

Clinical Policy: Phototherapy for Neonatal Hyperbilirubinemia

Reference Number: CP.MP.150

Date of Last Revision: 10/23

Coding Implications
Revision Log

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

Description

This policy details medical necessity criteria for home phototherapy for the treatment of neonatal hyperbilirubinemia. Almost all newborns will develop total serum bilirubin (TSB) levels greater than the upper limit of normal for adults, 1 mg/dL. Increasing TSB can cause jaundice, and newborns with severe hyperbilirubinemia are at risk for developing acute neurotoxicity as bilirubin crosses the blood-brain barrier. Acute bilirubin-induced neurologic dysfunction (BIND) can have chronic and permanent neurologic effects, termed kernicterus. Thus, screening for hyperbilirubinemia should be conducted on all infants prior to discharge.¹

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that conventional phototherapy in the home, applied by a single light source in the blue-green spectrum (460 to 490nm), for the treatment of physiologic hyperbilirubinemia in *term* (≥ 38 weeks gestation) infants is **medically necessary** when meeting all of the following guidelines:
 - A. Term infant status is one of the following:
 - 1. Previously discharged home and readmission is being considered only for hyperbilirubinemia;
 - 2. Infant is currently inpatient and ready for discharge except for needing treatment for elevated bilirubin;
 - B. The infant is feeding well, is active, and clinically well;
 - C. If breastfeeding or chestfeeding, lactation support from a qualified professional has been offered:
 - D. A primary care provider is willing to manage home care with established follow-up within 12 to 24 hours after discharge;
 - E. > 48 hours old;
 - F. An LED-based phototherapy device will be available in the home without delay;
 - G. No previous phototherapy;
 - H. Total serum bilirubin (TSB) will be measured daily;
 - I. Infant has none of the following risk factors:
 - 1. Isoimmune hemolytic disease (i.e., positive direct antiglobulin test), glucose-6-phosphate dehydrogenase (G6PD), or other hemolytic disease;
 - 2. Hypoxic Ischemia Encephalopathy (HIE)/Asphyxia;
 - 3. Temperature instability;
 - 4. Sepsis;
 - 5. Acidosis;
 - 6. Albumin < 3.0 g/dL (if measured);
 - 7. Birth weight < 2500g;
 - 8. Significant cephalohematoma or bruising;
 - 9. Weight loss $\geq 10\%$;

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- 10. Elevated direct-reacting/conjugated bilirubin;
- 11. Jaundice appearing in first 24 hours of life;
- 12. Laboratory or clinical evidence of hypothyroidism;
- 13. Significant clinical instability in the previous 24 hours;
- 14. Clinical history of a parent or sibling requiring phototherapy or exchange transfusion;
- 15. Exclusive breastfeeding or chestfeeding with suboptimal intake (≥ 10% weight loss);
- 16. Down syndrome;
- 17. Macrosomic infant of a diabetic mother;
- J. TSB is within the levels noted in Table 1 below: Table 1. Acceptable TSB levels for home phototherapy in infants without risk factors, by age:

Age	TSB Level
24 to 36 hours	\leq 11 mg/dL
36 to 48 hours	$\leq 14 \text{ mg/dL}$
48 to 60 hours	\leq 15 mg/dL
60 to 72 hours	$\leq 16 \text{ mg/dL}$
> 72 hours	≤ 17 mg/dL

^{*}Note: The TSB home phototherapy table above allows for conservative TSB levels to align with the lower age limit in hours provided in the age ranges for inpatient criteria for hyperbilirubinemia (see section II).

II. It is the policy of Centene Corporation that when criteria for home phototherapy are met, inpatient phototherapy for hyperbilirubinemia is **not medically necessary** unless documentation of extenuating circumstances (including, but not limited to, expected lack of compliance with therapy at home) is provided.

* Note:

- Infants should be admitted for inpatient phototherapy if the TSB concentration is more than 1 mg/dL above the American Academy of Pediatrics (AAP) guidelines phototherapy treatment threshold in the hyperbilirubinemia risk calculator at https://peditools.org/bili2022/index.php. The values in Table 1 above offer phototherapy at levels consistent with the AAP statement that phototherapy can be offered below the AAP treatment threshold per the provider's discretion.
- Additional criteria for inpatient phototherapy for hyperbilirubinemia, to be used in conjunction with this policy, can be found in clinical decision support tools.
- III. It is the policy of Centene Corporation that other treatment for hyperbilirubinemia, including inpatient phototherapy (when not meeting criteria for home phototherapy per this policy) and exchange transfusion, is **medically necessary** when meeting the most current version of the relevant nationally recognized decision support tools.

