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Related Clinical Coverage Policies

Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:

1.0 Description of the Procedure, Product, or Service

The Opioid Treatment Program (OTP) Service is an organized, outpatient treatment service for beneficiaries with an opioid use disorder. The OTP service utilizes methadone, buprenorphine formulations, naltrexone or other drugs approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorders. It is delivered by an interdisciplinary team of professionals trained in the treatment of opioid use disorders who provide person-centered and recovery-oriented individualized treatment, case management, and health education. A range of cognitive, behavioral, and other substance use disorder focused therapies, reflecting a variety of treatment approaches, shall be utilized to address the elimination of the use of any substance that could compromise recovery.

1.1 Definitions

None Apply

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. <u>Medicaid</u>

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Medicaid shall cover the Opioid Treatment Program Service for an eligible beneficiary 18 years of age and older who meets the criteria in **Section 3.0** of this policy.

b. NCHC

NCHC shall cover the Opioid Treatment Program Service for an eligible beneficiary who is 18 years of age till he or she reaches their 19th birthday and meets the criteria in Section 3.0 of this policy.

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: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 18 years of age

NC Medicaid 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 NC Medicaid 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 the Opioid Treatment Program Service when the beneficiary meets the following specific criteria:

a. A DSM-5 (or any subsequent editions of this reference manual) diagnosis of a severe opioid use disorder **AND**

b. Meets the American Society of Addiction Medicine (The ASAM Criteria, 3rd edition or subsequent editions of this reference manual) for Opioid Treatment Services (Opioid Treatment Program specific) level of care.

Admission Criteria

Due to the nature of this OTP service, a comprehensive clinical assessment (CCA) is not required prior to admission. An initial assessment, physical exam and service plan must be completed by a physician or approved medical provider to establish medical necessity for this service as a part of the admission process.

The initial assessment must include the following documentation in the service record:

a. the beneficiary's presenting problem;

b. the beneficiary's needs and strengths;

c. a provisional or admitting diagnosis;

d. a pertinent social, family, and medical history; and

e. other evaluations or assessments as appropriate.

The program physician may bill an E/M code separately for the admission evaluation and physical exam.

Within 5 calendar days of the admission, a comprehensive clinical assessment (CCA) shall be completed by a licensed professional to determine an ASAM level of care for discharge planning. Information from the abbreviated assessment may be utilized as part of the current CCA. Relevant diagnostic information must be obtained and be included in the treatment or service plan.

The clinician may update the initial assessment or a recent CCA from another clinician if a substantially equivalent assessment is available and reflects the current level of functioning. Information from that assessment may be utilized as a part of the current comprehensive clinical assessment. Relevant diagnostic information must be obtained and be included in the treatment or service plan.

Continued Stay Criteria

The beneficiary is eligible to continue this service if there is

A. Documentation of the beneficiary's current status based on the ASAM Criteria 6 dimensions for Opioid Treatment Program that indicates a need for continued stay. Justification must be provided based on current level of functioning in ASAM Dimensions 1-6. Documentation must include details of the assessment of each ASAM dimension.

AND

B. The beneficiary meets one of the following:

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1. The beneficiary has achieved current PCP goals and additional goals are indicated as evidenced by documented symptom; OR
2. The beneficiary is making satisfactory progress toward meeting goals and there is documentation that supports that continuation of this service will be effective in addressing the goals outlined in the PCP; OR
3. The beneficiary is making some progress, but the specific interventions in the PCP need to be modified so that greater gains, which are consistent with the beneficiary's pre-morbid or potential level of functioning are possible.

OR

C. If the beneficiary is functioning effectively with this service and discharge would otherwise be indicated, this service must be maintained when it can be reasonably anticipated that regression is likely to occur if the service is withdrawn. The decision shall be based on ANY ONE of the following:

a. history of regression in the absence of opioid treatment is documented in the beneficiary record; or
b. presence of a DSM-5 (or any subsequent editions of this reference material) diagnosis that would necessitate a chronic disease management approach, in the event that there are medically sound expectations that symptoms will persist and that ongoing treatment interventions are needed to sustain functional gains; or
c. there is a lack of a medically appropriate step down.

Transition and Discharge Criteria
The beneficiary meets the criteria for transfer or discharge if the following applies:

A. Documentation of the beneficiary's current status based on the ASAM Criteria 6 dimensions for Opioid Treatment Program that indicates a need for transfer or discharge. Justification must be provided based on current level of functioning in ASAM Dimensions 1-6. Documentation must include details of the assessment of each ASAM dimension.

