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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 a beneficiary with an opioid use disorder (OUD). 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, 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, must 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): NCHC shall cover the Opioid Treatment Program Service for an eligible beneficiary who is 18 years of age until he or she reaches their 19th birthday and meets the criteria in **Section 3.0** of this policy.

e. This service is provided under the provisions outlined in the 42 CFR 8.12

i. Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

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a. Medicaid

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 OTP Service for an eligible beneficiary who is 18 years of age until 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 OTP Service when the beneficiary meets the following specific criteria:

a. A DSM-5 (or any subsequent editions of this reference manual) diagnosis of an 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 OTP Services (Opioid Treatment Program specific) level of care.

3.2.1.1 Admission Criteria

Due to the nature of this OTP service, a comprehensive clinical assessment (CCA) or diagnostic assessment (DA) is not required prior to admission. An initial abbreviated assessment, physical exam and service plan must be completed by a physician or approved medical provider (nurse practitioner or physician assistant with a midlevel exemption from SAMHSA) to establish medical necessity for this service as a part of the admission process.

The initial assessment must contain 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 when the assessment is completed by an appropriately licensed professional;
d. a pertinent social, family, and medical history; and
e. evaluations or assessments as appropriate to the beneficiary's needs.

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

A licensed professional shall complete a CCA or DA Within five (5) calendar days of the admission, to determine an ASAM level of care for discharge planning. Information from the abbreviated assessment can be utilized as part of the current CCA. Relevant diagnostic information must be obtained and contained in the treatment or service plan.

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

3.2.1.2 Continued Stay Criteria

The beneficiary is eligible to continue this service if there is documentation of the beneficiary's current status based on the six (6) dimensions of the ASAM Criteria for OTP that indicates a need for continued stay. Justification must be provided based on current level of functioning in six (6) Dimensions of the ASAM Criteria 1-6. Documentation must contain details of the assessment of the six (6) dimensions.

a. In addition to the above, the beneficiary shall meet one of the following:
    1. The beneficiary has achieved current Person-Centered Plan (PCP) goals and additional goals are indicated as evidenced by documented symptoms;

2. The beneficiary is making satisfactory progress toward meeting goals and there is documentation that supports that continuation of this service is 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.

b. 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 must be based on ANY ONE of the following:
   1. A history of regression in the absence of opioid treatment is documented in the beneficiary's service record;
   2. A 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 persist and that ongoing treatment interventions are needed to sustain functional gains; or
   3. There is a lack of a medically appropriate step down.

3.2.1.3 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 OTP that indicates a need for transfer or discharge. Justification must be provided based on current level of functioning in the Six (6) dimensions of the ASAM Criteria. Documentation must contain details of the assessment of the six (6) dimensions; and

b. The beneficiary meets one 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, including a coordinated transition to Office Based Opioid Treatment (OBOT), and there are no medical expectations that symptoms 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 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, including a coordinated transition to OBOT, and the beneficiary is no longer in need of the OTP Service; or

3. The beneficiary or legally responsible person requests a discharge from OTP Service or other Medication Assisted Treatment.

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:

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 the following:

a. Any services in the OTP Service per diem as separate billable services unless otherwise indicated in this clinical coverage policy;
b. Transportation for the beneficiary or family members;
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 OTP 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 PCP;
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 PCP; 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 not require initial prior approval for the OTP Service.

Upon admission to OTP, a beneficiary is allowed a four (4) unit pass-through. An authorization from the Prepaid Inpatient Health Plan (PIHP), Prepaid Health Plan (PHP) or Utilization Management (UM) contractor is required after the initial four (4) unit pass-through. Refer to Subsection 5.3 for additional limitations.

A service order must be signed prior to or on the first day service is rendered. **Refer to Subsection 5.4** of this policy.

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 PCP. Medical necessity is determined by North Carolina community practice standards, as verified by the PIHP, PHP, or UM 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.

5.2.2.1 Reauthorization

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

No more than 1 weekly unit can be billed per week.

5.3 Additional Limitations or Requirements

A beneficiary can receive OTP Service from only one provider organization at a time.

5.4 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 12 months. The 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.

5.5 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 and NCHC. The staff person who provides the service shall sign and date the written entry. The signature must contain credentials for the staff member who provided the service. The PCP and a documented discharge plan must be discussed with the beneficiary and contained in the service record.

5.5.1 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 document 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 such as face-to-face, collateral or phone call;
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, 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.