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Background

Efforts to reduce kernicterus include prevention and management of hyperbilirubinemia. Preventive strategies focus on identifying at-risk infants and beginning preventive therapeutic interventions as needed, usually through universal screening of all neonates for hyperbilirubinemia, which may be performed by measurement of total serum bilirubin (TSB) or by use of a transcutaneous device to obtain a Transcutaneous bilirubin (TcB) level.²

G6PD deficiency is now recognized as one of the most significant causes of hyperbilirubinemia leading to kernicterus. Identifying neonates with G6PD deficiency is challenging, so knowledge of certain risk factors for this deficiency can lead to improved health outcomes. G6PD deficiency is more common in males because it is a sex-linked recessive gene located on the X chromosome, and males only have one X chromosome. G6PD deficiency is prevalent in populations with genetic ancestry from Sub-Saharan Africa, Middle East, Mediterranean, Arabian Peninsula, and Southeast Asia. Additionally, 13% of African American males and 4% of African American females have G6PD deficiency.³

Phototherapy is considered first-line treatment for neonatal hyperbilirubinemia, defined as TSB > 95th percentile on the hour-specific Bhutani nomogram for infants ≥ 35 weeks gestational age (GA).¹ Phototherapy has been used widely for over 60 years and has been associated with few adverse events in term infants. Phototherapy decreases or reduces the rate of rise of bilirubinemia in almost all cases, regardless of the cause.² It also reduces the risk that TSB will reach the level associated with increased risk of kernicterus and that at which exchange transfusion is recommended.

Some infants are more likely to be readmitted for treatment of hyperbilirubinemia after discharge from their birth hospitalization. Infants discharged in the first two days after birth were more likely to be readmitted for jaundice compared with infants who stayed longer than three days, an association that decreased with increasing GA.⁴ Other risk factors for hyperbilirubinemia include vaginal delivery, exclusively breastfeeding at discharge, primiparous mother, maternal age less than 20 years old, mother with an Asian country of birth, and higher TSB relative to the treatment threshold at phototherapy initiation.^{4,5}

Phototherapy works by using photons from light to alter bilirubin molecules in the superficial capillaries into water-soluble, non-neurotoxic molecules and reducing unconjugated TB levels. Conventional phototherapy is delivered by a single light source. The preferred treatment is intensive phototherapy delivered by irradiance in the blue-green spectrum (wavelengths of approximately 460 to 490 nm) of at least 30 $\mu W/cm2$ per nm (measured at the infant's skin directly below the center of the phototherapy unit) and is delivered to as much of the infant's surface area as possible. Conventional phototherapy may be delivered in the hospital or in the home setting.

Home phototherapy can be less disruptive to the family and is appropriate for otherwise healthy, term infants without hemolysis and other risk factors, who have TB levels 2 to 3 mg/dL below the recommended threshold level for initiation of hospital phototherapy, are feeding well, and can be closely followed. Per the updated 2022 clinical practice guidelines from the American



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Academy of Pediatrics (AAP), home phototherapy is an option that can be started at a lower threshold, such as 2 mg/dL below the phototherapy threshold, to reduce the risk of hospital readmission.³ During phototherapy, infants should be placed on their backs and fully exposed to the light with the exception of a diaper. Their eyes should be shielded with an opaque blindfold with attention given to prevent the blindfold from covering the nose or sliding off the eyes.¹

American Academy of Pediatrics (AAP)

In 2022 the AAP published updated clinical practice guidelines that are meant to replace the 2004 clinical guidelines concerning the assessment and treatment of neonatal hyperbilirubinemia in infants ≥35 weeks.³ The 2022 AAP guidelines focus on recommendations for when infants should have a direct antiglobulin test (DAT) and blood type testing; implementation of care practices that promote evidence-based breastfeeding support that is family-centered; recommendation against providing the infant with water or dextrose water as an oral supplementation to prevent hyperbilirubinemia or to decrease bilirubin levels; importance of assessing for glucose-6-phosphate dehydrogenase (G6PD) deficiency; assessment for hyperbilirubinemia neurotoxicity risk factors; recommendations for when total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) should be measured; recommendations for phototherapy treatment. The 2022 AAP guidelines address the issues of prevention, risk assessment, monitoring, and treatment of neonatal hyperbilirubinemia in infants ≥ 35 weeks.³