AND

B. Meets <u>one</u> of the following:

1. The beneficiary's level of functioning has improved with respect to the goals outlined in the PCP, inclusive of a transition plan to step down to a lower level of care and there are no medical expectations that symptoms will persist without ongoing medication or change in medication;

2. The beneficiary has achieved positive life outcomes that support stable and ongoing recovery, there is low potential for regression, there is no medical expectation that symptoms will persist and ongoing treatment interventions are not needed to sustain functional gains at this level of care, there is a transition plan to step down to a lower level of care and the beneficiary is no longer in need of the Opioid Treatment Program Service;
3. The beneficiary is not making progress or is regressing, and all reasonable strategies and interventions have been exhausted, indicating a need for more intensive services;
4. The beneficiary or legally responsible person no longer wishes to receive the Opioid Treatment Program Service.

3.2.2 Medicaid Additional Criteria Covered

None Apply

3.2.3 NCHC Additional Criteria Covered

None Apply

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:

d. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
e. the beneficiary does not meet the criteria listed in **Section 3.0;**
f. the procedure, product, or service duplicates another provider's procedure, product, or service; or
g. 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 the following:

a. Any services included in the Opioid Treatment Program Service per diem as separate billable services unless otherwise indicated in this clinical coverage policy;
b. Transportation for the beneficiary or family;
c. Any habilitation activities;
d. Time spent doing, attending or participating in recreational activities unless tied to specific planned social skill assistance;

e. Clinical and administrative supervision of Opioid Treatment Program Service staff, which is covered as an indirect cost and part of the rate;
f. Covered services that have not been rendered;
g. Childcare services or services provided as a substitute for the parent or other individuals responsible for providing care and supervision;
h. Services provided to teach academic subjects or as a substitute for education personnel;
i. Interventions not identified on the beneficiary's Person-Centered Plan;
j. Services provided without prior authorization by the PIHP;
k. Services provided to children, spouse, parents or siblings of the eligible beneficiary under treatment or others in the eligible beneficiary's life to address problems not directly related to the eligible beneficiary's needs and not listed on the Person-Centered Plan; and
l. Payment for room and board.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply

4.2.3 NCHC Additional Criteria Not Covered

a. None Apply
b. 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:
    1. No services for long-term care.
    2. No nonemergency medical transportation.
    3. No EPSDT.
    4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

    Note: **Subsection 4.2.3(b)** applies to NCHC only.

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

Medicaid and NCHC shall require prior approval for the Opioid Treatment Program (OTP) Service beyond the unmanaged unit limitation. Coverage of the OTP service is limited to four (4) unmanaged units once per episode of care per state fiscal year. Coverage of unmanaged units is limited to two (2) episodes of care per state fiscal year. Refer to Subsection 5.3 for additional limitations.

Upon admission to Opioid Treatment Program services, a beneficiary is allowed four (4) pass-through units. An authorization from the PIHP, PHP, or utilization management contractor is required after the initial 4 unit pass-through. A service order shall be signed prior to or on the first day service is rendered. Refer to Subsection 5.4 of this policy.

The PIHP, PHP or utilization management contractor may offer less restrictive limitations on unmanaged units but may not impose more restrictive limitations than the Medicaid Policy. All units beyond Medicaid limitations or limitations imposed by the PHIP, PHP, or utilization management contractor require prior approval.

PIHPs, PHPs, or utilization management contractor that offer less restrictive limitations on unmanaged units than that of the Medicaid policy shall provide assurance that there are mechanisms in place to prevent over-billing for services.

Providers shall seek prior approval if they are uncertain that the beneficiary has reached the unmanaged unit limit for the fiscal year.

Provider shall collaborate with beneficiary's existing provider to develop an integrated plan of care.

Prior authorization is not a guarantee of claim payment.

5.2 Prior Approval Requirements

5.2.1 General

None Apply

5.2.2 Specific

Utilization management of covered services is a part of the assurance of medically necessary service provision. Authorization, which is an aspect of utilization management, validates approval to provide a medically necessary covered service to an eligible beneficiary.

Services are based upon a finding of medical necessity, must be directly related to the beneficiary's diagnostic and clinical needs, and are expected to achieve the specific rehabilitative goals detailed in the beneficiary's Person-Centered Plan (PCP). Medical necessity is determined by North Carolina community practice standards, as verified by the PIHP, PHP or utilization management contractor who evaluates the request to determine if medical necessity supports intensive services. Medically necessary services are authorized in the most cost-effective modes, if the treatment that is made available is similarly efficacious as services requested by the beneficiary's physician, therapist, or another licensed practitioner. The medically necessary service must be recognized as an accepted method of medical practice or treatment.

