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**NC Division of Medical Assistance
Office-Based Opioid Treatment:
Use of Buprenorphine and
Buprenorphine-Naloxone**

**Medicaid and Health Choice
Clinical Coverage Policy 1A-41
Effective Date: August 1, 2017**

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Related Clinical Coverage Policies

Refer to <http://dma.ncdhhs.gov/> for the related coverage policies listed below:

8A, Enhanced Mental Health and Substance Abuse Services

8C, Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers

1H, Telemedicine and Telepsychiatry

1S-3, Laboratory Services

Refer to <https://www.nctracks.nc.gov/> for the PA criteria listed below:

Outpatient Pharmacy Prior Approval Criteria Buprenorphine and Buprenorphine and Naloxone

1.0 Description of the Procedure, Product, or Service

Buprenorphine and buprenorphine-naloxone combination product serves as an alternative to methadone as an evidence-based treatment of beneficiaries with opioid use disorders. This policy outlines the requirements for providers who prescribe buprenorphine and buprenorphine-naloxone combination product for the treatment of opioid use disorders in the office-based setting.

Public law 106-310 Section 3501, Drug Addiction Treatment Act of 2000 (DATA 2000) permits providers who meet certain qualifications to dispense or prescribe narcotic medications that have a lower risk of abuse, like buprenorphine and buprenorphine-naloxone combination product that are approved by the Food and Drug Administration (FDA) for opioid use disorders in settings other than an opioid treatment program (OTP), such as a provider's office. This allows beneficiaries who need the opioid agonist treatment to receive this treatment in a qualified provider's office providing certain conditions are met.

Due to the national opioid use epidemic and additional need for buprenorphine prescribers, the Substance Abuse and Mental Health Services Administration (SAMHSA) is developing a training and DATA waiver program for nurse practitioners (NP) and physician assistants (PA). NPs and PAs may take the eight-hour DATA-waiver course for treatment of opioid use disorder. For the additional 16 hours, SAMHSA will also offer the training through the PCSS-MAT once it has been developed. NPs and PAs who have completed the required training, and seek to become DATA-waiver providers for up to 30 beneficiaries, will be able to apply to do so beginning in early 2017.

Office-based Opioid Treatment (OBOT) is defined as treatment of opioid use disorders in the clinical setting by a qualified provider as defined under Public Law 106-310 Section 3501(a)(G)(ii) to prescribe buprenorphine or buprenorphine-naloxone medications. Opioid use disorder is considered a chronic condition, and the management of this disorder is incorporated into the general care of the beneficiary.

Treatment goals of Office-based Opioid Treatment are to reduce or stop opioid use, to improve the beneficiary's overall health and social functioning, and to help the beneficiary avoid some of the more serious consequences of opioid addiction.

1.1 Definitions

1.1.1 Buprenorphine

Buprenorphine, a synthetic, FDA-approved, derivative of Thebaine, is defined as a Schedule III opioid partial agonist that works by blocking the opioid receptors in the brain and is used for both long-term maintenance and for medically supervised detoxification from opioids.

1.1.2 Buprenorphine-Naloxone

Buprenorphine-naloxone is a synthetic, Federal Drug Administration (FDA) approved, Schedule III opioid partial agonist combination that works by blocking opioid receptors is the preferred formulation for non-pregnant beneficiaries. Naloxone is included to reduce the diversion potential of the drug, it is poorly absorbed sublingually or orally, and has no negative effects when used as directed.

1.1.3 Concomitant Conditions

Concomitant conditions are medical or psychiatric illnesses or conditions that occur simultaneously to the substance use disorder

1.1.4 Illicit Opioid Use

Illicit opioid use is the use of an illegal substance or the use of medication for reasons other than those in which the medication was intended or in higher doses than prescribed.

1.1.5 Induction

Induction is the initial phase of opioid treatment that may take place in the office setting or at home. Medication is adjusted until the beneficiary attains stabilization.

1.1.6 Maintenance Treatment

Maintenance treatment means the beneficiary has reached a stable, consistent schedule of medication and counseling that prevents the desire for opioid use while allowing for abstinence of illicit substances.