National Institute for Health and Care Excellence (NICE)

NICE guidelines cover diagnosing and treating jaundice in order to detect and prevent very high levels of bilirubin. They provide consensus-based thresholds for when phototherapy and exchange transfusion should be initiated by age in hours.⁸

United States Preventive Services Task Force (USPSTF)

The USPSTF stated there was insufficient evidence to make recommendations regarding screening for hyperbilirubinemia for infants ≥ 35 weeks. They note that risk factors for hyperbilirubinemia include family history of neonatal jaundice, exclusive breastfeeding, bruising, cephalohematoma, ethnicity (Asian or black), maternal age older than 25 years, male sex, glucose-6-phosphate dehydrogenase deficiency, and gestational age less than 38 weeks. The specific contribution of these risk factors to chronic bilirubin encephalopathy in healthy children is not well understood. Currently, the USPSTF notes this recommendation is "inactive."

Coding Implications

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CPT [®]	Description
Codes	
N/A	

HCPCS	Description
Codes	
E0202	Phototherapy (bilirubin) light with photometer
S9098	Home visit, phototherapy services (e.g., Bili-lite), including equipment rental, nursing services, blood draw, supplies, and other services, per diem

Reviews, Revisions, and Approvals		Approval
	Date 12/17	Date
New policy		12/17
References reviewed and updated. Specialist review.		10/19
Added criterion that "if the mother is breastfeeding, she has been offered	10/20	10/20
lactation support from a qualified professional." References reviewed		
and updated. Specialist review. Replaced "member" with		
"member/enrollee in all instances.		
Annual review. Clarified in section III. that the statement applies when	10/21	10/21
not meeting criteria for home phototherapy in this policy. References		
reviewed and updated. Background updated with no clinical significance.		
Changed "review date" in the header to "date of last revision" and "date"		
in the revision log header to "revision date."		
Annual review. Changed title from "Home phototherapy" to	10/22	10/22
"Phototherapy" Updated criteria I.D. from 24 to 48 hours to 12 to 24		
hours. Updated criteria to include the following: I.E. ≥48 hours old; I.F.		
An LED-based phototherapy device will be available in the home		
without delay; I.G. No previous phototherapy; I.H. TSB will be		
measured daily. Criteria I.I. #1 updated to include example of positive		
direct antiglobulin test for isoimmune hemolytic disease and to include		
glucose-6-phosphate dehydrogenase (G6PD) and other hemolytic		
disease. Criteria I.I. #2 updated to include hypoxic ischemia		
encephalopathy (HIE). Significant lethargy removed from Criteria I.I.		
Criteria I.I. updated to include the following: #13 Significant clinical		
instability in the previous 24 hours; #14 Clinical history of a parent or		
sibling requiring phototherapy or exchange transfusion; #15 Exclusive		
breastfeeding with suboptimal intake (≥10% weight loss); #16 Down		
syndrome; #17 Macrosomic infant of a diabetic mother. Added note		
below Table 1 that explains the values are conservative TSB values		
based on lower age range thresholds in inpatient criteria. Added		
clarification to II that extenuating circumstances can include lack of		
expected compliance with therapy at home. Added note below policy		
statement II stating: that infants should be admitted for inpatient		
phototherapy if the TSB concentration is more than 1 mg/dL above the		
AAP guidelines phototherapy treatment threshold per the bili risk tool,		

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
and that table 1 is consistent with AAP guidelines allowing treatment at lower levels per provider discretion; and that clinical decision support tools provider further criteria for inpatient phototherapy treatment. Updated background to include 2022 AAP clinical practice guidelines. Removed ICD-10 codes. References reviewed and updated. Reviewed by internal specialist and external specialist.		
Annual review. Reworded criteria I.C. and I.I.15. for inclusive language.	10/23	10/23
References reviewed and updated.		

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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.

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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.

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Note: For Medicaid members/enrollees, 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/enrollees, 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 <u>prior to</u> 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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