Duration of treatment varies with the severity of the beneficiary's illness and their response to treatment and desire to continue treatment.

Reauthorization

Medicaid may cover up to 6 months for the authorization based on medical necessity documented in the PCP, the authorization request form, documentation of the beneficiary's current status based on the ASAM Criteria 6 dimensions for Opioid Treatment Program that indicates a need for continued stay and supporting documentation. Reauthorization should be submitted prior to initial or concurrent authorization expiring.

No more than 1 unit can be billed per week.

Per Diem=1 Week

5.3 Additional Limitations or Requirements

A beneficiary can receive the Opioid Treatment Program Service from only one provider organization.

Service Orders
Service orders are a mechanism to demonstrate medical necessity for a service and are based upon an assessment of the beneficiary's needs. A signed service order must be completed by a physician, physician assistant, or nurse practitioner, per his or her scope of practice. Service orders are valid for twelve (12) months. Medical necessity must be revisited, and service must be ordered at least annually, based on the date of the original service order.

ALL the following apply to a service order:
a. Backdating of the service order is not allowed;
b. Each service order must be signed and dated by the authorizing professional and must indicate the date on which the service was ordered; and
c. A service order must be in place prior to or on the first day that the service is initially provided, to bill Medicaid for the service. Even if the beneficiary is retroactively eligible for Medicaid, the provider cannot bill Medicaid without a valid service order.

5.4 Documentation Requirements

The service record documents the nature and course of a beneficiary's progress in treatment. To bill Medicaid or NCHC, providers must ensure that their documentation is consistent with the requirements contained in this policy. The staff member who provides the service is responsible for accurately documenting the services billed to and reimbursed by Medicaid. The staff person who provides the service must sign and date the written entry. The signature must include credentials for the staff member who

provided the service. The PCP and a documented discharge plan must be discussed with the beneficiary and included in the service record.

5.4.1 Contents of a Service Note

For this service, a full service note is required for documenting all counseling or therapy sessions, case management activities, health education and for any other significant activities or events, changes in status, or situations outside the scope of medication administration for each contact or intervention for each date of service, written and signed by the person who provided the service is required.

More than one intervention, activity, or goal may be reported in one service note, if applicable and provided by the same staff member. A service note must include all the following elements:

a. Beneficiary's name;
b. Medicaid identification number;
c. Date of the service provision;
d. Name of service provided;
e. Type of contact;
f. Place of service;
g. Purpose of contact as it relates to the PCP goals:
h. Description of the intervention provided. Documentation of the intervention must accurately reflect treatment for the duration of time indicated;
i. Duration of service, amount of time spent preforming the intervention;
j. Assessment of the effectiveness of the intervention and the beneficiary's progress towards the beneficiary's goals; and
k. Date and signature and credentials or job title of the staff member who provided the service.

Each service note page must be identified with the beneficiary's name, Medicaid identification number and record number.

5.4.2 Content of a Medication Administration Record

A Medication Administration Record (MAR) or electronic Medication Administration Record (eMAR) shall be utilized to document each administration of methadone, buprenorphine, naltrexone, or other medication ordered for the treatment of an opioid use disorder. In addition, this service requires a record of all take-home doses ordered by a program physician, physician assistant or nurse practitioner and prepared for the beneficiary, and each Opioid Treatment Program [OTP] Exception Request and Record

of Justification submitted to the State Operated Treatment Administrator and Center for Substance Abuse Treatment under 42CFR § 8.11 (h).

Any of the following occurrences is considered a clinical event and is required to be documented in a full service note, a modified service note, the MAR with appropriate justification or physician order:

a. A change in medication or medication dose
b. A medication error
c. An adverse reaction to medication
d. A caution or advisory regarding a potential medication interaction
e. An OTP Exception Request and Record of Justification
f. A take-home level change
g. A positive alcohol or drug screening result
h. Outcome of a bottle call-back or pill count
i. An unexpected finding for the individual from an OTP query of the NC Controlled Substance Reporting System or other state prescription monitoring program
j. A report of possible medication diversion
k. A concern regarding safe medication storage
l. An event related to beneficiary instability or non-compliance with program requirements, including required program attendance and adherence with behavioral expectations in the clinic setting
m. Change in medical status
n. Provision of naloxone rescue kit and education

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;
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

An opioid treatment program is operated under a defined set of policies and procedures, including admission, discharge, and continued service criteria stipulated by federal regulations (42 CFR 8.12) and state regulations.