1.1.7 Medication Assisted Treatment

Medication Assisted Treatment (MAT) 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.

1.1.8 Office-based Opioid Treatment

Office-based Opioid Treatment (OBOT) is treatment of opioid use disorders in the clinical setting by a qualified provider as defined under Public Law 106-310 Section 3501(a)(G)(ii) to prescribe buprenorphine or buprenorphine-naloxone medications. Opioid use disorder is considered a chronic condition, and the management of this disorder is incorporated into the general care of the beneficiary.

1.1.9 Opioid Treatment Program (OTP)

An OTP is a treatment program federally certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) according to 42 CFR § 8, to provide supervised assessment and medication assisted treatment for beneficiaries

who have an opioid use disorder diagnosis. OTPs require registration with the US Drug Enforcement Association (DEA) and licensure by the Division of Health Service Regulation (DHSR).

1.1.10 Opioid Withdrawal Syndrome

Opioid withdrawal syndrome is hyper-excitability caused by the absence of opioids. Symptoms of opioid withdrawal are drug cravings, anxiety, dysphoria, sweating, yawning, excessive tearing, rhinorrhea, insomnia, nausea, vomiting, diarrhea, cramps, muscle aches, and fever. Symptoms may appear within 8-12 hours with resolution after 7-10 days. Long acting drug withdrawal symptoms may appear within 1-3 days and may persist for days to weeks.

1.1.11 Qualified Provider

A physician, nurse practitioner, or physician assistant who has met the requirements and received a waiver under the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe or dispense schedule III, IV, or V medications for the treatment of opioid addiction.

1.1.12 Stabilization

Stabilization is the lowest dose of buprenorphine or buprenorphine-naloxone at which the beneficiary discontinues the use of opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable cravings for the drug of use. The beneficiary is medically stable, fully-supported, able to perform activities of daily living, and substance free either with or without the assistance of medication.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. The NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

a. Medicaid

For office-based opioid treatment, an eligible Medicaid beneficiary who is a minor, 16 through 17 years of age, shall have a documented history of at least two prior unsuccessful withdrawal management attempts.

Refer to NCGS § 90-21.5. *Minor's consent sufficient for certain medical health services.*

b. NCHC

For office-based opioid treatment, an eligible NCHC beneficiary who is a minor, 16 through 17 years of age, shall have a documented history of at least two prior unsuccessful withdrawal management attempts. Refer to NCGS § 90-21.5. *Minor's consent sufficient for certain medical health services.*

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. That is unsafe, ineffective, or experimental or investigational.
2. That is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider’s documentation shows

that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <http://dma.ncdhhs.gov/>

2.2.1 EPSDT does not apply to NCHC beneficiaries

2.2.2 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary’s needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. The procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary’s caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC shall cover OBOT services for a beneficiary when **all** the following components are met: diagnosis and initial evaluation, initial laboratory testing, psychosocial treatment modalities, informed consent, treatment plan, treatment contract, and prescription drug monitoring.

a. Diagnosis and Initial Evaluation

A diagnosis of moderate or severe opioid use disorder supported by a comprehensive assessment signed and dated by the qualified provider completing the assessment is necessary. The assessment must address and document all of the following elements:

