Anthem

Clinical UM Guideline

Subject: Home Phototherapy Devices for Neonatal Hyperbilirubinemia
Guideline #: CG-DME-12
Status: Revised
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Description

This document addresses the use of home phototherapy and the devices used for the treatment of neonatal jaundice that is *physiologic* (that is, non-pathologic) in nature. In utero, the fetus requires larger amounts of hemoglobin for oxygenation. After birth, the need is reduced and hemoglobin is rapidly destroyed, producing increased levels of bilirubin. Jaundice results when the neonate's liver is unable to efficiently clear the accumulating bilirubin. Neonatal jaundice is a common occurrence and is frequently treated in the home setting. Infants with very high levels of bilirubin may be managed in the inpatient setting.

Clinical Indications

Medically Necessary:

Home phototherapy devices are considered **medically necessary** when the criteria below are met:

1. The infant has neonatal hyperbilirubinemia; **and**
2. Is ready to be discharged from the hospital or is already discharged;**and**
3. Has no known hyperbilirubinemia neurotoxicity risk factors;**and**
4. Total serum bilirubin concentration is no more than 1 mg/dL above the phototherapy treatment threshold as defined by the American Academy of Pediatrics Clinical Practice Guideline*; **and**
5. Phototherapy equipment used in the home, such as a fiberoptic blanket or band, is provided by a durable medical equipment (DME) provider.

*American Academy of Pediatrics Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation is available at: https://publications.aap.org/pediatrics/article/150/3/e2022058859/188726/Clinical-Practice-Guideline-Revision-Management-of?searchresult=1)

Not Medically Necessary:

Home phototherapy devices for neonatal hyperbilirubinemia are considered **not medically necessary** when the criteria above have not been met.

Home phototherapy devices for neonatal hyperbilirubinemia are considered **not medically necessary** when more than one phototherapy device (intensive phototherapy) is used in the home setting.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

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

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Hyperbilirubinemia is the most common condition requiring medical attention in newborns. A total of 50% of term neonates and 80% of preterm neonates develop jaundice in the first week of life. The jaundiced skin and sclera in newborns is the result of accumulation of unconjugated bilirubin. In most infants, unconjugated hyperbilirubinemia reflects a normal transitional phenomenon. However, in some infants, serum bilirubin levels may rise excessively, which can be a cause for concern as unconjugated bilirubin can be neurotoxic. As total serum bilirubin (TSB) rises closer to the phototherapy threshold, the potential need for escalation of care or future phototherapy also rises. The American Academy of Pediatrics (AAP) guideline for the *Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation* (Kemper, 2022) notes that some infants are at greater risk of developing bilirubin neurotoxicity. Those risk factors include gestational age less than 38 weeks; albumin less than 3.0 g/dL; isoimmune hemolytic disease (for instance, positive direct antiglobulin test), G6PD deficiency, or other hemolytic conditions; sepsis; and significant clinical instability in the previous 24 hours. Therefore, the presence of neonatal jaundice frequently requires diagnostic evaluation and treatment.

In the hospital setting, phototherapy is delivered by exposing the infant to fluorescent light. When this type of light source is used, the infant's eyes are protected from the lights with a mask. The infant is positioned in an incubator wearing only a diaper, exposing as much of the infant's skin surface as possible to the light source. For those infants with very high bilirubin levels, intensive phototherapy may be used. This type of phototherapy employs two light sources such as fluorescent and fiber optic light. The 2022

AAP guideline indicates, “Intensive phototherapy requires a narrow-spectrum LED blue light with an irradiance of at least 30 μW/cm^2 per nm at a wavelength around 475 nm.”

In the home setting, phototherapy is accomplished by using a blanket or a neck ring that emits fiber optic light. This light is directed below the infant’s head and is less intense than fluorescent light; therefore, masking the infant’s eyes is not necessary. The infant can also be fed without interrupting therapy. For home phototherapy to be safe and effective, the caregivers must be compliant with the treatment protocol and daily follow-up appointments must be kept. Additionally, the infant should be alert, eating, and voiding and stooling well. If the serum bilirubin level is rising in spite of home phototherapy, the infant may be treated with intensive phototherapy in the inpatient setting.

