

Naltrexone Medication Assisted Treatment (MAT) Program Description
Division of TennCare**Overview of the Opioid Use Disorder Medication Assisted Treatment Program**

The Division of TennCare along with the contracted Managed Care Organizations (Amerigroup, BlueCare and United Healthcare) has determined the need for a comprehensive network of providers who offer specific treatment for members with opioid use disorder. These providers may be agencies or licensed independent practitioners, but all must attest to provide treatment as outlined in this program description to be included in this network.

Medication Assisted Treatment (MAT) for persons diagnosed with opioid-use disorder is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Research shows that when treating substance-use disorders, a combination of medication and behavioral therapies is most successful. The duration of treatment should be based on the needs of the persons served. The Food and Drug Administration (FDA) has approved several medications for the use in treatment of opioid-use disorder (OUD) which include buprenorphine containing products and naltrexone products

Treatment with buprenorphine and naltrexone for opioid use disorders is considered an evidence-based best practice by the Substance Abuse and Mental Health Services Administration (SAMHSA) Center and the American Society of Addiction Medicine (ASAM) for substance abuse treatment. This **naltrexone MAT Program Description** outlines treatment and clinical care activities expected of providers who prescribe naltrexone products and professionals who provide therapy, care coordination or other ancillary services for those members who are being treated with naltrexone products. For providers who prescribe buprenorphine based products, refer to Buprenorphine MAT Program Description.

Treatment Elements

The required treatment elements for providers rendering Medication Assisted Treatment using **naltrexone** are as follows:

- The decision to begin naltrexone as the preferred pharmacologic agent for Medication Assisted Treatment should be conducted through shared-decision making with the patient. This should include a review of the evidence, risks, and benefits of all medication assisted therapy modalities.
- The naltrexone formulation prescribed should be covered by the TennCare formulary or contracted Managed Care Organization's formulary. Prescription of naltrexone should adhere to all prescribing protocols of the TennCare pharmacy benefits manager. TennCare's pharmacy benefits manager will also work with providers included in the MAT network to reduce barriers to access, support an efficient prior authorization process when required, and regularly update the formulary to support appropriate evidence-based naltrexone products for members.
- While oral formulation naltrexone can be used in MAT, it should only be considered for patients where adherence can be supervised and enforced. Extended-release injectable naltrexone is more suitable and preferred for all patients, especially those who have issues with adherence.

- A physician would document initial screenings of each patient to determine whether the patient meets the diagnostic criteria for an opioid use disorder as defined in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) or ICD-10.
- The program would provide initial and on-going training and resources to patients receiving care including:
 - The risk of neonatal abstinence syndrome if opioids were to be used and use of voluntary long-acting reversible contraception for all female patients of child bearing age and potential (ages 15-44)
 - Prevention and treatment of chronic viral illnesses, such as HIV and hepatitis C
 - Expected therapeutic benefits and adverse effects of treatment medication
 - Education regarding increased risks of opioid overdose, and especially the increased risk of death, for patients who discontinue naltrexone therapy and resume opioid use
 - Overdose prevention and reversal agents
- Discontinuation of medication could occur if and when the member has achieved maximum benefit from treatment. Duration of treatment depends on clinical judgment and patient's individual circumstances. While there is no physical dependence with naltrexone, evidence shows that many people may require ongoing treatment.
- Involuntary termination of treatment may occur under certain circumstances, but abandonment should be avoided. Physicians should have written policies and procedures that should be discussed with beneficiaries who should agree to comply with these policies.
- Patients who discontinue or do not achieve desired therapeutic outcomes with naltrexone may switch to buprenorphine Medication Assisted Treatment. Switching from naltrexone to a different MAT modality should be planned, considered, and monitored.