1. Screening for concomitant conditions that can necessitate a higher level of care or emergent care;
2. Substance use history consisting of the following: age of first use, substances used, change in effects over time, history of tolerance, history of overdose, history of withdrawal, attempts to quit, current legal issues due to drug use, and current problems with compulsivity or drug cravings;
3. Addiction treatment history consisting of the following: previous treatments for addiction, types of treatments tried, and outcomes of treatment;
4. Psychiatric history consisting of the following: diagnosis or diagnoses, psychiatric treatments recommended or tried, and outcomes of treatment attempts;
5. Family history consisting of the following: substance use disorders in the family, family medical history, and family psychiatric history;
6. Medical history consisting of the following: a detailed review of systems, past medical and surgical history, sexual history, likelihood of pregnancy for female beneficiaries, current and past medications, current medication (prescription and over the counter) doses, allergies, and pain history;
7. Social history consisting of the following: quality of recovery, family, and living environments, and substance use by other members of the support network;
8. Readiness for change consisting of the following: the beneficiary's understanding of their substance use disorder, the beneficiary's interest in treatment now, and whether treatment is voluntary or coerced;
9. A complete physical examination focusing on physical findings related to addiction and any current signs of opioid intoxication, withdrawal, or overdose;
10. A mental status examination evaluating the following: general appearance, behavior and interaction, speech and voice, motor activity, mood and affect, perceptions or hallucinations, thought process and content, insight, judgement, motivation and readiness for change, beneficiary's stated goals and expectations, cognitive function, personality, coping skills, and defense mechanisms. **If the beneficiary's psychiatric disorder is beyond the provider's expertise and comfort**

level, referral to an addiction psychiatrist or psychologist for a full mental health evaluation or formal diagnosis is indicated prior to starting treatment;

11. The qualified provider shall document the benefits outweigh risks when prescribing buprenorphine and buprenorphine-naloxone combination product when the beneficiary is currently prescribed and taking antiretrovirals, hepatitis medication, benzodiazepines, sedatives, tranquilizers, antidepressants, or any other central nervous system depressant; and
12. The qualified provider shall document that office-based opioid treatment and the required counseling is an appropriate level of care for a beneficiary 16 through 17 years of age who meets eligibility requirements in **Subsection 2.1.2.**

Note: Steps 1, 2, 3, 4, 5, 7, 8, and 10 may be performed by a physician extender or behavioral health professional trained in substance use disorders and signed off by the prescribing provider

***Note: The 12 components (listed in subsection 3.2.1.a) of the comprehensive assessment are essential for the thorough care of a beneficiary with a substance use disorder diagnosis; however, completion of the full initial evaluation need not delay the initiation of treatment. Prompt treatment is a priority and completion of the 12 components over two or three visits is permissible at the discretion of the provider.**

b. Initial Lab Testing

Initial laboratory testing is an important aspect of the initial evaluation and placement assessment. A urine pregnancy test must be performed on female beneficiaries of child bearing age unless known to be positive. Toxicology tests for drugs of abuse must be performed on all beneficiaries considered for OBOT services. Baseline labs consisting of serum electrolytes, blood urea nitrogen (BUN) and creatinine, complete blood count (CBC) with differential and platelet count, liver function tests, and lipid profile, may be collected during initial evaluation if deemed necessary by the OBOT provider to aide in determination of appropriateness for buprenorphine or buprenorphine-naloxone therapy. The following tests may be offered according to Centers for Disease Control (CDC) guidelines during the initial evaluation unless known to be positive:

1. Human Immunodeficiency Virus (HIV);
2. Hepatitis B and C;
3. Syphilis; and
4. Purified protein derivative (PPD)

c. Psychosocial Treatment Modalities

Evidence has demonstrated that greater success is achieved when combining medication assisted treatment with education and counseling for opioid dependence when compared to pharmacotherapy alone.

Medicaid and NCHC shall require a minimum of once monthly individual or group therapy sessions during the induction and stabilization phases of treatment conducted by a behavioral health professional licensed to treat substance use disorders and trained in the use of the American Society of Addiction Medicine (ASAM) Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions. Counseling sessions needed beyond induction and stabilization shall be at the discretion of the practitioner and beneficiary, based on the beneficiary's ongoing needs and treatment goals.

The provider shall inquire whether the beneficiary is in counseling for their opioid use disorder and other co-occurring diagnoses, as applicable. If the beneficiary is not currently in counseling, the provider shall promptly refer the beneficiary to a licensed, North Carolina Local Management Entity-Managed Care Organization (MCO) enrolled, behavioral health professional. Optimally, counseling should begin within 48 hours of induction if urgent need is indicated.

