 studies were included in the review; of them, 11 were RCTs (n = 2279) and 10 were CPSs (n = 3715). Conclusions from the review found that methadone dosages ranging from 60-100mg/day are more effective than lower dosages in retaining patients and in reducing use of heroin and cocaine during treatment.
appropriate program evaluation tools, to improve treatment quality. Should be appropriate and tailored to each patient. OTPs should measure their outcomes continuously, using dosages without regard to arbitrary dose-level ceilings that are unsupported by research evidence. Dosage decisions programs should monitor and adjust patients’ dose levels of methadone to ensure that they receive therapeutic methadone is more effective when it includes individual and/or group counseling, with even better outcomes when patients are provided with, or referred to, other needed medical/psychiatric, psychological, and social services (e.g., employment or family services).

In a research-based guide (last revised 2012), NIDA states that methadone is effective in helping individuals addicted to heroin or other opioids stabilize their lives and reduce their illicit drug use. Buprenorphine and methadone are prescribed or administered under monitored, controlled conditions and are safe and effective for treating opioid addiction when used as directed. Research has shown that methadone maintenance has been demonstrated repeatedly to be safe and effective when used with appropriate safeguards and psychosocial services. Programs should monitor and adjust patients’ dose levels of methadone to ensure that they receive therapeutic dosages without regard to arbitrary dose-level ceilings that are unsupported by research evidence. Dosage decisions should be appropriate and tailored to each patient. OTPs should measure their outcomes continuously, using appropriate program evaluation tools, to improve treatment quality.

In their 2015 clinical practice guideline for the management of substance use disorders, the VA/DOD recommends that for patients with opioid use disorder, either methadone in an opioid treatment program or buprenorphine/naloxone be offered, considering patient preferences. The guidelines note that buprenorphine and methadone are recommended for the treatment of opioid use disorder based on high quality evidence from multiple RCTs and meta-analyses.

In its 2009 guidelines for the psychosocially assisted pharmacological treatment of opioid dependence, the WHO states that methadone and buprenorphine have a strong evidence base for use, and have been placed on the WHO model list of essential medicines. The guidelines state that compared to detoxification or no treatment, methadone maintenance treatment significantly reduces opioid and other drug use, criminal activity, HIV risk behaviors and transmission, opioid overdose, and all-cause mortality; it also helps to retain people in treatment. In general, methadone is recommended over buprenorphine because it is more effective and costs less. Psychosocial assistance should be offered to all patients.

OTPs must use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder (SAMHSA 2016).

A National Coverage Determination (NCD) exists for Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic.
### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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### REFERENCES


HISTORY/REVISION INFORMATION

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<td>3/14/2018</td>
<td>• Annual Update: Updates to formatting, references</td>
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