Treatment Protocols and Guidelines

Patients who have been abstinent from short-acting opioids (including tramadol) for 7 to 10 days or long-acting opioids (e.g., methadone, buprenorphine) for 10 to 14 days can initiate and continue therapy with naltrexone that includes the following:

During Initiation of Naltrexone treatment:

- (a) Provider should complete a thorough history and physical exam which includes at a minimum a medical, psychiatric, substance use, and substance use treatment history.
- (b) Provider should establish OUD diagnosis and assess for other substance use disorders, including those that involve alcohol, benzodiazepines, or stimulants.
- (c) Provider should ensure baseline evaluation includes at least the following confirmatory laboratory tests as clinically indicated¹:
 - A complete blood count (CBC). Injectable naltrexone should be used with caution in patients with thrombocytopenia or coagulation disorders.
 - Hepatic function analysis through laboratory tests that include liver transaminase levels, bilirubin, and coagulation.
 - Creatinine clearance. Naltrexone should be used with caution in patients with renal impairment as defined as a creatinine clearance <50 ml/min.

¹ The provider should follow all clinical guidelines should any laboratory results be outside of the expected normal limits.

- A negative urine or blood based beta-hCG (human chorionic gonadotropin) testing for females.
 - Hepatitis and HIV screening when possible, with treatment referral as appropriate².
- (d) Provider should confirm that an adequate period of opioid abstinence has occurred prior to naltrexone administration. This could be accomplished via:
- Assessing recent opioid use, including frequency, quantity, type, route, and last day of use.
 - A reliable urine drug screen negative for all opioids (including morphine, methadone, buprenorphine, and oxycodone)³.
 - The Naloxone Challenge may be considered if clinically indicated. The SAMHSA Treatment Improvement Protocol (TIP) #63 provides guidelines for administration of the Naloxone Challenge.
 - In regions known to have significant prevalence of buprenorphine diversion, the Naltrexone Challenge may also be administered, following Naloxone Challenge, as low dose naloxone does not displace buprenorphine whereas naltrexone does.
 - Assessment for evidence of opioid withdrawal and physiological dependence, completed with a validated tool:
 - The Clinical Opioid Withdrawal Scale (COWS) or the Clinical Institute Narcotic Assessment (CINA) Scale for Withdrawal Symptoms can be used to assess withdrawal signs (see “Resource Alert: Opioid Withdrawal Scales”).
 - The patient should not exhibit any signs of opioid withdrawal before taking the first dose of naltrexone in order to avoid precipitated withdrawal.
- (e) Provider should conduct additional drug and alcohol tests including as clinically indicated for benzodiazepines, cocaine, and other drugs commonly used in the area.

Patients who test the opioid blockade of naltrexone may discontinue use of naltrexone because it blocks the euphoric effects of illicit opioids. Patients who miss a dose can restart medication (using procedures outlined in this section) after an adequate period of opioid abstinence (7 to 14 days).

Follow-up care during first month after initial naltrexone treatment dose

- (a) Examine patients within one week of administering their first naltrexone dose:
- Provide supportive counseling
 - Assess ongoing drug or alcohol use
 - Perform one observed urine drug screen
- (b) Have follow up office visits scheduled every 1-2 weeks for the first month
- (c) Receive appropriate counseling sessions at least twice a month, as defined in **Program Components**, below
- (d) Be subject to one (1) observed drug screen during each follow up visit
- (e) Receive care coordination services weekly, if indicated

Continued care for ongoing treatment:

- (a) Have a scheduled office visit monthly

² The Centers for Disease Control and Prevention recommends hepatitis B vaccine for individuals seeking treatment for SUDs.

³ The provider should recognize the limitations of a drug screen, including the sensitivity and specificity of the test, as clinically indicated.

- (b) Recommend counseling sessions at least monthly unless clinically stable and with continued signs of recovery, as defined in **Program Components**, below
- (c) Be subject to a random observed drug screen at least four (4) times annually
- (d) Receive care coordination services at least monthly, if indicated
- (e) Periodic monitoring of liver, renal, and additional relevant clinical laboratory values at 6- to 12-month intervals⁴
- (f) Follow up on status of referrals to counseling or other services
- (g) Coordinate care with patient's primary care physician

Educate patients and their families about what to expect from naltrexone treatment

Throughout treatment, a naltrexone medication guide should be dispensed to patients with each prescription for oral medication or each dose of injection. At a minimum, the provider should caution both patients and families about increased risk of overdose if they stop treatment and return to illicit opioid use. Patients, family members, and other key supports should be educated that if patients previously used opioids, the fact that they have completed detoxification means that in the future they will be more sensitive to lower doses of opioids and at risk of accidental overdose should they use opioids when their next dose is due, if they miss a dose, or if treatment is discontinued.