This facility must be licensed under 10A NCAC 27G .3600 rules, unless provided by a IHS or compact operated by a Federally Recognized Tribe as allowed in 25 USC 1621t and 1647a.
NC Division of Health Service Regulation
Mental Health Licensure and Certification Section

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Refer to https://info.ncdhhs.gov/dhsr/mhlcs/mhpage.html

6.2 Provider Certifications

Staffing Requirements

Medical Staff		
Position	**Minimum Requirements**	**Responsibilities**
Medical Director	The **Medical Director** must be licensed as a physician in North Carolina and meet one of the following requirements: a. Have two years documented experience in the provision of services to persons with a substance use disorder, including at least one year of experience in the treatment of opioid use disorder with medication. **OR** b. has a current certification in addiction medicine by the American Society of Addiction Medicine (ASAM) or the American Board of Preventive Medicine (ABPM), or in addiction psychiatry by the American Board of Psychiatry and Neurology. **AND** The **Medical Director** must be proficient in the treatment protocols for all FDA-approved medications for opioid use disorders.	The medical director is responsible for assuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered at the OTP are conducted in compliance with federal regulations at all times. The medical director should be present at the program a sufficient number of hours to assure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation. Responsibilities also include ensuring regulatory compliance of the opioid treatment program. • Responsible for Providing consultation to after hours medical or mental health emergencies. • Responsible for providing supervision of Physician Extender as necessary.
Program Physician/Physician Extender	a. The **OTP program physician** (with appropriate federal waiver of 42 CFR Part 8.12 (h)) must be actively licensed with the NC Medical Board **or physician assistant** (with appropriate federal waiver of 42 CFR Part 8.12	The **program physician (or physician extender with appropriate waiver)** is responsible for providing all medical services according to the

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	(h)) must be licensed and in good standing with the NC Medical Board and certified with National Commission on Certification of Physician Assistants (NCCPA) and in good standing **or nurse practitioner** (with appropriate federal waiver of 42 CFR Part 8.12 (h)) must be licensed and in good standing with the NC Board of Nursing (NCBON). **AND** b. Have at least 1 year of experience in the provision of substance use disorder treatment services or be supervised by the OTP medical director or be supervised by the OTP program physician who holds current certification in addiction medicine by the American Society of Addiction Medicine (ASAM) or the American Board of Preventive Medicine (ABPM), or in addiction psychiatry by the American Board of Psychiatry and Neurology	policies and protocols of the opioid treatment program under the supervision of the Medical Director. A physician or physician extender shall be available for consultation and verbal medication orders 24 hours a day, 365 days a year. The physician or physician extender must be able to conduct intakes and induction services, and ongoing patient care 5 days per week. All other physician medical services may be provided physically on-site or through telehealth as medically appropriate. Responsibilities also include the following: • Perform a medical history and physical exam; • Determine diagnosis of opioid use disorder per program eligibility requirements; •Responsible for monitoring the Controlled Substance Reporting System (CSRS); • Review and approve person-centered plans; • Determine medically necessary dosage and order for FDA-approved opioid use disorder medications including dosage changes; • Evaluate, prescribe and/or monitor all medications currently being taken by the beneficiary including coordination with other prescribers; • Order take-home privileges in accordance with the eight-point criteria set forth in 42 CFR 8.12; • Order medically necessary medical and laboratory tests; • Submit appropriate documentation to the designated state and federal authorities for

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		take home and other protocol exceptions; • Provide case consultation with interdisciplinary treatment team; • Assess for co-occurring medical and psychiatric disorders; • Make appropriate referrals and follow up for treatment of co-occurring medical and/or psychiatric disorders; and • Coordinate care with other medical and/or psychiatric providers.
Nursing Staff	The **supervising Registered Nurse** must have, at a minimum, one year of experience working with adults with a substance use disorder. a. The Supervising Registered Nurse must hold active licensure as an RN and be in good standing with the NCBON AND b. must have, at a minimum, one year of experience working with adults with a substance use disorder.	The **supervising Registered Nurse** will be responsible for maintaining an adequate level of nursing for the program's dispensing and medical operations under the supervision of the medical director. Nursing staff are responsible for performing the following key roles, with LPNs responsible for tasks within their scope of practice and under the supervision of an RN. When the supervising RN, physician, NP or PA is not on site an on-call RN, physician, NP or PA must be continuously available to the LPN whenever providing beneficiary care. Continuous availability includes the ability to be available by phone immediately and physically arrive within one hour and be present on site in a timely manner as much as needed to address beneficiary assessment and care needs. <u>Nursing staff responsibilities also include the following</u>: • Conducts a nursing evaluation upon admission in accordance with their scope of work (RN