Note: Urgent need for substance abuse counseling is defined as a condition in which the person is not imminently at risk of harm to self or others or unable to adequately care for self, but, by virtue of their substance use, is in need of prompt assistance to avoid further deterioration in the person's condition which could require emergency assistance. The initial appointment for an urgent need must be within 48 hours.

If the beneficiary has already initiated counseling for substance use disorder, the qualified provider shall request ASAM placement recommendations from the behavioral health professional to ensure the beneficiary's needs do not exceed early intervention or outpatient service capability and document the results in the health record within ten (10) calendar days of induction.

If the beneficiary has not yet begun counseling for substance use disorder, the placement recommendations supplied by the behavioral health professional shall be documented in the health record within ten (10) calendar days of counseling initiation.

Alcoholics Anonymous (AA), Narcotics Anonymous (NA), Self-Management and Recovery Training (SMART) recovery and other self-help or guided recovery groups are not required by NC Medicaid or NCHC for continued service, however the OBOT provider can have additional requirements based on the beneficiary's needs

If the beneficiary was identified by the behavioral health professional as requiring intensive outpatient services or higher, it does not preclude Office-based Opioid Treatment in addition to the higher level of care required. Documentation must be placed in the health record that a referral has been made, where the beneficiary was referred to, and whether the beneficiary was

accepted. If there is a delay in treatment at the appropriate level of care due to space availability, OBOT services may continue. The OBOT provider shall document in the health records that the beneficiary is awaiting an opening in the higher level of care and when placement availability is expected. This documentation must be updated weekly until the beneficiary is placed in the higher level of care or no longer requires advanced services.

Counseling attendance records signed by the behavioral health professional shall be obtained by the OBOT provider and placed in the health record.

d. Informed Consent

Before induction is initiated, the beneficiary shall be made aware of all treatment options available to them as well as the risks and benefits of office-based opioid treatment. Informed consent for office-based buprenorphine or buprenorphine-naloxone treatment must consist of all of the following information:

1. What buprenorphine or buprenorphine-naloxone is, how it works, how to administer, potential side effects, and signs of allergic reaction;
2. The importance of being in withdrawal for induction and consequences of not being in a state of withdrawal;
3. Buprenorphine or buprenorphine-naloxone maintains physical dependence and a sudden discontinuation may precipitate withdrawal;
4. A description of induction, stabilization, maintenance, and tapering phases of treatment and expected or estimated timeframes for each phase;
5. Counseling requirements specific to this policy and any additional requirements as directed by the OBOT qualified provider;
6. Signs and symptoms of overdose and withdrawal due to inadequate dosing during the induction phase of treatment;
7. Possible interaction between buprenorphine or buprenorphine-naloxone and other prescription medications, such as HIV and hepatitis medications;
8. Risk of using buprenorphine or buprenorphine-naloxone while taking benzodiazepines, alcohol, or other central nervous system depressants. **It must be noted that deaths have occurred when buprenorphine was taken concurrently with benzodiazepines;**
9. Obstetrical risks for pregnant women with continued substance use. Risks to the pregnancy, mother, and fetus include preeclampsia, miscarriage, premature delivery, intrauterine growth restriction (IUGR), Neonatal Abstinence Syndrome (NAS) and fetal death; and
10. Any other information deemed necessary by the qualified provider.

e. Treatment Plan

A documented, individualized treatment plan must be kept in the beneficiary's health record and updated as goals, beneficiary condition, expectations change. Topics to be addressed in the treatment plan are:

1. All current medications and doses;
2. Contact information for ancillary service providers for coordination of care;
3. Current medical and psychological diagnoses;
4. Short and long term goals with expected timeframes for meeting goals;
5. Interventions or treatment modifications based on subjective and objective findings;
6. Contingency plan for non-compliance with treatment;
7. Signed release of information and notice of privacy practices; and
8. Any other information deemed necessary by the qualified provider.

f. Treatment Contract

Medicaid and NCHC shall delegate the decision to obtain a signed treatment contract to the qualified provider. If the provider elects to obtain a signed treatment contract, the following elements may be addressed in the treatment contract:

