

Clinical Policy: Neonatal Sepsis Management

Reference Number: CP.MP.85

Last Review Date: 07/19

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Through the increased incidence of intra-partum antibiotics, early-onset neonatal sepsis is occurring less frequently. However, it continues to be a common cause of neonatal morbidity and mortality. The CDC (Centers for Disease Control and Prevention) defines early onset sepsis as a blood or cerebrospinal fluid culture-proven infection occurring within the first seven days of life.

Group B Streptococcus (GBS) remains the leading cause of neonatal sepsis. More than half of GBS cases occur in infants of mothers with negative GBS cultures, emphasizing the need to remain vigilant for signs of sepsis in all newborns. These infants require comprehensive assessment and treatment, as well as discharge planning, in order to ensure timely treatment in an effort to reduce morbidity and mortality.²

Policy/Criteria

It is the policy of Health Plans affiliated with Centene Corporation that the management of neonatal sepsis is **medically necessary** at the indicated level of care for the following circumstances:

I. Episode Day 1

- A. Well-appearing infants who are on 48 hours of antibiotics pending blood culture results are appropriate for level II (rev code 172) nursery.
- B. Symptomatic infants are appropriate for level III (rev code 173) nursery with all the following:
 1. Hypotonia, lethargy, or poor oral feeding;
 2. Temp $\geq 100.4^{\circ}\text{F}$ or $\leq 96.8^{\circ}\text{F}$ ($\geq 38.0^{\circ}$ or $\leq 36.0^{\circ}\text{C}$);
 3. On 48 hours of antibiotics pending blood culture results or treatment of positive blood cultures.

II. Episode Day 2 and Subsequent

- A. 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.
- B. Symptomatic infants are appropriate for level III (rev code 173) nursery when meeting the following criteria:
 1. Hypotonia, lethargy, or poor oral feeding; and
 2. Temp $\geq 100.4^{\circ}\text{F}$ or $\leq 96.8^{\circ}\text{F}$ ($\geq 38.0^{\circ}$ or $\leq 36.0^{\circ}\text{C}$); and
 3. On 48 hours of antibiotics pending blood culture results or treatment of positive blood cultures.
- C. Asymptomatic infants on 48 hours of antibiotics pending blood culture results for ≤ 2 days are appropriate for Level II (rev code 172) nursery.
- D. Asymptomatic infants with a positive blood culture and no other indications are appropriate for transitional care or level I nursery (rev code 171).

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. Transitional care nursery should be considered if antibiotics cannot safely be administered at home or at home with home health care.

III. Discharge criteria, with or without home antibiotics, meets all, 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. A home infusion company is contracted which is experienced in neonatal IV (intravenous) therapy or short-term intramuscular therapy;
 - 2. Secure IV access is in place if chosen;
 - 3. The responsible physician (neonatologist, primary care pediatrician) and back-up health care facility (neonatal intensive care unit [NICU], community hospital) should be clarified to the family and home care agency prior to discharge.

Background

I. Identification and treatment of mother during pregnancy and labor⁹

- A. Women with GBS isolated in the urine any time during the current pregnancy or who had a previous infant with invasive GBS disease should receive IV intrapartum antibiotic prophylaxis. Third trimester screening for GBS colonization is not needed in this population.
- B. Women 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 pregnant women, 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, intrapartum antibiotic prophylaxis should be given to all pregnant women 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 woman 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 women who present in labor with a substantial risk of preterm birth, who have preterm prelabor rupture of membranes (PPROM), rupture of membranes ≥ 18 hours at term, or who present with intrapartum temperature $\geq 100.4^{\circ}$ F ($\geq 38.0^{\circ}$ C). If a woman has none of the risks above but has 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 $\geq 10^5$ colony forming units (CFU)/mL, antimicrobial agents should not be used before the intrapartum period to eradicate GBS genitoretal colonization because such treatment has not been shown to provide better maternal or neonatal outcomes.
- 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