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		only); • Responsible for monitoring the Controlled Substance Reporting System (CSRS), when delegated by a physician; • Provides ongoing nursing assessment, planning and evaluation of beneficiaries in accordance with their scope of work (RN only); • Prepares and supplies medication to beneficiaries, maintaining medication inventory records and logs in compliance with federal and state regulations; • Provide documentation in the beneficiary's service record of all nursing activities performed related to beneficiary care; • Ensures medical orders are being followed and carried out; • Provide psychoeducation, including HIV/AIDS, TB, Hepatitis C, pregnancy and other health education services; • Coordinates medical treatment and referral for biomedical problems; • Performs auxiliary testing based on medical orders; • Consults with the medical director, program physician, physician assistant or nurse practitioner for guidance in medical matters concerning the well-being of beneficiaries; and • Participates in staff meetings and treatment team meetings.

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Program Administrative and Clinical Staff			
Position	**FTEs**	**Minimum Requirements**	**Responsibilities**
Program Director	**1.0 FTE Program Director** *The Program Director does not count toward the 1:50 LCAS, LCAS-A or Certified Alcohol & Drug Counselor to beneficiary staff ratio, as described in 10A NCAC 27G .3600*	The **program director** must have a minimum of a bachelor's degree in a human services field from an accredited college or university or hold a CADC or LPN or RN; b. two years of work experience providing direct care services to individuals with substance use disorders; **AND** c. three years of work experience in administration or programmatic supervision in human services.	The **program director** is responsible for managing the daily operations of the opioid treatment program based on the written program policies and procedures. Responsibilities also include the following: • Day-to-day business operations and management of the program. • Overall administrative oversight of all program operations. • Supervises staff in compliance with Federal and State regulations, and assists in planning, interpreting, and implementing the program protocol. • Develops communication mechanisms that provide interested parties (e.g. social services, health departments, law enforcement, etc.) with general information about the program outside of regular operating hours. This includes community outreach such as attendance at community functions, sponsorships and educating the public.
Clinical Staff	A. Each OTP must have a **1.0 FTE Licensed Clinical Addictions Specialist (LCAS), who may serve up to 50 individuals (per caseload)** **AND**	The **LCAS, LCAS-A and CADC** must have a valid license or certification from the NC Addiction Specialist Professional Practice Board.	The **Licensed Clinical Addiction Specialist** is responsible for providing a range of cognitive, behavioral, and other substance use focused and co-occurring therapies, reflecting a variety of medically necessary evidence-based, individualized, person-centered care.

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	B. **the OTP service must have an additional 1.0 FTE LCAS, LCAS-A or Certified Alcohol and Drug Counselor (CADC) for every additional 50 individuals (per caseload)** based on the total census for the opioid treatment program.		Additionally, the LCAS will provide clinical supervision to the opioid treatment clinical staff. The licensed professionals (LCAS and LCAS-A) may bill separately for eligible CPT code services beyond the 2 required counseling or therapy sessions per beneficiary per month during the first year of opioid treatment services and one required counseling session per beneficiary per month thereafter. All clinical services must be identified and meet medical necessity criteria based on the clinical assessment and documented in the beneficiary's individualized person-centered plan. Clinical services may be provided on-site or through telehealth based on beneficiary's needs. LCAS & LCAS-A (when applicable) responsibilities also include the following: •Acts as a primary therapist to address substance use and co-occurring disorders; • Develops individualized, person-centered plan and its ongoing revisions in coordination with the beneficiary and ensures its implementation; • Provides ongoing assessment and reassessment of the beneficiary based on their person-centered plan and goals; • Provides individual, group and family therapy based on the beneficiary's individualized, person-centered plan; • Provides crisis interventions,

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			when clinically appropriate; • Provides substance use, health and community services education; • Provides coordination and consultation with medical, clinical, familial and ancillary relevant parties with beneficiary consent; • Ensures linkage to the most clinically appropriate and effective services including arranging for psychological and psychiatric evaluations; • Provides appropriate linkage and referrals for recovery services and supports; • Informs the beneficiary about benefits, community resources, and services; • Advocates for and assists the beneficiary in accessing benefits and services; • Monitors and documents the status of the beneficiary's progress and the effectiveness of the strategies and interventions outlined in the PCP; • Maintains accurate service notes and documentation for all interventions provided; •Participates in staff meetings and treatment team meetings; and • Provides clinical supervision to relevant staff (LCAS only). The **Certified Alcohol and Drug Counselor** is responsible for providing a range of cognitive, behavioral, and other substance use focused counseling, reflecting a variety of medically necessary evidence-based, individualized, person-centered care. <u>CADC responsibilities (when applicable) also include the</u>

