

Clinical Policy: Neonatal Abstinence Syndrome Guidelines

Reference Number: WNC.CP.168

Last Review Date: 08/23

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

Maternal drug use and intrauterine exposure of the fetus during pregnancy can lead to drug withdrawal in the infant after delivery. Clinically important neonatal withdrawal most commonly results from intrauterine opioid exposure. However, maternal use of central nervous system depressants (e.g., benzodiazepines, barbiturates and alcohol) and other drugs also results in signs of neonatal symptoms/withdrawal in exposed infants. Neonatal opioid withdrawal syndrome (NOWS) describes opioid-only withdrawal symptoms while Neonatal Abstinence Syndrome (NAS) describes neonates who are at-risk for exposure to other substances, with or without opioids. The term NAS will be used here for exposures related to opioids and/or other substances.

Signs of withdrawal will develop in 55 - 94% of neonates exposed to opioids in utero. Fetal methadone exposure results in a 60-80% risk of NAS, whereas the risk from buprenorphine exposure is 30-40%. Typical signs of withdrawal from specific drugs occur based on the half-lives of elimination of the drug. Maternal use of multiple drugs during pregnancy will also have an impact on the onset and severity of NAS. In general, if one week has elapsed between the last maternal opioid use and delivery, the incidence of NAS is relatively low.

Mothers who are prescribed methadone or buprenorphine should continue to take them and not stop them prior to delivery. The same is true for mothers prescribed antidepressant medications such as fluoxetine (Prozac), and Selective Serotonin Reuptake Inhibitors (SSRI) such as, sertraline, citalopram (Zoloft, Celexa). A mother can still breastfeed if taking methadone, buprenorphine, fluoxetine, and SSRI's as prescribed. Marijuana is contraindicated in pregnancy as it can cause stillbirth, preterm birth, neonatal intensive care unit (NICU) admission, and affect growth and development. The half-life of marijuana's tetrahydrocannabinol (THC) is ~67 days.

Thus, it will take 3-6 months for THC to be completely eliminated. The Centers for Disease Control and Prevention (CDC) advise against mothers using marijuana and marijuana products containing cannabidiol (CBD) if breastfeeding. ¹² Table 1 below lists common drugs abused along with the typical onset of NAS symptoms.

Table 1. Common Drug NAS Symptom Onset

Drug	Typical Onset
Heroin	Within 24 hrs. with delay up to 5-7 days or later
Methadone	24-72 hrs. with delay up to 5-7 days later
Morphine & Hydrocodone	Within 3 days
Buprenorphine	Within 40 hrs.



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Ethanol	3-12 hrs.
Barbiturate	4-7 days with delay up to 14 days
Diazepam	12 days
Chlordiazepoxide	21 days
Cocaine	48 to 72 hours
Selective Serotonin Reuptake Inhibitors	Hours to weeks

Policy/Criteria

- **I.** It is the policy of WellCare of North Carolina® that the management of neonatal abstinence syndrome (NAS) is medically necessary at the indicated level of care for the following circumstances:
 - A. Asymptomatic infants at risk for NAS due to maternal drug history are appropriate in **one** of the following:
 - 1. Transitional level or level 1 nursery for 4 to 7 days for observation using the modified Finnegan's Neonatal Abstinence Scoring Tool, with duration of observation for symptoms dependent on the drugs used during pregnancy (see Table 1 above);
 - 2. Level 2 nursery for 4-7 days when assessed and treated using the Eat, Sleep, Console (ESC) approach, depending on the drugs used during pregnancy (see Table 1 above);
 - B. Level of care for symptomatic infants should be managed using the appropriate nationally recognized clinical decision support tools if assessed and treated per modified Finnegan's scoring, or are appropriate in Level 2 nursery if assessed and treated by ESC.

Note: The dosing interval for morphine should be no longer than every four hours to avoid subtherapeutic levels prior to the next dose. *Home-based withdrawal therapy* may be considered if no more than 2 modified Finnegan's scores are ≥ 8 or 1 score is ≥ 10 in the prior 48 hours and all of the discharge criteria in section I.C. are met. The home environment, caregiver, and support team must be taken into consideration.

If treated with pharmacologic therapy using ESC, discharge should be consistent with ESC recommendations.

C. Discharge Criteria

Prior to discharge home with home health, **all** of the following must be met:

- 1. Infant is clinically stable and meets **all** of the following criteria:
 - a. Infant is taking oral feeds and gaining weight satisfactorily;
 - b. Infant is physiologically stable with normal vital signs including blood pressure;
- 2. Infant is showing neurobehavioral recovery evidenced by reaching full alert state, responding to social stimuli, and being consoled with appropriate measures 24-48 hours after the last dose of morphine prior to discharge, based on gestational age.