Regarding home phototherapy, the 2022 AAP guideline states:

> Home phototherapy can be less costly and disruptive to family routines and breastfeeding and may help improve bonding and reduce stress compared with readmission for phototherapy. However, its effectiveness depends on the quality of the home phototherapy device as well as the ability of the family to appropriately use it. Therefore, caution is needed when considering home phototherapy. Furthermore, home phototherapy is not recommended for infants with any hyperbilirubinemia neurotoxicity risk factor.
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> Home phototherapy should not be used if there is any question about the quality of the home phototherapy device, the ability to have the device delivered to the home rapidly, concerns about the family’s ability to use the device, or concerns about the ability to measure bilirubin concentrations daily. As with inpatient phototherapy, it is an option to start home phototherapy at a lower threshold (eg, 2 mg/dL below the phototherapy threshold) to reduce the readmission risk.

The document also provides guidance on discontinuation of phototherapy. That guidance indicates:

> Discontinuing phototherapy is an option when the TSB has decreased by at least 2 mg/dL below the hour-specific threshold at the initiation of phototherapy. A longer period of phototherapy is an option if there are risk factors for rebound hyperbilirubinemia (eg, gestational age <38 weeks, age <48 hours at the start of phototherapy, hemolytic disease).

The AAP/American College of Obstetrics and Gynecologists (ACOG) guidelines for perinatal care (2017) state that home phototherapy is a therapy option and eligible candidates require proper home care follow-up and supervision including obtaining blood samples to measure TSB levels. This is to allow for close monitoring to ensure TSB levels are decreasing, and to ensure swift intervention in the event that levels are not responding to home phototherapy.

In 2020, Chang and Waite published the results of a retrospective cohort study evaluating home phototherapy for neonatal hyperbilirubinemia. A total of 1324 infants born at ≥ 35 weeks gestation met inclusion criteria. The primary endpoint was hospitalization for inpatient phototherapy during or within 24 hours of completion of home phototherapy. The mean initial TSB was 16.9 ± 2.5 mg/dl, the mean duration of treatment was 53 hours (interquartile range [IQR], 44-72 hours; range, 15-280 hours), the median number of home nursing visits was 4 (IQR, 4-5; range, 3-13). All infants were treated with the BiliBed® (Medela, McHenry, IL) and a total of 414 (31.3%) infants were treated with both the BiliBed and a fiberoptic pad. The mean rate of TSB decline was similar for infants that were treated using BiliBed only versus the BiliBed and fiberoptic pad (0.08 ± 0.06 mg/dL/hour versus 0.09 ± 0.07 mg/dL/hour; p=0.14). A total of 25 infants were admitted to the hospital, 15 were admitted for rising TSB levels and 3/15 caregivers were not compliant with home phototherapy due to “fussiness.” A total of 14/15 infants with rising TSB levels had TSB above the treatment threshold (mean 3.7 ± 2.6 mg/dL above). The remaining 10 admissions were a result of parental request (n=3), other clinical concern (n=6), and power outage (n=1); 5 of these admissions had TSB above the treatment threshold and 5 were below. A second course of treatment was required for 18 infants (1.4%; 95% confidence interval [CI], 0.9-2.1%). Starting home phototherapy at or above the AAP treatment threshold was a risk factor for admission or repeat home therapy. If the infant was less than 96 hours of age at initial treatment, then a longer duration of phototherapy was required. A potential bias was physician selection of families to participate with home phototherapy. The results may not be generalizable due to the equipment used and the large selection of phototherapy options available. In conclusion, this study adds to the growing body of literature demonstrating the efficacy of home phototherapy as an effective treatment for neonatal hyperbilirubinemia.

In 2020, Chu and colleagues published the results of a systematic review and meta-analysis to determine if home based phototherapy is as effective as hospital-based phototherapy. A total of 4 studies met inclusion criteria with 259 infants included, 138 infants received home phototherapy and 121 received hospital-based phototherapy. The rate of TSB decrease was not different in home-based phototherapy versus hospital-based phototherapy (standard mean deviation [SMD] = 32; 95% CI, -0.22-0.86; p=0.04). There was no significant difference in the duration of treatment between home-based phototherapy and hospital-based phototherapy (SMD = 0.59; 95% CI, 0.28-0.90; p=0.06). This meta-analysis further confirms the efficacy of home-based phototherapy as an effective alternative to hospital-based phototherapy for the reduction of TSB concentrations with comparable durations of therapy.

