Clinical Policy: Neonatal Sepsis Management

Reference Number: WNC.CP.167 Coding Implications
Last Review Date: Revision Log

See Important Reminder **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

Through the increased incidence of intra-partum antibiotics, early-onset neonatal sepsis is occurring less frequently. However, sepsis continues to be a prevalent cause of neonatal morbidity and mortality.[2,5]

Group B Streptococcus (GBS) infection remains the leading cause of early-onset neonatal sepsis and a major cause of late-onset sepsis. The American Academy of Pediatrics defines GBS early-onset disease as a blood or cerebrospinal fluid culture-proven infection occurring within the first six days of life. GBS late-onset disease is defined as isolation of GBS from a normally sterile site from seven to 89 days of age.[8] More than half of GBS cases occur in infants of individuals with negative GBS cultures, emphasizing the need to remain vigilant for signs of sepsis in all newborns. To ensure timely treatment and to reduce morbidity and mortality, these infants require comprehensive assessment and treatment, as well as discharge planning.[2,5]

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that the management of neonatal sepsis is medically necessary at the indicated level of care for the following circumstances:

A. Episode Day 1

1. Well-appearing infants who are on 48 hours of antibiotics pending blood culture results are appropriate for level II (rev code 172) nursery.
2. Symptomatic infants are appropriate for level III (rev code 173) nursery when meeting **ALL** of the following criteria:
   a. Signs of neonatal sepsis (e.g.: hypotonia, lethargy, poor oral feeding, tachycardia, bradycardia, grunting, nasal flaring, cyanosis);
   b. Temp ≥ 100.4◦ F or ≤ 96.8◦ F (≥ 38.0◦ or ≤ 36.0◦ C);
   c. On 48 hours of antibiotics pending blood culture results or treatment of positive blood cultures.

B. Episode Day 2 and Subsequent Days

1. Infants with negative cultures who are determined to require antibiotics beyond 48 hours may be appropriate for transitional care or level I nursery (rev code 171)

once antibiotics are the only intervention necessitating continued stay and if outpatient antibiotics are inappropriate or unmanageable.

2. Symptomatic infants are appropriate for level III (rev code 173) nursery when meeting **all** the following criteria:
   a. Signs of neonatal sepsis (e.g.: hypotonia, lethargy, poor oral feeding, tachycardia, bradycardia, grunting, nasal flaring, cyanosis);
   b. Temp ≥ 100.4◦ F or ≤ 96.8◦ F (≥ 38.0◦ or ≤ 36.0◦ C);
3. On 48 hours of antibiotics pending blood culture results or treatment of positive blood cultures.
4. Asymptomatic infants on 48 hours of antibiotics pending blood culture results for ≤ 2 days are appropriate for Level II (rev code 172) nursery.
5. Asymptomatic infants with a positive blood culture and no other indications are appropriate for transitional care.

Once the culture and sensitivity results are known and antibiotic therapy is established, a medically stable infant should be transitioned to a lower level of care for treatment completion if no other indications exist that require the current level of care.

It is difficult to administer intravenous (IV) antibiotics in the home with home health care due to the challenge of keeping very small catheters in place and patent. Transitional care nursery should be considered if antibiotics cannot safely be administered at home or at home with home health care.

II. Discharge criteria, with or without home antibiotics, meets all of the following, as applicable:

A. Member is clinically stable;
B. Home situation is assessed and deemed adequate;
C. Parent or caretaker is agreeable with the plan of care;
D. If going home with antibiotics, **all** the following are met:
   1. Contractual agreement of care signed with a home infusion company experienced in neonatal IVtherapy or short-term intramuscular therapy;
   2. Secure IV access is in place, if chosen;
   3. Contact information regarding the responsible physician (e.g., neonatologist, primary care pediatrician) and back-up health care facility (neonatal intensive care unit [NICU], community hospital) should be provided to the family and home care agency prior to discharge;
E. Provider follow-up scheduled within 48 hours of discharge.

Background

I. Identification and treatment of birthing individual during pregnancy and labor[6,7,9]

A. Birthing individuals with Group B streptococcus (GBS) isolated in the urine any time during the current pregnancy or who had a previous infant with invasive GBS disease

should receive intravenous (IV) intrapartum antibiotic prophylaxis. Third trimester screening for GBS colonization is not needed in this population.

B. Birthing individuals with symptomatic or asymptomatic GBS urinary tract infection (UTI) detected during pregnancy should be treated according to current standards of care for UTI during pregnancy and should receive intrapartum antibiotic prophylaxis to prevent early-onset GBS disease.

C. All other birthing individuals, including those with a scheduled cesarean delivery, should be screened at 36 0/7 – 37 6/7 weeks gestation for vaginal and rectal GBS colonization.

D. At the time of labor or rupture of membranes (ROM), intrapartum antibiotic prophylaxis should be given to all birthing individuals whose vaginal-rectal cultures were positive for GBS colonization, including those undergoing cesarean delivery. If cesarean delivery is performed before onset of labor on a birthing individual with intact amniotic membranes, prophylaxis need not be given.