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			following: • Acts as primary counselor to address substance use disorders; • Develops individualized, person-centered plan and its ongoing revisions in coordination with the beneficiary, and ensures its implementation; • Provides ongoing assessment and reassessment of the beneficiary based on their person-centered plan and goals; • Provides individual and group counseling based on the beneficiary's individualized, person-centered plan; • Provides crisis interventions, when clinically appropriate; • Provides substance use, health and community services education; • Provides coordination and consultation with medical, clinical, familial and ancillary relevant parties with beneficiary consent; • Ensures linkage to the most clinically appropriate and effective services including arranging for psychological and psychiatric evaluations; • Provide appropriate linkage and referrals for recovery services and supports; • Informs the beneficiary about benefits, community resources, and services; • Advocates for and assists the beneficiary in accessing benefits and services; • Monitors and documents the status of the beneficiary's progress and the effectiveness of the strategies and interventions outlined in the PCP; • Maintains accurate service notes and documentation for all interventions provided; and

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			• Participates in staff meetings and treatment team meetings.

Clinical Supervision Requirements

Clinical Supervision is the provision of guidance, feedback, and training to staff to assure that quality services are provided to beneficiaries and maintaining and facilitating the supervisee's competence and capability to best serve beneficiaries in an effective manner. Clinical supervision is a critical factor in determining the appropriate acquisition of evidence-based practices by supervised staff.

Clinical supervision for the licensed professional and certified counseling or therapy staff is provided by a Licensed Clinical Addictions Specialist (LCAS) designated by the opioid treatment program director. Clinical supervision must be documented and provided by an individual who has the knowledge, skills, and abilities required by the population served. The LCAS will facilitate a weekly face-to-face (including virtual as long as it is audio/visual and interactive) individual or group supervision meeting to ensure that the planned support interventions are provided; to allow the staff to briefly discuss the status of all beneficiaries receiving services; problem-solve emerging issues; and plan approaches to intervene and prevent crises. The LCAS monitors the delivery of opioid treatment program services to ensure the interventions are provided effectively to help the beneficiary restore personal, social, daily living, and community skills; develop natural supports; manage their recovery; and reduce crises. Additional supervision or support may be provided as a group or with individual staff as needed to address specific concerns or challenges. Supervision plans must be implemented and documented in each staff member's personnel file.

Non-licensed staff shall be trained in and provide only the aspects of these practice(s) or model(s) that do not require licensure and are within the scope of their education, training, and expertise. Non-licensed staff must practice under supervision per the policy and 10A NCAC 27G. It is the responsibility of the LCAS and the Program Director to ensure that the non-licensed staff practice within the scope of their education, training, and expertise and are not providing any services that require licensure.

The licensed practical nurse (LPN) practice is always dependent and directed by at all times by the appropriately licensed medical professional. LPNs deliver care based on an established health care plan as assigned by a Registered Nurse (RN), Physician, Nurse Practitioner (NP), or Physician Assistant (PA). Supervision of the LPN must be conducted by a RN, physician, NP, or PA, and the supervisor must be either on site or continually available, including the ability to physically arrive and be present on site in a timely manner as much as needed to address beneficiary care. Supervision plans must be implemented and included in the personnel file.

When the supervising RN, physician, NP or PA is not on site, an on-call RN, physician, NP or PA must be continuously available to the LPN whenever providing beneficiary care. Continuous availability includes the ability to be available by phone immediately and

physically arrive within one hour and be present on site in a timely manner as much as needed to address beneficiary assessment and care needs.

6.3 **Program Requirements**

The OTP service is delivered by an interdisciplinary team of professionals trained in the treatment of opioid use disorders who provide person-centered and recovery-oriented individualized treatment, case management, and health education. Treatment with methadone, buprenorphine formulations, or other medications approved by the FDA are designed to address the beneficiary's need to achieve changes in his or her level of function. Beneficiaries who are admitted to treatment must be evaluated for specific objective and subjective signs of opioid use disorder as defined in 42 CFR 8.12. Agonist, partial agonist, or antagonist medications should be administered to address the physiological aspects of opioid use disorder, including craving and withdrawal symptoms. Person-centered substance use disorder and co-occurring disorder therapy, counseling, supports, and intervention should be offered to address the emotional, psychological, and behavioral aspects of opioid use disorder. To accomplish this, the person-centered plan will address major lifestyle issues that have the potential to undermine the beneficiary's recovery-oriented goals and inhibit their ability to cope with major life tasks.

