



SCOPE OF WORK TEMPLATE

Name of Program/Services: Medication-Assisted Treatment: Buprenorphine

Procedure Code: Modification of 99212, 99213 and 99214:

99212 22

99213 22

99214 22

Definitions:

Buprenorphine

An opioid partial agonist that is a synthetic derivative of thebaine. Two sublingual formulations of buprenorphine, the Schedule III pharmaceuticals Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone), received Food and Drug Administration (FDA) approval in October 2000 for use in the treatment of opioid addiction. This service definition covers use of the buprenorphine monotherapy and buprenorphine/naloxone combination through the above or other FDA-approved brands or generic preparations.

Description of Services: Opioid treatment programs provide medication-assisted treatment for persons diagnosed with opioid-use disorder. Medication assisted treatment 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 medications used to achieve treatment goals include buprenorphine, which is approved by the Food and Drug Administration (FDA) for the use in the treatment of opioid-use disorder.

Required Elements of the Program/Service

Treatment with buprenorphine for opioid use disorders is considered an evidence-based best practice by the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment and the American Society of Addiction Medicine (ASAM). Both agencies have published the following documents that provide guidance regarding clinical treatment standards.

- SAMHSA Treatment Improvement Protocol (TIP) # 40, “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction”



- SAMHSA Treatment Improvement Protocol (TIP) # 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs”
- ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use

These documents are comprehensive best practice guidelines for the use of buprenorphine in treating opioid use disorders and include the following as a part of what would be considered best practice for buprenorphine treatment:

Required treatment elements for treatment using buprenorphine are as follows:

- a. The preferred medication would be the buprenorphine/naloxone combination (Suboxone) for induction as well as stabilization unless contraindicated (e.g. pregnancy) and then the buprenorphine monotherapy is recommended. The buprenorphine/naloxone combination serves to minimize diversion and intravenous abuse.
- b. Maintenance treatment – three phases and approximate length
 1. Induction – one week; with suggested frequency of daily administration for at least the first two days.
 - i. Goal of induction is defined minimum dose of buprenorphine at which the beneficiary discontinues the use of other opioids, experiences no withdrawal symptoms, has minimal or no side effects, and no uncontrollable cravings for drugs of abuse.
 - ii. Induction phase occurs on site in the physician office and should be guided by written protocols.
 2. Stabilization – Two to three months
Goal is to reduce cravings and use of illicit opioids as evidenced by negative toxicology. Suggested frequency is weekly. Pill counts are recommended.
 3. Maintenance – 12 months to indefinite; suggested frequency is monthly for beneficiaries who are stable, making progress toward treatment goals, and have negative drug tests. Attention must be maintained to issues such as: psychosocial, family, relapse prevention, cravings, psychiatric comorbidity, other alcohol or drug abuse, somatic consequences of drug use, legal consequences of drug use, and financial considerations.
- c. Termination
 - Ideally, discontinuation of medication should occur when the beneficiary has achieved maximum benefit from treatment.

- Buprenorphine should be tapered slowly while psychosocial services continue to be provided. Beneficiaries should be assessed for continued stability. Involuntary termination of treatment may occur under certain circumstances but abandonment should be avoided and physicians should have written policies and procedures that should be discussed with beneficiaries who should agree to comply with these policies.
- d. Weekly random drug testing until three consecutive tests are negative and then monthly random drug testing.
 - e. Counseling and relapse prevention treatment occur at a minimum weekly for the first 12 weeks and then at least monthly if the beneficiary is abstinent and compliant with treatment.
 - f. If there is evidence of diversion:
 - Diversion could result in discharge. Discharge protocols should include tapering of medication in a manner that is consistent with clinical guidelines.
 - g. Illicit use could result in:
 1. increasing clinic visits;
 2. more frequent drug testing and pill counts;
 3. increasing the intensity or frequency of treatment for the opioid use disorder or other substance use disorders; or
 4. detoxification and referral to more intensive treatments.
 - h. Harm reduction philosophy focuses on keeping the beneficiary in treatment.