1. Agreement to keep all scheduled appointments;
2. Agreement to adhere to all office policies;
3. Agreement not to sell, share, or give any medications to another person;
4. Agreement to store medication in a secure location;
5. Understanding that mixing buprenorphine or buprenorphine-naloxone with benzodiazepines, alcohol, and other central nervous system depressants can lead to respiratory distress and deaths have been reported;
6. Agreement to take all medication as prescribed and to inform the OBOT provider when any medication is changed, discontinued, or prescribed by another provider;
7. Agreement to use an effective form of birth control during the entire course of treatment and to inform the OBOT provider immediately if pregnancy is suspected;
8. Timeframe in which to return to the office for urine drug screens and pill counts;
9. Specific stepwise consequences for unanticipated drug test results, sample tampering, diversion, lost or stolen medications, missed appointment, discrepancies between beneficiary supplied medication list and the North Carolina Controlled Substance Reporting System and any other violation of the treatment contract or non-compliance with the treatment plan;
10. An explanation of how requests for early refills or reports of lost, stolen, or damaged medication are handled; or
11. Any other information deemed necessary by the qualified provider.

g. Prescription Drug Monitoring

A check of the North Carolina Controlled Substance Reporting System (CSRS) must be performed and the results documented in the health record prior to beginning induction to ensure a beneficiary is not currently receiving buprenorphine or buprenorphine-naloxone from another provider.

Any prescriptions found in this query, particularly opioids and benzodiazepines, must be confirmed with the beneficiary.

CSRS inquiries must also be conducted and documented with any buprenorphine or buprenorphine-naloxone dose change, any exceptions (signs or symptoms of withdrawal, reported loss of medication, unexpected result on urine drug test, admission of using illicit substances); **or** every six months at a minimum if the beneficiary is stable. If undisclosed prescriptions are discovered, patients shall be asked to sign a release of information (ROI) form allowing their treatment status to be communicated to the prescribers; signing the ROI is requisite for remaining in treatment.

3.2.2 Phases of Treatment

3.2.2.1 Induction

Induction usually takes place over the course of one (1) week either at home or in the office setting. Office visits may be as frequently as daily or infrequently as weekly based on clinical findings and the needs of the beneficiary. The goal of induction is to find the lowest dose of buprenorphine or buprenorphine-naloxone combination at which the beneficiary discontinues use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no uncontrollable cravings for drugs of abuse. Induction protocol will depend on the opioids of abuse and whether the beneficiary is in a state of withdrawal at time of induction.

3.2.2.2 Stabilization

Stabilization usually takes place over the course of one to three months with office visits being weekly or bi-weekly until full stabilization has occurred as evidenced by stable buprenorphine or buprenorphine-naloxone dose, no reported cravings or withdrawal, and urine drug screen is negative for opioids and positive for buprenorphine or buprenorphine-naloxone.

3.2.2.3 Maintenance

The beneficiary is opioid free without signs of withdrawal, no increase in buprenorphine or buprenorphine-naloxone has been required, there have been no irregularities with urine drug screens or drug registry inquiries, and the beneficiary is making progress towards or meeting desired goals. Once maintenance stage has been achieved, visits may be as frequent as once (1) monthly if deemed necessary by the qualified provider. Maintenance treatment may continue as long as the beneficiary meets the continued service criteria in **Subsection 3.2.4** or they meet discharge criteria in **Subsection 3.2.5** and the tapering process begins. Extenuating circumstance may arise that necessitate visits more frequently than once per month and medical justification for more frequent visits must be documented in the beneficiary's health record.

3.2.3 Urine Drug Screens

Presumptive urine drug testing (UDT) may be ordered by the qualified provider caring for a beneficiary when it is necessary to rapidly obtain or integrate results into clinical assessment and treatment decisions.

Definitive UDT may be ordered by the qualified provider caring for a beneficiary when it is necessary to confirm any one of the following when making clinical treatment decisions:

- a. Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT;
- b. Definitively identify specific drugs in a large family of drugs;
- c. Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic or analog drugs;
- d. Identify drugs when a definitive concentration of a drug is needed to guide management
- e. Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a beneficiary's self-report, presentation, medical history, or current prescribed pain medication plan;
- f. Rule out an error as the cause of a presumptive UDT result;
- g. Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; or
- h. Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

The clinician's rationale for the presumptive and definitive UDT and the tests ordered must be documented in the patient's medical record.