Access to timely services within the OTP will include:

- Screenings will be offered and provided within 20 minutes of initial client contact during normal business hours;
- Intake assessments will be offered and provided a minimum of 5 days per week, a minimum of 3 hours per day;
- Admission to OTP shall be offered and provided within 1 business day from the initial screening, if appropriate for admission;
- Average wait time for dosing alone shall not exceed 20 minutes based on monthly clinic averages;
- Clinical staff will be available 5 days per week to offer and provide counseling, as needed;
- Medical provider staff will be available 5 days per week to offer and provide inductions and patient care, as needed.
- In-Clinic Dosing Services will be available 7 days per week.

Necessary support systems within the OTP include:

- Linkage with or access to psychological and psychiatric consultation;
- Linkage with or access to emergency medical and psychiatric care through affiliations with more intensive levels of care;
- Linkage with or access to evaluation and on-going primary and preventative medical care;
- Ability to conduct or arrange for appropriate laboratory and toxicology tests;

- Provider will act as a first responder providing crisis response 24-hours a day, 7 days a week, 365 days a year, to an individual receiving this service.

These supports and interventions also need to address co-occurring issues (mental health disorders, infectious diseases, and other co-occurring illnesses), based on a person-centered, multidimensional assessment and beneficiary's recovery goals. Integrated concurrent care for the beneficiary's various conditions is recommended, where possible, but these services may need to be provided across different settings with appropriate direct coordination of care.

Therapies within the Opioid Treatment Program Service include:

- Individualized, person-centered assessment and treatment;
- Assessing, ordering, administering, supplying, monitoring, and regulating medication and dose levels appropriate to the beneficiary;
- Supervising withdrawal from opioid analgesics, including methadone and buprenorphine;
- Monitoring drug testing, to be conducted at least one time per month;
- A range of cognitive, behavioral, and other substance use disorder focused evidenced-based therapies, reflecting a variety of treatment approaches, provided to the beneficiary on an individual, group, or family basis;
- Case management, including medical monitoring and coordination of on and off-site treatment services and supports; and
- Health education, including education about HIV, tuberculosis, hepatitis C, pregnancy and sexually transmitted infections.

Ongoing assessments and person-centered plan reviews should occur regularly; be completed based on changes with beneficiary needs or goals to ensure progress and improve beneficiary's response to treatment; and at a minimum annually.

Assessment and treatment planning within the Opioid Treatment Program Service include:

- An in-person comprehensive medical history, physical examination, and laboratory tests provided in accordance with state and federal regulations;
- And individual biopsychosocial assessment;
- An appropriate regimen of methadone or buprenorphine, as required by the Center for Substance Abuse Treatment (CSAT) regulation, at a dose established by a physician or appropriately licensed medical provider at admission and monitored carefully until the beneficiary is stable and an adequate dose has been established. The dose is then reviewed as indicated by the beneficiary's course of treatment;
- Continuing evaluation and referral for care of any biomedical problems;
- And individualized, recovery-focused person-centered plan, including problem formulation and articulation of short-term, measurable treatment goals and activities designed to achieve these goals. Person-centered plans are developed collaboratively with the beneficiary, are reflective of their personal goals for recovery, and are updated regularly, as specified by the plan.

Activities included in the weekly bundled rate for this service:

- managing medical plan of care including medical monitoring;
- individual, recovery focused person-centered plan;
- a minimum of 2 required counseling or therapy sessions per beneficiary per month during the first year of opioid treatment services and one required counseling session per beneficiary per month thereafter;
- nursing services related to administering medication, preparation, monitoring and distribution of take-home medications;
- cost of the medication;

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- presumptive drug screens and definitive drug tests;
- pregnancy tests;
- TB tests;
- psychoeducation including HIV/AIDS education and other health education services; and
- case management including coordination of on and off-site treatment and supports.

In addition to the weekly bundled rate activities, providers may bill separately for:

- evaluation and management billing codes;
- diagnostic assessments or comprehensive clinical assessments;
- medication assisted treatment induction;
- medication management visits;
- laboratory testing (excluding pregnancy test, TB test, & drug toxicology);
- individual, group, and family counseling (provided beyond the minimum 2 counseling or therapy sessions per month during the first year or one counseling or therapy session per month thereafter) (licensed professionals only); and
- peer support services.

Providers must have the ability to admit a beneficiary at least 5 days per week

Staff Training Requirements

OTP services shall be provided by an interdisciplinary team of individuals who have strong clinical skills, professional qualifications, experience, and competency to provide the range of practices. All OTP team members are expected to receive initial and ongoing training in core and evidence-based practices that support the implementation of ethical, person-centered, high-fidelity OTP practices.