Note: The half-life of morphine in term infants (37 0/7weeks and older) is estimated to be 6.5 +/- 2.8 hours. The half-life of morphine in pre-term infants (less than 37 0/7 weeks) is estimated to be 9.0 +/- 3.4 hours. It takes three to five half-lives to be sure



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morphine is out of the baby's system and there are no symptoms of withdrawal afterwards.

- 3. Home situation is assessed and deemed adequate;
- 4. Parent or caretaker is agreeable with the plan of care;
- 5. Appropriate transportation is available for follow up appointments;
- 6. Home care services are arranged for nursing assessments;
- 7. The responsible physician (neonatologist, primary care pediatrician or family medicine provider) and back-up health care facility (NICU, community hospital) should be clarified to the family and home care agency prior to discharge.
- 8. Follow up appointment with the primary care pediatrician or family medicine provider is scheduled prior to discharge.
- II. It is the policy of WellCare of North Carolina[®] that if the infant is clinically stable but remains in the nursery due to social issues, these days are considered **not medically necessary** unless there is a benefit coverage requiring such days.

Background

The diagnosis and management of NAS is briefly described below. The presentation of NAS is widely variable in the onset of symptoms and types and severity of clinical manifestations. Universal screening and subsequent close observation of high-risk neonates is essential for timely diagnosis and treatment of the neonate. 15,16

- A. **Screening** The following screening steps should be taken
 - 1. Universal screening for maternal drug abuse
 - 2. Maternal toxicology testing in known or suspected cases of NAS based on any of the following characteristics: (note legal implications of testing and need for consent from the mother may vary among states)
 - a. Known history of maternal substance abuse
 - b. Maternal engagement in high-risk behaviors
 - c. Disclosure of recent substance abuse
 - d. Acting in an intoxicated manner on admission or during office visits
 - e. Previous unexplained late fetal demise, repeated spontaneous abortion
 - f. Precipitous labor, placental abruption, hypertensive episodes, severe mood swings
 - g. Cerebrovascular accidents, myocardial infarction
 - 3. Newborn urine and/or meconium screening and/or umbilical cord testing can be performed for recent substance abuse.
 - a. False negatives may occur more commonly with urine testing due to urinary excretion of most drugs being relatively short
 - b. Meconium screening and umbilical cord testing both have a window of detection up to 20 weeks prior to delivery

B. Observation location/Assessment tool/Level of Care

1. If the hospital uses the Eat, Sleep, Console (ESC) assessment tool for infants at risk for NAS, the infant may remain in the room with the primary caregiver to provide intensive



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comfort care measures and to promote caregiver bonding and maternal breastfeeding. This is considered Level II care with or without the need for medications. The baby does not have to be transferred away from his/her caregiver to NICU for Level II care to be authorized so long as the ESC assessment tool is being used and followed.

- 2. If the hospital uses the older modified Finnegan's Neonatal Abstinence Scoring Tool, infants at risk for NAS should be observed in the neonatal nursery for signs/symptoms of neonatal withdrawal. Level II care is appropriate under the modified Finnegan Neonatal Abstinence Scoring Tool if medications are given and/or if the baby is transferred to the neonatal intensive care unit (NICU). A copy of the modified Finnegan Neonatal Abstinence Scoring tool is available at http://www.academyofneonatalnursing.org/NAS/FinneganNASTool.pdf
- 3. Timing and severity of withdrawal symptoms depends upon the maternal drug(s) used and last time of use. Duration of neonatal nursery observation should be dependent on the half-life of the drug based on maternal drug use history.
 - a. For example, maternal use of a drug with a short half-life of 4 hours (e.g., hydrocodone) indicates an infant may be safely discharged if there are no signs of withdrawal by three days of age.
 - b. Maternal use of a drug with a prolonged half-life (e.g., methadone) indicates an infant should be observed for a minimum of five to seven days.
 - c. Polysubstance abuse and/or unknown substance abuse should be observed for a minimum of five to seven days
- 4. Some hospitals may continue to assess using modified Finnegan scoring along with ESC scoring. However, only the scoring system used to direct care decisions should inform medical necessity for the requested level of care.

C. Diagnosis

- 1. Withdrawal symptoms such as seizures, fever, irritability, and poor feeding can all be signs of other conditions. Appropriate assessment and diagnostic tests are necessitated to differentiate NAS from other diagnoses.
- 2. Clinical diagnosis is made based on maternal history of drug use and neonatal screening, observation, and assessment findings.