3.2.4 Continued Service Criteria

The beneficiary shall meet the following criteria for continued service:

- a. The beneficiary is attending office visits and counseling as required, but the desired outcome or level of functioning has not been restored, improved, or sustained over the timeframe outlined in the beneficiary's treatment plan; **or**
- b. The beneficiary has attended office visits and counseling as required, has achieved current treatment plan goals, and additional goals are indicated as evidenced by documented symptoms.

3.2.5 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 level of care; or

- 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.

3.2.6 Telemedicine

Telemedicine and telepsychiatry services may be used for the medical or counseling portions of OBOT services providing they are in accordance with DMA policy 1H, *Telemedicine and Telepsychiatry*. If telemedicine is utilized for the medical management portion of OBOT services, the beneficiary shall be located at a facility where a physical exam can be conducted by a nurse practitioner, physician assistant, or MD at the time of the telemedicine visit.

3.2.7 Medicaid Additional Criteria Covered

In addition to the specific criteria covered in **Section 3.2** of this policy, Medicaid shall cover OBOT when the following criteria are met for the following special populations:

- a. **Pregnant Women:** If it is determined by the OBOT provider that a higher level of care is not required and the beneficiary meets criteria for Office-based Opioid Therapy in **subsection 3.2**, the beneficiary shall be referred for prenatal care, encouraged to remain in a substance use treatment program, and be considered for a licensed Opioid Treatment Program if office-based treatment compliance cannot be guaranteed.

Note: Providers shall refer pregnant beneficiaries to another provider if they do not have the skill set or comfort level to care for a pregnant beneficiary with a substance use disorder

- b. **Women of Childbearing Age:** Shall be encouraged to use effective birth control methods and referred for family planning services. In the event of pregnancy, the beneficiary shall inform the qualified provider immediately as a change in the treatment plan and medication may be required if the beneficiary is currently taking buprenorphine combined with naloxone.
- c. **Breastfeeding mothers:** shall be encouraged to remain in OBOT services for the duration of their breastfeeding. Buprenorphine metabolite levels secreted in breastmilk is thought to be low. Mothers with HIV, or with active alcohol, cocaine, or amphetamine substance use require special consideration when encouraging breastfeeding.

3.2.8 NCHC Additional Criteria Covered

In addition to the specific criteria covered in **Section 3.2** of this policy, NCHC shall cover OBOT when the following criteria are met for the following special populations:

- a. **Women of Childbearing Age:** Shall be encouraged to use effective birth control methods and referred for family planning services. In the event of pregnancy, the beneficiary shall inform the qualified provider immediately as a change in the treatment plan and medication will be required.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. The procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover Office-based Opioid Treatment services when:

- a. A diagnosis of substance use disorder for opioids cannot be made or supported by assessment or documentation;
- b. The provider has not complied with the requirements and limitations in **Sections 5.0, 7.0, and subsection and 3.2**;
- c. Initial diagnosis and evaluation, or prescribing of buprenorphine or buprenorphine-naloxone by physicians, nurse practitioners, physician assistants, and locum tenens physicians without a DATA 2000 waiver; or
- d. The beneficiary no longer meets the requirements in **Subsection 3.2.4**.

4.2.2 Medicaid Additional Criteria Not Covered

Medicaid shall not cover medical office visits beyond the annual legislative limit for mandatory services for any the following circumstances:

- a. The signed treatment contract is violated without a documented intervention by the provider;
- b. Buprenorphine or buprenorphine-naloxone is not detected by qualitative or quantitative testing on more than two occasions in a consecutive 90 calendar day period without a documented medical cause; or
- c. Failure of the provider to make and document changes to the treatment plan based on subjective or objective data that suggests a medication dose change or other change in treatment is required as evidenced by signs or symptoms of withdrawal, ongoing use of illicit substances, missed appointments, or evidence of diversion.