Time Frame	Training Required	Who	Total Minimum Hours Required
Within **30 calendar days** of hire to provide service	▪ 2 hours OTP Service Definition Required Components ▪ 3 hours of Crisis Response	▪ All Staff	5 hours
	▪ 3 hours of PCP Instructional Elements	▪ Licensed professional and Certified Alcohol & Drug Counselor responsible for PCP	3 hours
	▪ 1 hour of scope of practice in the OTP (per the NC Board of Nursing)	▪ RN & LPN	1 hour

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Time Frame	Training Required	Who	Total Minimum Hours Required
		staff and Program Director	
	▪ NC State Opioid Treatment Authority (SOTA) Webinar Series	▪ RN, LPNs MDs, all extenders & Program Director	3 hours
	▪ OTP program physicians must complete the training in the use of buprenorphine required by DATA 2000	▪ MD and all extenders	8 hours
Within **180 calendar days** of hire to provide this service	3 hours of ASAM Criteria Training** ▪ 1 hour of Pregnancy and Opioid Use Disorder Treatment	▪ Medical Staff, including Medical Director, Program Physician, Nursing Supervisor, Registered Nurses, and Licensed Practical Nurses.	4 hours
	▪ 6 hours of Introductory Motivational Interviewing* (MI) ▪ 6 hours of ASAM Criteria Training** ▪ 3 hours of Co-Occurring Treatment Training ▪ 3 hours of Trauma Informed Care ▪ 3 hours of Pregnancy and Opioid Use Disorder Treatment	▪ Counseling Staff, including the Program Director and all counselors (LCAS, LCAS-A, CADCs)	21 hours

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Time Frame	Training Required	Who	Total Minimum Hours Required
		and any non-licensed staff providing clinical services under supervision.	
	▪ 6 hours of training in Medication Assisted Treatment	▪ All Staff (except MDs and all extenders)	6 hours
Annually	▪ 3 hours of Crisis Response Training ▪ 10 hours of continuing education in an evidence-based treatment practices	▪ All Staff	13 hours

The initial training requirements may be waived by the hiring agency if the employee can produce documentation certifying that training appropriate for the population being served was completed no more than 24-months prior to hire date.
*Motivational Interviewing training must be provided by a Motivational Interviewing Network of Trainers (MINT) trainer. If a staff person is a MINT trainer, they are not required to have this training.
**ASAM certified physicians are not required to participate in this training.

The program director shall maintain documentation of both supervision and training activities. All team members shall receive ongoing clinical supervision as designated under Section 6.2 in this policy.

Expected Outcomes

The expected clinical outcomes for this service are specific to recommendations resulting from clinical assessments and meeting the identified goals in the beneficiary's PCP. Expected outcomes as follows:

- reduced symptomatology;
- decreased frequency or intensity of crisis episodes;
- increased ability to function in the major life domains (emotional, social, safety, housing, medical or health, educational, vocational, and legal) as identified in the PCP;
- engagement in the recovery process;
- increased ability to function as demonstrated by community participation (time spent working, going to school, or engaging in social activities);

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- increased ability to live as independently as possible, with natural and social supports;
- increased identification and self-management of triggers, cues, and symptoms;
- increased ability to function in the community and access financial entitlements, housing, work, and social opportunities;
- increased coping skills and social skills that mitigate life stresses resulting from the beneficiary's diagnostic and clinical needs;
- increased ability to use strategies and supportive interventions to maintain a stable living arrangement;
- decreased judicial system involvement related to the beneficiary's mental health or substance use disorder diagnosis; and
- maintenance phase, wherein demonstrated improvement, is not criteria for discharge.

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:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA), 42 CFR Part 2 and record retention requirements; and
b. All NC Medicaid's clinical (medical) 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).

All providers will be in compliance with 42 CFR Part 2- Confidentiality of Substance Use Disorder Patient Records.

8.0 Policy Implementation and History

Original Effective Date: Month Day, Year

History:

Date	Section or Subsection Amended	Change
MM/DD/YYYY	All Sections and Attachment(s)	The existing Service definition, Opioid Treatment removed from policy 8A, to become a stand-alone clinical coverage policy, 8A-XXXX, Opioid Treatment Program Service

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid'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 and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) 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.

HCPCS Code(s)	Billing Unit
H0020	Per Diem= 1 week

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).

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F. Place of Service

Outpatient.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov//

Note: North Carolina Medicaid and North Carolina Health Choice will not reimburse for conversion therapy.

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