5.5.2 Content of a Medication Administration Record

A Medication Administration Record (MAR) or electronic Medication Administration Record (eMAR) shall be used to document each administration of methadone, buprenorphine, naltrexone, or other medication ordered for the treatment of an OUD. 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 OTP Exception Request and Record of Justification submitted to the State Opioid Treatment Authority 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. Any findings for the beneficiary 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; and
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 OTP is operated under a defined set of policies and procedures and must comply with 42CFR 8.12 Federal opioid treatment standards 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
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 SUD 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 ASAM or the American Board of Preventive Medicine (ABPM), or in addiction psychiatry by the American Board of Psychiatry and Neurology. **AND** c. The **Medical Director** shall 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 and state regulations, consistent within appropriate standards of care. The medical director shall be present at the program to assure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation. Responsibilities are: • Ensuring regulatory compliance of the opioid treatment program. • Providing consultation to after-hours medical or mental health emergencies. • Providing supervision of Physician Extender as necessary.
Program Physician/Physician Extender	An OTP program physician must be either: a. An M.D or D.O. who is actively licensed with the NC Medical Board, OR b. A Physician Assistant (PA) who is licensed and in good standing with the NC Medical Board	The **program physician (or physician extender with appropriate waiver)** is responsible for providing all medical services according to the policies and protocols of the opioid treatment program under

	and certified and in good standing with the National Commission on Certification of Physician Assistants (NCCPA), with appropriate federal waiver of 42 CFR Part 8.12(h), **OR** c. A Nurse Practitioner (NP) who is licensed and in good standing with the NC Board of Nursing (NCBON), with appropriate federal waiver of 42 CFR Part 8.12(h). **AND** d. 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 ASAM or the American Board of Preventive Medicine (ABPM), or in addiction psychiatry by the American Board of Psychiatry and Neurology	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 are 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 medications for treating opioid use disorder and dosage changes; • Evaluate, prescribe, and monitor all medications currently being taken by the beneficiary along with coordination with other prescribers;

		• Order take-home privileges according to 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 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 psychiatric providers.
Nursing Staff	• The S**upervising Registered Nurse (RN)** must have at a minimum, one year of experience working with adults with a substance use disorder. • The Supervising RN must hold active licensure as an RN and be in good standing with the NCBON • Additional nurses can be Licensed Practical Nurse (LPN) or RN working within their scope of practice, holding an active licensure and be in good standing with the NCBON.	The **Supervising RN** shall 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 shall be continuously available to the LPN whenever

		providing beneficiary care. Continuous availability means 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. Nursing staff responsibilities are the following: • Conducts a nursing evaluation upon admission in accordance with their scope of work (RN only); • Responsible for monitoring the CSRS, when delegated by a physician; • Provides ongoing nursing assessment, planning, and evaluation of beneficiaries according to 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 performed; • Provide psychoeducation, and 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, PA, or NP for guidance in medical matters concerning the well-being of beneficiaries; and • Participates in staff meetings and treatment team meetings.
Program Administrative and Clinical Staff			
Position	**FTEs**	**Minimum Requirements**	**Responsibilities**
Program Director	**1.0 FTE** **Program Director** *The Program Director may cover caseloads on a temporary basis in emergency situations as a result of staffing shortages and count towards the 1:50 LCAS, LCAS-A or Certified Alcohol & Drug Counselor to beneficiary staff ratio, as described in 10A NCAC 27G .3600*	a. The **Program Director** must have 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 OTP 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 (social services, health departments,

			law enforcement) with general information about the program outside of regular operating hours. This involves community outreach such as attendance at community functions, sponsorships and educating the public.
Clinical Staff	Program must have a **1.0 FTE Licensed Clinical Addictions Specialist (LCAS), who may serve up to 50 individuals (per caseload)** **AND** **Program must have an additional 1.0 FTE LCAS, Licensed Clinical Addiction Specialist- Associate (LCAS-A), Certified Substance Abuse Counselor (CSAC) or Certified Alcohol and Drug Counselor (CADC) for every additional 50 individuals (per caseload)** based on the total census for the opioid treatment program.	The **LCAS, LCAS-A, CSAC, 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. Additionally, the LCAS provides clinical supervision to the OTP clinical staff. 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 consist of the following: •Acts as a primary therapist to address substance use and co-occurring disorders; • Develops individualized, PCP and its ongoing revisions in coordination with the beneficiary and ensures its implementation;

			• Provides ongoing assessment and reassessment of the beneficiary based on their PCP and goals; • Provides individual, group and family therapy based on the beneficiary's individualized, PCP; • 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 along with arranging 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 or Certified Substance Abuse 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. CADC and CSAC responsibilities (when applicable) consist of the following: • Acts as primary counselor to address substance use disorders; • Develops individualized, PCP and its ongoing revisions in coordination with the beneficiary, and ensures its implementation; • Provides ongoing assessment and reassessment of the beneficiary based on their PCP and goals; • Provides individual and group counseling based on the beneficiary's individualized, PCP; • 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 along with arranging 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 • Participates in staff meetings and treatment team meetings.