4.2.3 NCHC Additional Criteria Not Covered

NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:

- a. No services for long-term care.
- b. No nonemergency medical transportation.
- c. No EPSDT.
- d. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

- a. Medicaid and NCHC shall not require prior approval for initiation of Office-based Opioid Treatment services.
- b. Medicaid and NCHC shall require Pharmacy Prior Authorization for use of buprenorphine or buprenorphine-naloxone combination medication (refer to pharmacy prior approval and renewal criteria located at <https://www.nctracks.nc.gov/>); and
- c. Medicaid and NCHC shall require prior approval for office visits for Office-based Opioid Treatment services that are in excess of the annual legislated limit for mandatory services.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. All health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

For continued OBOT services beyond the annual legislative limit for mandatory services, the OBOT provider shall submit all of the following:

- a. current treatment plan;
- b. signed treatment contract (if one was obtained);
- c. behavioral health attendance records (if beneficiary is attending counseling);
- d. any disciplinary contracts signed by the beneficiary and provider;
- e. last five encounter notes (or initial evaluation through current if the beneficiary has not had five visits); and
- f. last ten urine drug screens (both presumptive and definitive) by date of service

5.3 Additional Limitations or Requirements

None Apply.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation and be enrolled as a North Carolina Medicaid provider;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. Bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

Qualified providers shall complete the required specialized training, and shall be granted the waiver authority from the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe and dispense buprenorphine or buprenorphine-naloxone in an office-based practice. In addition to the DATA 2000 waiver, both DEA and North Carolina Division of Mental Health, Developmental Disabilities and Substance Abuse Services Drug Control Unit registrations are required to operate as an Office-based Opioid Treatment Practice. Providers working in licensed Opioid Treatment Programs (OTPs) shall dispense buprenorphine or buprenorphine-naloxone following the federal and state OTP rules and policies. Nurses working in licensed Opioid Treatment Programs (OTPs) shall administer buprenorphine or buprenorphine-naloxone following the federal and state OTP rules and policies.

Providers who utilize Buprenorphine or buprenorphine-naloxone in Office-based Opioid Treatment (OBOT) shall be able to recognize opioid use disorders and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Providers shall demonstrate required qualifications according to DATA 2000 and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA).

Providers of counseling and other therapeutic services to a beneficiary in an Office-based Opioid Treatment program shall 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 a beneficiary in an Office-based Opioid Treatment program shall follow the outpatient Clinical Coverage Policy 8C, *Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers*, located on DMA's website at <http://dma.ncdhhs.gov/>.

6.2 Provider Certifications

6.2.1 SAMHSA Waiver

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

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

- Provider(s) shall comply with the following in effect at the time the service is rendered:
- All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
 - All DMA's clinical coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

In addition to the above, the provider shall comply with the following:

- Policies of the North Carolina Medical Board; and
- Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

7.2 Documentation

7.2.1 Health Record Documentation

Provider(s) shall document and maintain, in each beneficiary's health record, at a minimum, the following:

- Demographic information: the beneficiary's full name, contact information, date of birth, race, gender, and admission date;
- The beneficiary's name and date of birth must be on each page generated by the office;
- The health record number of the beneficiary must be on each page generated by the office;
- The Beneficiary's Identification Number for services must be on all contracts, progress note pages, billing records, and other documents or forms that have a place for it;
- An individualized treatment plan and treatment contract;
- Initial diagnosis and any tools used during the initial evaluation period;
- Signed and dated copies of any testing, consultations, encounter notes, and reports; and

- h. Communication regarding coordination of care activities; and

7.2.2 Encounter Notes

There must be a note documenting the following information for each encounter. Notes may be handwritten if legible, otherwise they must be dictated or in electronic health record (EHR), reviewed, and signed within three business days of the encounter. Pre-filled electronic health records must be reviewed for accuracy prior to being electronically signed. All notes must be dated and the provider shall sign all documents with their name and credentials.