- A. Any infant with signs of sepsis should receive a full diagnostic evaluation and antibiotic therapy pending the results of the evaluation. The evaluation should include a blood culture; CBC including white blood cell differential and platelet count; and chest radiograph if any abnormal respiratory signs are present.¹
- B. A lumbar puncture should only be performed if the infant is stable enough to tolerate the procedure and (1) the infant has a positive blood culture, (2) infant has a high probability of sepsis on the basis of clinical signs or laboratory values, or (3) infant does not clinically improve when treated with appropriate antibiotic therapy.¹ 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.¹⁰
- C. Therapy for an infant at risk of early-onset sepsis 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.^{1,10}
- D. Any symptomatic infant without risk factors for infection, who improves over the first 6 hours of life, may not require treatment but must be monitored closely.¹
- E. Well-appearing infants whose mothers had suspected chorioamnionitis should undergo a limited evaluation and receive antibiotic therapy pending culture results. The evaluation should include a blood culture and a CBC including white blood cell differential and platelet count, but no routine chest radiograph or lumbar puncture is needed in this case. Consultation with obstetric providers to assess whether chorioamnionitis was suspected is important to determine neonatal management.¹
- F. Well-appearing infants whose mothers had no chorioamnionitis and no indication for GBS prophylaxis should be managed according to routine clinical care.¹
- G. Well-appearing infants whose mothers had no chorioamnionitis and no indication for GBS prophylaxis but with suspected infection due to slightly abnormal lab results may receive 48 hours of antibiotics pending blood cultures. They would otherwise be managed according to routine care.¹
- H. Well-appearing infants of any gestational age whose mothers had indications for GBS prophylaxis and received adequate intrapartum GBS prophylaxis (≥ 4 hours of penicillin, ampicillin, or cefazolin before delivery) should be observed for ≥ 48 hours and no routine diagnostic testing is recommended. Such infants may be discharged home as early as 24 hours after delivery if the infant is medically stable, ready access to medical care exists, and a person able to comply fully with instructions for home observation will be present.¹
- I. For well-appearing infants born to mothers who had an indication for GBS prophylaxis but received no or inadequate prophylaxis, if the infant is well-appearing and ≥ 37 weeks and 0 days' gestational age and the duration of membrane rupture before delivery was < 18 hours, the infant should be observed for ≥ 48 hours, and no routine diagnostic testing

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is recommended. If the infant is well-appearing and either <37 weeks and 0 days' gestational age or the duration of membrane rupture before delivery was ≥18 hours, then the infant should undergo a limited evaluation (a blood culture and CBC including white blood cell differential and platelet count) and observation for ≥ 48 hours.¹

- J. Antibiotics use for more than 2 days should not be based solely on elevated C-reactive protein (CRP). Evidence for CRP as a screening test for neonatal sepsis suggests that although the negative predictive value is high, the positive predictive value is low, particularly among healthy-appearing term infants. CRP levels are most useful in combination with other tests as a part of a sepsis screen.¹ Serial evaluation of inflammatory markers such as CRP and procalcitonin should not be used to assess well-appearing term newborn infants for risk of early-onset sepsis.¹⁰

III. General Considerations

- 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, 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.¹⁰

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|-------|---------------|
| Policy developed, Neonatologist reviewed | 08/13 | 08/13 |
| Renamed “Authorization Protocol” to Policy/Criteria and reformatted text to episode days and discharge criteria. Remaining information moved to background. Background updated regarding timing of lumbar puncture Updated nursery levels based on updated Interqual criteria nursery leveling Neonatologist reviewed | 09/14 | 09/14 |
| References reviewed and updated; converted to new template. Neonatologist reviewed | 09/15 | 09/15 |
| Clarified bullets under III.D. No criteria change | 04/16 | |
| References reviewed and updated. Minor wording changes for clarification. | 08/16 | 09/16 |
| References reviewed and updated. | 09/17 | 09/17 |
| References reviewed and updated. | 07/18 | 07/18 |
| Policy reviewed by neonatologist and pediatrician. | 05/19 | |
| Edits to background information regarding identification and treatment of the mother, and identification and treatment of the newborn, per new ACOG and AAP guidelines. | 07/19 | 07/19 |

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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

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

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Note: For Medicaid members, 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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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