D. Treatment

- 1. Nonpharmacologic
 - a. Infants showing early signs of withdrawal should have treatment directed at minimizing environmental stimuli. This includes placing the infant in a dark, quiet environment, careful positioning and comfort techniques such as swaddling, responding early to an infant's signals, and breastfeeding or formula feeding as indicated.. Rooming-in (i.e., the co-location of maternal and infant care after delivery and beyond), has been shown to reduce NAS severity.
 - b. Careful observation for signs of fever, dehydration or weight loss.
 - c. Ensure adequate sleep and caloric intake.
 - d. Additional supportive care such as IV fluids, electrolyte replacement and gavage feedings may be indicated to stabilize the infant in the acute phase and obviate the need for pharmacologic intervention.



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e. Breastfeeding has been associated with less severe NAS and should be encouraged in mothers who are adherent to a supervised drug treatment program including methadone or buprenorphine.

2. Pharmacologic

- a. Pharmacologic therapy should be reserved for the infants with moderate to severe signs of NAS, and to relieve complications of such, when nonpharmacologic support is ineffective. Drug withdrawal may be life-threatening, but it is ultimately a self-limited process and unnecessary pharmacologic treatment prolongs exposure to harmful drugs. Studies have only shown clear benefits of pharmacologic therapy for the short-term amelioration of clinical signs of NAS. Long term benefits or harm have not been clearly studied.
- b. The optimal screening modified Finnegan's score for the initiation of pharmacologic therapy is not clearly defined. However, pharmacologic therapy is generally started for the neonate who has 3 or more consecutive scores above 8 or 2 consecutive scores averaging 12 or greater despite adequate supportive care.
- c. The ESC method is a functional scoring approach, considering whether the baby can:
 - i. i. Breastfeed well or greater than 1oz (30 ml)
 - ii. Sleep undisturbed for greater than or equal to one hour
 - iii. Be consoled within 10 minutes
 - If the baby is able to do these things, then his/her NAS is being treated adequately. If not, intensive comfort care measures involving the caregiver are utilized first. After which, opioid medication, usually morphine, can be given to lessen the withdrawal so the baby can eat, sleep, or be consoled. Once started, opioid medication, usually morphine, does not have to be continued or increased unless the baby fails to eat, sleep, or be consoled.
- d. When nonpharmacologic treatment fails, the recommended first drug of choice is an opioid, either morphine or methadone. Clonidine and phenobarbital are second line drugs to be used in addition to an opioid to treat NAS. Phenobarbital is an anti-seizure medicine that can help calm an infant. Clonidine is a centrally acting alpha-adrenergic receptor agonist that helps lower blood pressure and heart rate. It helps relieve neuromotor symptoms such as hypertonia, jitteriness, and agitation. Paregoric and diazepam are no longer recommended.
- e. The general course of opioid therapy is determined by the response of the infant based on abstinence scoring. If the infant remains symptomatic based on abstinence scoring, an increased dose is indicated. Once the infant responds to therapy with a decrease in scoring and weight gain is established, weaning of the medication can begin. Metabolic demands need to be considered as part of the weaning process. The rate of wean is dependent on the infant's clinical status with use of the abstinence score facilitating this process.
- f. Weaning of morphine may occur every 24 to 48 hours for infants on single drug regimens and no more frequently than every 48 hours for infants on multiple drug regimens or those who have recently failed a wean. Morphine may be discontinued after reaching 0.02 mg/kg/dose every three to four hours. Morphine should not be spaced out further than every three to four hours to avoid subtherapeutic levels of



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- morphine before the next dose. Clinical judgment is vital in the management of pharmacotherapy.
- g. Weaning of clonidine may occur every 24 hours by 0.25 to 0.5 mcg/kg/dose as tolerated. Blood pressure and vital signs must be monitored every two hours for 12 hours after clonidine is completely weaned to prevent rebound hypertension or tachycardia.
- h. Weaning of phenobarbital may occur every 48 hours by decreasing the dose by 20%. Alternatively, the baby can be discharged home on phenobarbital and be allowed to outgrow the dose within two to three weeks before stopping it.

Prematurity

Preterm infants have been found to be at lower risk of drug withdrawal with less severe and/or prolonged courses of NAS. Several possible causes of this effect include relation to developmental immaturity of the central nervous system (CNS) in preterm infants, lower total drug exposure, less fat deposits of the drug, or possibly that the severity of NAS is more difficult to determine in preterm infants due to scoring tools being developed for full-term infants.

Opioids

The clinical presentation of NAS is dependent on multiple variables, including opioid used; maternal drug use history; maternal, placental and infant metabolism; and other factors. Because opioid receptors focus on the central nervous system (CNS) and gastrointestinal (GI) tract, the majority of NAS symptoms reflect CNS irritability, autonomic over-reactivity, and GI tract dysfunction. Excess stimuli and hunger exacerbate the perceived severity of NAS.