Note: Refer to NCGS § 90-113.31A (6) for definition of Certified Alcohol and Drug Counselor (CADC). The certification name for Certified Substance Abuse Counselor (CSAC) is amended to Certified Alcohol and Drug Counselor (CADC). Policy amendment(s) will be effective the date the related rule for 10A NCAC 27G is finalized.

Note: According to 25 U.S.C. 1621t, licensed health professionals employed by a tribal health program are exempt, if licensed in any state, from the licensing requirements of the State (North Carolina) in which the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.).

6.2.1 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 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 facilitates a weekly face-to-face (including virtual if it is audiovisual 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 OTP 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 can 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 shall 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 LPN practice is always dependent on and directed by the appropriately licensed medical professional. LPN delivers care based on an established health care plan as assigned by a RN, Physician, NP, or 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, and 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.

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. A Beneficiary who is 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 are administered to address the physiological aspects of opioid use disorder, such as cravings and withdrawal symptoms. Person-centered substance use disorder and co-occurring disorder therapy, counseling, supports, and intervention are offered to address the emotional, psychological, and behavioral aspects of opioid use disorder. To accomplish this, the PCP must 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.

a. Access to timely services within the OTP are the following:
    1. Clinical staff available five (5) days per week to offer and provide counseling, as needed (either in person or telehealth);
    2. Medical provider staff available five (5) days per week to offer to provide methadone and buprenorphine inductions and patient care, as needed.
    3. In-Clinic Dosing Services available seven (7) days per week for a beneficiary who is in the induction phase or who is not stable enough for unsupervised take home doses.
    4. When the supervising RN, physician, NP or PA is not on site an on-call RN, physician, NP or PA shall be continuously available to the LPN whenever providing beneficiary care. Continuous availability is 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.
b. Necessary support systems within the OTP include:
    1. Linkage with or access to psychological and psychiatric consultation;
    2. Linkage with or access to emergency medical and psychiatric care through affiliations with more intensive levels of care;
    3. Linkage with or access to evaluation and on-going primary and preventative medical care;
    4. Ability to conduct or arrange for appropriate laboratory and toxicology tests;
    5. Provider acts as a first responder providing crisis response 24-hours a day, 7 days a week, 365 days a year, to a beneficiary receiving this service.

    These supports and interventions 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, and where possible these services need to be provided across different settings with appropriate direct coordination of care.

c. Therapies within the OTP Service are the following:
    1. Individualized, person-centered assessment and treatment;

2. Assessing, ordering, administering, supplying, monitoring, and regulating medication and dose levels appropriate to the beneficiary;
3. Supervising withdrawal from opioid analgesics, including methadone and buprenorphine;
4. Monitoring drug testing, to be conducted at least one time per month;
5. 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;
6. Service coordination activities, consist of coordination with care management entity, medical monitoring, and coordination of on and off-site treatment services and supports; and
7. Health education, reproductive and life planning education consisting of education about HIV, tuberculosis, hepatitis C, pregnancy and sexually transmitted infections.

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

d. Assessment and treatment planning within the OTP Service consists of the following:
   1. An in-person comprehensive medical history, physical examination, and laboratory tests provided according to state and federal regulations;
   2. A biopsychosocial assessment;
   3. 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;
   4. Continuing evaluation and referral for care of any biomedical problems;
   5. An individualized, recovery-focused PCP, consisting of problem formulation and articulation of short-term, measurable treatment goals and activities designed to achieve these goals. PCPs are developed collaboratively with the beneficiary, are reflective of their personal goals for recovery, and are updated regularly, as specified by the plan.