Given the high risk of return to illicit opioid use, offer patients information about opioid overdose prevention and a naloxone prescription they can use in case of overdose. For more information, see the *SAMHSA Opioid Overdose Prevention Toolkit* (<https://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf>).

Detailed Drug Screen Protocol

Appropriate drug screening and the use of consistent drug screening protocols are an important and required process in the delivery of MAT services. Providers must ensure that the following or similar protocol is in place:

- (a) Random observed urine drug screening and other adequately tested toxicological procedures shall be used for the purposes of assessing the patient's abuse of drugs and evaluating a patient's progress in treatment.
- (b) Drug screening procedures shall be individualized and shall follow the required drug screen frequency described in phases of treatment.
- (c) More frequent collection and analysis of drug samples during episodes of relapse or medically-supervised or other types of withdrawal may occur.
- (d) Collection and testing shall be done in a manner that assures that samples collected from patients are unadulterated. Any ordered qualitative/ confirmatory screens should be ordered for the drugs or drug classes in question. Collection and testing shall include random direct observation that is conducted professionally, ethically, and in a manner which respects patient privacy.
- (e) A positive test is a test that results in the presence of any drug or substance that is illegal, for which the patient cannot provide a valid prescription, or prohibited by the Facility. Any refusal to participate in a random drug test assigned by the Facility shall also be considered a positive result.

⁴ Testing may be done at smaller intervals if indicated by other clinical treatment guidelines.

- (f) Discuss any unexpected results, including both unexpected positive results and negative results, with the member immediately. Appropriate changes to treatment plan and interventions should follow any unexpected results.
- (g) The Facility shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.
- (h) Absence of medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the program physician, accordingly.
- (i) Nothing shall preclude any Facility from administering any additional drug tests it determines necessary.

Program Components

In addition to providing high quality evidence-based treatment, providers must also **ensure the availability** of the program components listed below. Providers must also make available relevant documentation for the quality-of-care reviews performed by the Managed Care Organizations:

- Include protocols to query the Controlled Substance Monitoring Database (CSMD) each time a prescription is written or electronically prescribed and dispensed.
- Employ, contract, or partner with a behavioral health counselor to provide psychosocial assessment⁵, addiction counseling, individual/group counseling, self-help and recovery support, and therapy for co-occurring disorders. (The member's counselor may be either co-located with the MAT provider or may participate in an SUD practice attended by the member).
- Include confidential documentation of care including individualized treatment plans completed within 30-days of admission and reviewed every six months thereafter.
- Include and document appropriate behavioral health counseling sessions throughout the MAT treatment period as described in the Treatment Protocols⁶:
 - At least twice a month for patients in the initial treatment initiation phase
 - At least monthly for patients in the first year of ongoing treatment phase (for patients who remain in ongoing treatment with naltrexone beyond one year, behavioral health counseling at least monthly may still be recommended)
- Employ, contract, or partner with a local care coordination resource to
 - Facilitate communication between prescriber and counselor
 - Maintain telephone contact with member, as needed
 - Coordinate urinary drug screens
 - Refer members for appropriate counseling
 - As indicated, provide other recovery support services (e.g. 12-step)
- Employ, contract, partner, or show effort towards engagement with a Certified Peer Recovery Specialist (has certification through TDMHSAS) in the community for consumer education, treatment engagement, and recovery planning
- Include appropriate care coordination:
 - At least weekly for patients in the first month of treatment initiation with naltrexone MAT to maximize treatment adherence

⁵ A standardized, evidenced-based psychosocial assessment is recommended (e.g. DLA-20 or QOL-10)

⁶ Behavioral Health Counseling is defined as individual or group sessions of no less than 30 minutes in duration. Provider's counseling professional should hold at least a master's degree in the mental health discipline and be under the direct supervision of a licensed mental health provider practicing within their scope of licensure.