E. When screening results are not available at the time of labor and delivery, intrapartum antibiotics should be given to birthing individuals who present in labor with a substantial risk of preterm birth, who have preterm pre-labor rupture of membranes (PPROM), rupture of membranes ≥ 18 hours at term, or who present with intrapartum temperature ≥100.4º F (≥ 38.0ºC). If none of the above risks are present but there is a history of GBS colonization in a previous pregnancy, it is reasonable to offer intrapartum antibiotic prophylaxis and/or discuss it as an option in a shared decision-making process with the provider.

F. If intraamniotic infection is suspected, broad-spectrum antibiotic therapy that provides coverage for polymicrobial infections as well as GBS should replace the antibiotic that provides coverage for GBS prophylaxis specifically.

G. In the absence of GBS UTI that is symptomatic, or with GBS present at levels ≤ 10^5 colony forming units (CFU)/mL, antimicrobial agents should not be used before the intrapartum period to eradicate GBS genito-rectal colonization because such treatment has not been shown to provide better outcomes to the birthing individual or neonate.

H. Obstetric interventions, when necessary, should not be delayed solely to provide 4 hours of antibiotic administration before birth.

II. Identification and Treatment of the newborn[7,8]

A. Infants born at ≥35 weeks' gestation should be managed according to risk, as determined by categorical risk assessment, clinical condition, or multivariate risk assessment. A copy of a risk assessment,the Neonatal Early-Onset Sepsis Calculator, is available at https://neonatalsepsiscalculator.kaiserpermanente.org/

B. Preterm infants born at ≤34 weeks are at highest risk for early-onset sepsis (EOS) in the following circumstances: Infants born preterm because of cervical insufficiency, preterm labor, premature rupture of membranes, intraamniotic infection, and/or acute and otherwise unexplained onset of nonreassuring fetal status are at the highest risk of EOS and GBS early-onset disease (EOD). A blood culture and initiation of empirical antibiotic treatment is recommended for infants with any of these risk factors.

C. Preterm infants born at ≤34 weeks' are at lower risk for EOS when meeting all of the following: 1) maternal and/or fetal indications for preterm birth (such as maternal preeclampsia or other noninfectious medical illness, placental insufficiency, or fetal growth restriction), (2) birth by cesarean delivery, and (3) absence of labor, no attempts to induce labor, or no rupture of membranes (ROM) before delivery.

D. For lower risk preterm infants, initial approaches include (1) no laboratory evaluation and no empirical antibiotic therapy or (2) blood culture and clinical monitoring. For infants who do not improve after initial stabilization and/or those who have severe systemic instability, the administration of empirical antibiotics may be reasonable but is not mandatory.

E. Physicians should use their best judgment to determine when cerebrospinal fluid analysis should be performed in the absence of bacteremia, as culture-confirmed meningitis in the absence of culture-confirmed bacteremia is approximately 1 to 2 cases per 100,000 live births. However, the rate of meningitis is higher in preterm infants, and a lumbar puncture for culture and analysis of CSF should be considered in clinically ill infants when there is a high suspicion for GBS EOD, unless the procedure will compromise the neonate's clinical condition.

F. Therapy for a term infant at risk of EOS should include antimicrobial agents active against GBS (including IV ampicillin and gentamicin), as well as other organisms that might cause neonatal sepsis, such as E. coli, et al.

G. Early-onset GBS infection is diagnosed by blood or CSF culture. Common laboratory tests such as the complete blood cell count and C-reactive protein do not perform well in predicting early-onset infection, particularly among well-appearing infants at lowest baseline risk of infection. Procalcitonin has also been suggested as a biomarker for determining the risk of early onset sepsis. However, it is not definitive in ruling in or ruling out an infection in neonates.

III. General Considerations[7]

A. Stable infants at 35 weeks gestational age or older who are treated for sepsis should be discharged the same day the antibiotics are discontinued,

B. For ruling out sepsis due to perinatal risk factors, 36-48 hours of antibiotic administration is considered appropriate pending culture results and evaluation of lab data.

C. When blood cultures are sterile, antibiotic therapy should be discontinued by 36 to 48 hours of incubation unless there is clear evidence of site-specific infection.

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 2025, 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.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Revised criteria in Section II.D. References reviewed and updated.	05/22	08/22
Annual review. Description updated. Background updated. II.C. Minor rewording for clarity. II.G. added verbiage about procalcitonin. III.A. added verbiage "if no other conditions require ongoing inpatient hospital care." III.B, changed 48 hours to 36-48 hours. References reviewed and updated.	11/22	11/22
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual review completed. Description and background updated with no effect on criteria. Criteria II.B. changed "and" to "all the following." References reviewed and updated.	11/23	11/23
Annual review. Reworded description with no clinical significance. Reworded criteria under I.A.2. "when meeting all of the following criteria" with no impact to criteria. Expanded criteria under I.B.1. and II.B.1. "Signs of neonatal sepsis (e.g.: hypotonia, lethargy, poor oral feeding, tachycardia, bradycardia, grunting, nasal flaring, cyanosis). Reworded criteria under II.D.1., II.D.3. and II.E. with no impact to criteria. References reviewed and updated.	02/24	02/24
Annual Review. References reviewed.	02/25	02/25
References updated. Under NC Guidance/Claims related information, updated state web address.	02/25	02/25
Description and background updated with no clinical significance. Criteria updated with no impact to 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

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
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.
   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/meetingsnotices/medicaid-state-plan-public-notices.
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 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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