Each of the following issues must also be addressed by the treatment program:

- a. The physician must refer the beneficiary into appropriate substance use disorder treatment services. Treatment should be individualized and may include higher intensity services such as SACOT or SAIOP, depending upon clinical needs of the consumer. Additional supports such as self-help groups should also be considered.
- b. The licensed professional receiving the referral from the prescribing physician should demonstrate the use of evidence-based practices in the treatment of substance use disorders. Qualifications for counseling staff should include training in opiate use disorders, opioid maintenance treatment (OMT) and Medication-Assisted Treatment.
- c. North Carolina Controlled Substances Reporting System (NCCSRS) check at time of enrollment and periodically over course of treatment
- d. Random drug testing (blood, hair, or urine) is required either on site or in conjunction with a certified laboratory.
 1. Random drug testing and follow-up testing should be done according to TIP 40, 40 and ASAM guidelines, using tests that are able to screen for buprenorphine levels. .
 2. Policies shall be in place for confirmatory testing with a certified laboratory.

3. Policies shall be in place for responding to drug tests that are negative for buprenorphine. These policies should include timely meeting between the beneficiary and the physician (or counselor) to discuss the results to consider and manage following possibilities:
 - the beneficiary is not taking the prescribed dose
 - the beneficiary is not taking the buprenorphine at all
 - the beneficiary recently ingested a large amount of water or other liquid to dilute the urine sample
 - the beneficiary ingested the buprenorphine dose only on the date of the drug test
4. Incidents of negative tests should be handled on a case-by-case basis with the beneficiary, but if there is continued suspicion of diversion then discontinuation of buprenorphine treatment should be considered so as to provide greater clinical oversight.
5. Policies shall be in place for responding to drug tests positive for other substances (including but not limited to alcohol, opiates, cocaine, marijuana, and benzodiazepines) and should include timely meeting between the beneficiary and the physician (or counselor) to discuss the positive drug test to consider and manage an appropriate treatment response.
- e. Call-backs for confirmation of remaining pill supply (pill counts).
- f. Physicians or appropriate staff shall provide beneficiary and staff education and training. Training should include patient and family education on substance use disorders, treatment options, and Medication-Assisted Treatment.
- g. The program shall have a policy for the treatment of pregnant and breast-feeding women.
- h. Physicians shall utilize the North Carolina Controlled Substance Reporting System (NCCSRS) to help in preventing diversion and be aware of any other sources of controlled substances being prescribed to the beneficiary.
- i. Other considerations:
 1. Require permission to communicate with other treating physicians, etc.
 2. Require pharmacy lockbox in home
 3. Set expectations for referral and coordination for MI, physical illness, family planning, etc.
 4. Require controlled substance use contracts that provide clear expectations for the consumer regarding prescription medication use, diversion, and other treatment expectations.
 5. Utilize patient-provider agreements as necessary

Target Population and Eligibility Criteria

All of the following criteria are necessary for admission to a buprenorphine treatment program:

- a. A comprehensive clinical assessment to support a DSM-5 (or its successor) diagnosis of opioid use disorder moderate or severe.
- b. ASAM criteria are met for Office-Based Opioid Treatment (OBOT) / ASAM Level 1.
- c. The beneficiary must be assessed to be:
 1. motivated for treatment
 2. expected to be compliant with treatment
 3. no contraindications that preclude the beneficiary from being a candidate for Buprenorphine
- d. The beneficiary must be in counseling or other treatment for their opioid use disorder and other co-occurring diagnoses as applicable or be scheduled to start treatment.
- e. Toxicology screen must be completed on admission.
- f. If the beneficiary requires a higher level of care based on ASAM criteria, it does not preclude office-based treatment.
- g. The beneficiary is capable of developing skills to manage symptoms, make behavioral changes, and respond favorably to therapeutic interventions.
- h. There is no evidence to support that alternative interventions would be more effective, based on North Carolina community practice standards (e.g., Best Practice Guidelines of the American Psychiatric Association, American Board of Addiction Medicine)
- i. Adolescents ages 16-18 are eligible to receive treatment if the following additional criteria are met:
 1. have at least 1-year history of opioid dependence
 2. have failed at least one prior treatment attempt or as part of medically supervised tapering

Continued Services Criteria

The criteria for continued service must meet a, b and c below:

- a. Any ONE of the following criteria:
 - 1) The desired outcome or level of functioning has not been restored, improved, or sustained over the timeframe outlined in the beneficiary's treatment plan;
 - 2) The beneficiary continues to be at risk for relapse based on current clinical assessment, and history: or
 - 3) Tenuous nature of the functional gains;
- b. Any ONE of the following criteria (in addition to a.)
 - 1) The beneficiary has achieved current treatment plan goals, and additional goals are indicated as evidenced by documented symptoms; or
 - 2) The beneficiary is making satisfactory progress toward meeting goals and there is documentation that supports that continuation of this service is expected to be effective in addressing the goals outlined in the treatment plan.