Cocaine and other CNS Stimulants

Neurobehavioral symptoms from intrauterine exposure to CNS stimulants such as cocaine and amphetamine frequently occur on the second or third day postnatal. Symptoms include irritability, hyperactivity, tremors, high-pitched cry, and excessive sucking. However, since cocaine and its metabolites can be detected in the neonatal urine for up to 3 days postnatal, symptoms may reflect drug effect rather than withdrawal. Pharmacological treatment of infants with neurobehavioral symptoms due to intrauterine cocaine exposure has not been carefully evaluated, thus no standard of care exists.

Selective Serotonin Reuptake Inhibitors

Selective serotonin reuptake inhibitors (SSRIs) are the most common class of anti-depressants used to treat depression in the general population and during pregnancy. Studies have linked third trimester use of SSRIs to a group of symptoms including continuous crying, irritability, jitteriness, and/or restlessness, shivering, fever, tremors, hypertonia or rigidity, tachypnea or respiratory distress, feeding difficulty, sleep disturbance, hypoglycemia, and seizures. Onset of these symptoms generally begins several hours to several days after birth and subsides within 1 to 2 weeks. It is not clear if these symptoms reflect serotonin syndrome or SSRI withdrawal. Clinicians should arrange for early follow up after hospital discharge for infants at risk from the effects of SSRI exposure in utero.



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Eat, Sleep, Console (ESC) Assessment Approach

The Finnegan scoring system, the most widely adopted scoring system, and modified versions of this tool are designed for use in term infants. Other assessment tools have been developed including the Eat, Sleep, Console (ESC) assessment approach that evaluates the neonates' ability to eat, sleep, and be consoled. The ESC method's approach is for the treatment (both non-pharmacologic and pharmacologic treatment) of the infant and should be based on infant function and comfort, rather than reducing signs and symptoms of withdrawal. The use of this tool emphasizes maternal/caregiver involvement with a goal of reducing opioid therapy and length of birth hospitalization. The effectiveness of the ESC method has been validated by quality improvement initiatives and reviews. The ESC functional assessment and family centered treatment methodology is slowly replacing the modified Finnegan scoring system for the assessment and treatment of NAS.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®*	Description			
Codes				
No applicable codes.				

HCPCS ®* Codes	Description
No applicabl	e codes.

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code Description
No applicable codes.

Reviews, Revisions, and Approvals		Approval
		Date
Original approval date	03/21	06/21
Annual Review	07/21	08/21
Updated Description. Added cocaine and SSRIs, to the NAS symptom onset	08/22	08/22
table.		
Criteria Updates - Clarifying edits added to I.A.1. regarding "duration of		
observation for symptoms." In I.B., replaced portion of note reflecting a 6-		

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Reviews, Revisions, and Approvals	Date	Approval Date
hour dosing interval with a 4-hour morphine dosing interval. Added		
requirement in I.C.2. discharge criteria that infant is consolable with		
appropriate measures 24-48 hours after the last dose of morphine prior to		
discharge, based on gestational age, with note about morphine half-lives		
applicable to a range of gestational ages.		
Background Updates - Website for Modified Finnegan scoring added to the		
background under B.1. Updated A.3.b. regarding screening that meconium		
and umbilical blood reflect drug use for 20 weeks of gestation and later.		
Changed background heading "Observation/Assessment" to "B.		
Observation location//Assessment tool/Level of Care," and in that section:		
expanded information regarding LOC for Finnegan scoring, and added		
section for LOC for ESC scoring. In nonpharmacologic treatment section,		
changed recommendation from frequent feedings of calorie dense formular		
or fortified breastmilk to "breastfeeding or formula feeding as indicated."		
Added c under pharmacologic treatment regarding ESC assessment		
categories. Added details regarding morphine, clonidine, and phenobarbital		
weaning. Added additional background to "ESC Assessment Approach."		
References reviewed and updated.	0.4/20	0.4/2.2
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual review. Minor rewording in description and criteria. Updated	08/23	08/23
criteria I.C.7. to include family medicine provider. Added criteria I.C.8.		
regarding follow up appointment with the primary care pediatrician or		
family medicine provider scheduled prior to discharge. Background updated		
with no impact on criteria. References reviewed and updated.		

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North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid 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.

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



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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.

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/

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

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

- a. meet Medicaid 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.

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) 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).

Claims-Related Information

Provider(s) shall comply with the NC Tracks 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:

- a. Claim Type as applicable to the service provided:
 - Professional (CMS-1500/837P transaction)
 - Institutional (UB-04/837I transaction)
 - Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- 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. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

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.



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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 Providers shall follow applicable modifier guidelines.
- e. Billing Units Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments For Medicaid refer to Medicaid State Plan:
 https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
- g. Reimbursement Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible



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for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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