Encounter documents must contain the following elements at a minimum:

- a. Date of service;
- b. Subjective response to treatment;
- c. Review of Systems(ROS) which may be carried over on electronic charting or documented in the handwritten or dictated note;
- d. Documentation of physical examination and possible signs of withdrawal or intoxication;
- e. Medication list, including new and changed prescriptions, updated at each visit;
- f. Results of periodic tests and interventions such as urine drug screens, pill counts, CSRS inquiries, and actions taken for unanticipated lab results or missed appointments;
- g. Any consults made with other providers (mental health, OB/GYN, PCP, etc.) or family members of the beneficiary; and
- h. Follow up plans.

Note: There needs to be clear documentation when a beneficiary cancels, they no show or reschedules encounters. If there is any gap in services, there needs to be an explanation in the health record about what the issue is. If the client has attendance problems, that needs to be addressed with the client, and documented in the health record with an explanation for the missed appointments.

Note: When an electronic signature is entered into the electronic record by agency staff (employees or authorized individuals under contract with the agency), the standards for Electronic Signatures found in the September 2011 Medicaid Bulletin (<http://dma.ncdhhs.gov/document/archived-medicaid-bulletins-2010-2013>) must be followed. In addition, electronic signatures must comply with federal guidelines found in 45 CFR parts 160 and 162.

8.0 Policy Implementation and History

Original Effective Date: Month Day, Year

History:

Date	Section or Subsection Amended	Change
02/01/2017	All Sections and Attachment(s)	New policy on Buprenorphine or buprenorphine-naloxone Treatment Services.
02/21/2017	Attachment A (C)	Typographical error fixed; 99213 changed to 99203 on first line of CPT Codes.
03/15/2017	Subsection 3.2.1 (c)	<p>Clarified counseling requirements as follows: Medicaid and NCHC shall require a minimum of once monthly individual or group therapy sessions during the induction and stabilization phases of treatment conducted by a behavioral health professional licensed to treat substance use disorders and trained in the use of the American Society of Addiction Medicine (ASAM) Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions. Counseling sessions needed beyond induction and stabilization shall be at the discretion of the practitioner and beneficiary, based on the beneficiary’s ongoing needs and treatment goals.</p> <p>The provider shall confirm the beneficiary is in counseling for their opioid use disorder and other co-occurring diagnoses, as applicable. If the beneficiary is not currently in counseling, the provider shall promptly refer the beneficiary to a licensed, North Carolina Local Management Entity-Managed Care Organization (MCO) enrolled, behavioral health professional. Optimally, counseling should begin within 48 hours of induction if urgent need is indicated.</p>
03/15/2017	Subsection 5.2.2 (c)	Added “if beneficiary is attending counseling”
08/01/2017	Subsection 3.2.1 (a)	<p>Added clarifying statement: **Note: The 12 components (listed in subsection 3.2.1.a) of the comprehensive assessment are essential for the thorough care of a beneficiary with a substance use disorder diagnosis; however, completion of the full initial evaluation need not delay the initiation of treatment. Prompt treatment is a priority and completion of the 12 components over two or three visits is permissible at the discretion of the provider.</p>

Date	Section or Subsection Amended	Change
08/01/2017	Subsection 3.2.1 (c)	Clarified counseling requirements as follows: The provider shall inquire whether the beneficiary is in counseling for their opioid use disorder and other co-occurring diagnoses, as applicable. If the beneficiary is not currently in counseling, the provider shall promptly refer the beneficiary to a licensed, North Carolina Local Management Entity-Managed Care Organization (MCO) enrolled, behavioral health professional. Optimally, counseling should begin within 48 hours of induction if urgent need is indicated.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, Tenth Revision (ICD-10) and Procedures

Provider(s) shall report the ICD-10 and procedures code(s) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

CPT Code(s)			
99201	99202	99203	99204
99205	99211	99212	99213
99214	99215	99241	99242
99243	99244	99245	T1015

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Office, clinics, and Federally Qualified Health Centers

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at <http://www.ncdhhs.gov/dma/plan/sp.pdf>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <http://dma.ncdhhs.gov/>