- At least monthly for patients who receive ongoing treatment
- Perform routine and random urine drug screening as follows:
 - Once within the first week for patients initiating naltrexone treatment
 - At least twice within the first month of initiating naltrexone treatment
 - At least four times per year for patients in ongoing treatment after the first month
- Maintain a Diversion Control Plan as needed
- Maintain a plan to address medical emergencies including naloxone on-site
- Maintain a plan to address psychiatric emergencies including involuntary hospitalization
- Communicate timely with both other providers who are treating the member as well as with member's informal support system.

While counseling is a recommended component of Medication Assisted Treatment, a member may continue to receive prescribed naltrexone even if not participating in the counseling. This decision should be based on the provider's clinical judgment and the member's overall involvement in their treatment and recovery.

In instances when the provider is unable to link to a counseling professional, the contracting managed care organization can provide assistance to identifying and connecting to counseling services. A MAT network provider can reach out to the managed care organization for support at the following numbers:

Amerigroup: Provider Services at (800) 454-3730

BlueCare: MAT Referral Line at (800) 814-8936

United Healthcare: Provider customer service at (800) 690-1606

Treatment discontinuation

When patients wish to discontinue naltrexone, engage in shared decision making and explore:

- Their reasons for wanting to discontinue
- The risks and benefits of discontinuing
- Problem-solving strategies that can help them make an informed choice
- Their appropriateness for buprenorphine or methadone treatment

Signs that a patient may be ready to discontinue medication include:

- Clinically stable and sustaining abstinence of opioids and illicit drugs in accordance with treatment plan
- Having stable housing and income
- Having no legal problems
- Having substantially reduced craving
- Attending counseling or mutual-help groups

Patients who discontinue should have a recovery plan that may include monitoring as well as adjunctive counseling and recovery support. If they return to opioid use, encourage them to return for assessment and reentry into treatment.

Monitoring Quality of Care

An annual quality of care review shall be collaboratively conducted by the provider and MCO. MAT providers shall co-operate with on-site monitoring performed by the Managed Care Organizations. The MAT provider quality of care review shall include

- Inspection of medical records for adherence to MAT program standards/requirements, protocols, and clinical treatment guidelines
 - Functional assessment reviews
- Assessments of member experience, completed and collected at providers' offices. At a minimum, member perspectives shall be measured regarding:
 - Support received during MAT treatment initiation
 - Outpatient MAT provider identification
 - 7-day follow-up behavioral and/or physical health appointment accessibility
 - Ease of pharmacy service
 - Ability to obtain prescription fills for both MAT and psychiatric medications

Monitoring of non-MAT SUD providers shall focus on adherence to clinical treatment guidelines as documented in medical records.

Quality Review:

The Managed Care Organizations will provide to each MAT provider in its quality of care monitoring process, a focused assessment of the treatment patterns and patient health outcomes for Opioid Use Disorders and Substance Abuse Disorders. The MCO, in collaboration with the MAT provider, will provide analysis using nationally available measures, claims based metrics, and through medical record assessment of treatment practices and patterns at the provider level. The quality review will focus on, but is not limited to, outcome measures in the following clinical and treatment areas:

- (a) Length of MAT treatment
- (b) Use of behavioral health services during MAT
- (c) Urine Drug Screen frequency
- (d) Health care utilization patterns of MAT patients (e.g. emergency room visits, hospitalizations)
- (e) Concurrent use of benzodiazepines and/or opioids while on MAT

References and Resources

Additional resources, references, and published comprehensive best practice guidelines for the use of naltrexone in treating opioid use disorders are listed below. This program description and the treatment elements have been developed from these documents for naltrexone treatment.

SAMHSA Resources:

- For SAMHSA resources, please visit: <https://www.samhsa.gov/> and <http://store.samhsa.gov>
- SAMHSA Treatment Guide *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide*
- SAMHSA Treatment Improvement Protocol (TIP) # 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs"
- SAMHSA Treatment Improvement Protocol (TIP) # 63, "Medications for Opioid Use Disorder"
- ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use
- Examples of screenings are found at <http://www.samhsa.gov/sbirt>