

Clinical Policy: Phototherapy for Neonatal Hyperbilirubinemia

Reference Number: WNC.CP.131

Last Review Date:

Coding Implications

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

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 WellCare of North Carolina® that conventional phototherapy in the home, applied by a single light source in the blue-green spectrum, (460-490nm), for the treatment of physiologic hyperbilirubinemia in infants is **medically necessary** when meeting all of the following guidelines:
 - A. Infant is ≥ 38 weeks gestation;
 - B. 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;
 - C. The infant is feeding well, is active, and clinically well;
 - D. If breastfeeding or chest feeding, lactation support from a qualified professional has been offered;
 - E. A primary care provider is willing to manage home care with established follow-up within the next 12-24 hours after discharge;
 - F. ≥ 48 hours old;
 - G. An LED-based phototherapy device will be available in the home without delay;
 - H. No previous phototherapy;
 - I. Total Serum Bilirubin (TSB) will be measured daily;
 - J. Infant has none of the following risk factors:
 1. Iso-immune hemolytic disease (i.e., positive direct antiglobulin test), glucose-6-phosphate dehydrogenase (G6PD), or other hemolytic disease;

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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 $\geq 10\%$;
 10. Elevated direct reacting/conjugated bilirubin;
 11. Jaundice appearance 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 chest feeding with suboptimal intake ($\geq 10\%$ weight loss);
 16. Down syndrome;
 17. Macrosomic infant of a diabetic mother.
- K. TSB is within the levels noted in Table 1 below¹: **Acceptable TSB levels for home phototherapy in infants without risk factors, by age:**

Age	TSB Level
24-36 hours	≤ 11 mg/dL
36-48 hours	≤ 14 mg/dL
48-60 hours	≤ 15 mg/dL
60-72 hours	≤ 16 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 WellCare of North Carolina[®] 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 ability to adhere to 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

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<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 WellCare of North Carolina® 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.

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 the 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}

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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.¹ 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 460–490 nm) of at least 30 $\mu\text{W}/\text{cm}^2$ per nm (measured at the infant's skin directly below the center of the phototherapy unit) and delivered to as much of the infant's surface area as possible.^{1,6} Conventional phototherapy may be delivered in the hospital setting or in the home setting.⁷

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.¹ Per the updated 2022 clinical practice guidelines from the American 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

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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.”⁹

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 2024, 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.

HCPCS® Codes	Description
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	Reviewed Date	Approval Date
Original approval date	03/21	05/21
Reviewed HCPCS and ICD-10-CM codes.	08/21	11/21
Annual review. Clarified in section III. that the statement “applies when not meeting criteria for home phototherapy in this policy.” Background updated with no clinical significance. References reviewed and updated.	08/22	08/22
Annual review. Changed title from “Home phototherapy...” to “Phototherapy...” Updated criteria I.D. from 24-48 hours to 12-24 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 iso-immune 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	11/22	11/22

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Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
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, 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. References reviewed and updated. Reviewed by internal specialist and external specialist.		
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual Review. I.C. "If the mother is breastfeeding, she has been offered lactation support from a qualified professional;" is changed to: "If breastfeeding or chest-feeding, lactation support from a qualified professional has been offered;" I.I.15 "Exclusive breastfeeding with suboptimal intake ($\geq 10\%$ weight loss);" has been changed to "Exclusive breastfeeding or chest-feeding with suboptimal intake ($\geq 10\%$ weight loss);" Removed ICD-10-CMS codes.	11/23	11/23
Annual Review. Added I.A. 'Infant is ≥ 38 weeks gestation. Criteria I.B. removed "term" Criteria II. Verbiage updated with no impact to criteria. Removed CPT empty code table. References reviewed and updated.	11/24	11/24
Annual review. Criteria I.J.9. changed $>$ to \geq . References updated. Under NC Guidance/Claims related information, updated state web address.		

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North Carolina Guidance*Eligibility Requirements*

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- 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

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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.

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- 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,

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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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