- c. The beneficiary must be actively engaged in counseling or other treatment for their opioid use disorder and other co-occurring diagnoses as applicable.

Discharge Criteria

Any ONE of the following criteria must be met:

- a. The beneficiary or legally responsible person no longer wishes to receive these services; or
- b. The beneficiary, based on presentation and failure to show improvement, despite modifications in the treatment plan, requires a more appropriate best practice or evidence-based treatment modality based on North Carolina community practice standards (for example, National Institute of Drug Abuse, American Psychiatric Association).
- c. The beneficiary has achieved current treatment plan goals and the desired outcome or level of functioning has been restored, improved, or sustained over the timeframe outlined in the beneficiary's treatment plan; and there is no indication that continuation of this service would be needed to sustain beneficiary's improved level of functioning.

Required Outcomes and Reporting Requirements:

- Reduced symptomatology, abstinence from the use of opiates, abstinence or decreased use of alcohol and other drugs;
- Employment or education (getting and keeping a job);
- Decreased criminal offending (e.g., arrests and incarceration);
- Stability in housing; and
- Increased social supports.

Staffing Qualifications, Credentialing Process, and Levels of Supervision Administrative and Clinical) Required:

Physicians who consider providing office-based treatment of opioid addiction must be able to recognize opioid use disorders and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Physicians must also demonstrate required qualifications in accordance with DATA 2000 and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA).

Physicians providing this service must be licensed to practice in North Carolina by the North Carolina Medical Board. Physicians must also have the training and have been granted the SAMHSA waiver to prescribe buprenorphine in an office-based practice to North Carolina Medicaid beneficiaries. Physicians working in a licensed Opioid Treatment Programs (OTPs) may dispense buprenorphine following the federal and state OTP rules and policies.

Individuals providing counseling and other therapeutic services to beneficiaries in a buprenorphine treatment program must be licensed to provide those services and directly enrolled with North Carolina division of medical assistance or the appropriate LME-MCO. Licensed professionals providing outpatient treatment services to beneficiaries in a buprenorphine treatment program must follow the outpatient Clinical Coverage Policy 8C.

Buprenorphine Waiver:

The Drug Enforcement Administration (DEA) issues a special identification number for physicians who have been granted the waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe buprenorphine. Providers of this service are required to have the SAMHSA buprenorphine waiver.

Utilization Management

Prior Approval

Prior approval is not required before starting a beneficiary on buprenorphine, and services will not require prior authorization. Service utilization will be monitored based on claims and post-payment record review.

Targeted Length of Service:

Clinical guidelines do not define duration of maintenance treatment for these medications. The Federal guidelines (Federal Guidelines for Opioid Treatment Programs, March 2015, SAMHSA) recommend that it be decided between patient and physician on a case-by-case basis, with consideration of all relevant factors. For some patients, indefinite medication-assisted treatment may be clinically indicated.

Finance. Compensation paid to Provider for UCR services at a following rates per unit:

E&M Code	Modifier	Rate
99212	22	\$53.23
99213	22	\$76.91
99214	22	\$108.10

Description of Process for Reporting Encounter Data (include record type, codes to be used, etc.)

Provider will bill for each unit of service provided. Claims data will reflect fee for service billing. Data will be uploaded to DMA by the MCO.

Encounter Data will be recorded by providers with the minimum standard of a service note for each contact, service event, or intervention.

Description of Monitoring Activities:

The MCO will review claims monthly to monitor patterns and trends in utilization of this service.

The MCO will monitor service utilization through and post payment reviews.

The MCO will measure outcomes minimally through LOCUS scores and ASAM Levels. The Provider will be asked to review and update the LOCUS scores and ASAM Level monthly. The reviewed/updated scores/levels will be submitted with re-authorization requests. It is expected that this service would be effective and resulting in positive outcomes when a lower LOCUS score and ASAM Level are reported in the request for re-authorization.

Quality Management:

Alliance requires Contractor to develop a formal Quality Management program. Elements of that program include: (1) establishing internal performance standards for the delivery of the services for which Contractor has contracted, (2) collecting data related to the delivery of those services, and (3) creating reports measuring the Contractor's performance and adherence to required outcomes.

The Contractor shall also document its efforts to identify areas for improvement, implement Quality Improvement Projects (QIPs), and analyze the results of its quality-improvement efforts.

Upon Alliance's request, the Contractor shall submit all documentation related to its Quality Management program and other quality-related activities.