   NOTE: OTP providers shall have the ability to admit a beneficiary at least five (5) days per week. OTP providers shall ensure that all programs have access to naloxone on site, and that all staff have training and education on the use of naloxone in suspected opioid overdoses. OTP programs must develop policies that detail the use, storage and education provided to staff regarding naloxone.

e. Activities in the bundled rate for this service are:
   1. managing medical plan of care and medical monitoring;
   2. individualized recovery focused person-centered plan;
   3. 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;

4. nursing services related to administering medication, preparation, monitoring and distribution of take-home medications;
5. cost of the medication;
6. presumptive drug screens and definitive drug tests;
7. pregnancy tests;
8. TB tests;
9. Psychoeducation consisting of HIV and AIDS education and other health education services; and
10. service coordination activities consisting of coordination with care management entity and coordination of on and off-site treatment and supports.

f. In addition to the bundled rate activities, providers can bill separately for:
   1. evaluation and management billing codes;
   2. diagnostic assessments or comprehensive clinical assessments;
   3. laboratory testing (excluding pregnancy test, TB test, & drug toxicology);
   4. individual, group, and family counseling (provided beyond the minimum 2 counseling of therapy sessions per month during the first year or one counseling or therapy session per month thereafter) (licensed professionals only); and
   5. Peer Support Services.

6.3.1 Staff Training Requirements

OTP services must 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.

All staff shall be trained in crisis response within the first 30 days.

Time Frame	Training Required	Who	Total Minimum Hours Required
Upon Hire, Prior to First Day Worked	▪ 1.5 hours of Narcan and Harm Reduction training	All Staff	1.5 hours
Within **30 calendar days** of hire to provide service	▪ 2 hours OTP Service Definition Required Components	All Staff	2 hours
	▪ 3 hours of PCP Instructional Elements	Licensed professional and Certified Alcohol & Drug Counselor responsible for PCP	3 hours

	▪ NC State Opioid Treatment Authority (SOTA) Webinar Series	RN, LPNs MDs, DOs, all extenders & Program Director	
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
	▪ 3 hours of Introductory Motivational Interviewing**(MI) ▪ 3 hours of ASAM Criteria Training*** ▪ Co-Occurring Treatment Training**** ▪ Trauma Informed Care**** ▪ 3 hours of Pregnancy and Opioid Use Disorder Treatment	▪ Counseling Staff, consisting of the Program Director and all counselors (LCAS, LCAS-A, CADCs) and any non-licensed staff providing clinical services under supervision.	9 hours
	▪ 3 hours of training in Medication Assisted Treatment	▪ All Staff (except MDs, DOs, and all extenders)	3 hours
Annually	▪ 10 hours of continuing education in an evidence-based treatment practices including crisis response****	▪ All Staff	10 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 MINT training.

*** Training must be approved and certified by a nationally recognized program that issues continuing education for licensed or clinical professionals. Approved programs are the North Carolina Addictions Specialist Professional Practice Board (NCASPPB), National Association of Addiction Professionals (NAADAC), National Board for Certified Counselors (NBCC), Approved Continuing Education Provider (ACEP), and National Association of Social Workers (NASW)

OTP program physicians shall complete the training in the use of buprenorphine as required by DATA 2000.

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.

6.3.2 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 are as follows:

a. reduced symptomatology;
b. decreased frequency or intensity of crisis episodes;
c. 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;
d. engagement in the recovery process;
e. increased ability to function as demonstrated by community participation (time spent working, going to school, or engaging in social activities);
f. increased ability to live as independently as possible, with natural and social supports;
g. increased identification and self-management of triggers, cues, and symptoms;
h. increased ability to function in the community and access financial entitlements, housing, work, and social opportunities;
i. increased coping skills and social skills that mitigate life stresses resulting from the beneficiary's diagnostic and clinical needs;
j. increased ability to use strategies and supportive interventions to maintain a stable living arrangement; and
k. decreased judicial system involvement related to the beneficiary's mental health or substance use disorder diagnosis.

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

8.0 Policy Implementation and History

Original Effective Date: March 15, 2019

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-9, Opioid Treatment Program Service

DRAFT

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. Federally recognized tribal and Indian Health Service providers may be exempt from one or more of these items in accordance with Federal Law and regulations

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	1 Unit = 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). Federally recognized tribal or Indian Health Service providers may be entitled to alternate reimbursement methodologies under Federal Law and Regulations.

Licensed professionals (LCAS and LCAS-A) can 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.

F. Place of Service

Opioid Treatment Services are provided in a licensed Opioid Treatment Facility (**10A NCAC 27G .3601)**

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.