An unblinded randomized controlled study performed by Pettersson in 2021 set out to determine safety and efficacy, length of stay, and number of failed treatments in term newborns that were randomized to either home phototherapy or conventional in-hospital phototherapy. The study included 147 participants; of which, 78 were randomized to home phototherapy and 69 were randomized to conventional phototherapy. The secondary outcomes were weight gain during treatment and the number of blood samples taken. The inclusion criteria denoted that the newborns needed to have a gestational age above 36 + 0 weeks, a chronological age of more than 48 hours, and a TSB above 18 mg/dL between 48 and 72 hours of age or a TSB higher than 20.5 mg/dL after 72 hours of age. Additionally, the caregivers of the newborns needed to be capable of performing the therapy and agree to return to the hospital for daily checkups. The device used for home phototherapy was the BiliSoft™ Phototherapy System (GE HealthCare, Chicago, IL) which is a single light-emitting diode fiber optic device. The control group receiving hospital-based phototherapy was treated with either the same BiliSoft unit and/or overhead devices. Caregivers in the study group were instructed to keep a diary of the duration of phototherapy, where the phototherapy took place, and the times the newborn was fed. The authors noted that no advice was given on nutrition or using formula, so the newborns were fed per the caregivers’ choice. The results showed that there were no statistically significant differences in the duration of treatment, weight change, amount of blood tests, or length of stay between the two groups. No participants required blood exchanges and 4% (n=3) of the participants in the study group were admitted to the hospital. All 3 participants received less than 10 hours of therapy under the lights within the previous 24 hours. There were three protocol violations in which infants received a treatment that they were not randomized to. These 3 participants were analyzed in the groups they were randomized to in accordance with the intention-to-treat principle. There were also 3 participants whose home therapy was discontinued due to the caregivers’ wishes. In the final analysis, 3 participants (2 in the control group and 1 in the study group) were not included because the families decided to stop taking part in the study. One participant in the control group was lost to follow-up. The authors concluded that for otherwise healthy newborns who have hyperbilirubinemia, home phototherapy could be a safe alternative to inpatient phototherapy if daily checkups and around-the-clock telephone support can be provided.

References

Peer Reviewed Publications:

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2. Chu L, Qiao J, Xu C. Home-based phototherapy versus hospital-based phototherapy for treatment of neonatal hyperbilirubinemia: a systematic review and meta-analysis. Clin Pediatr (Phila). 2020; 59(6):588-595.
3. Moerschel SK, Cianciaruso LB, Tracy LR. A practical approach to neonatal jaundice. Am Fam Physician. 2008; 77(9):1255-1262.
4. Pettersson M, Eriksson M, Albinsson E, Ohlin A. Home phototherapy for hyperbilirubinemia in term neonates-an unblinded multicentre randomized controlled trial. Eur J Pediatr. 2021; 180(5):1603-1610.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Guidelines for perinatal care. 8th ed. Elk Grove Village (IL): AAP; Washington, DC: American College of Obstetricians and Gynecologists; 2017.
2. Kemper AR, Newman TB, Slaughter JL, et al. Clinical practice guideline revision: management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics. 2022; 150(3):e2022058859.
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5. Okwundu CI, Okoromah CA, Shah PS. Prophylactic phototherapy for preventing jaundice in preterm or low birth weight infants. Cochrane Database Syst Rev. 2012;(1):CD007966.

Websites for Additional Information

1. National Institutes of Health. Newborn jaundice. Reviewed January 24, 2023. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001559.htm. Accessed on August 14, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted Clinical Indications section. Revised Clinical Indications to address neurotoxicity risk factors and remove criteria related to environment, follow-up, and eating, etc. Revised link to AAP Clinical Practice Guideline in Clinical Indications. Revised Discussion/General Information, References, Websites for Additional Information, and Index sections.
Reviewed	08/11/2022	MPTAC review. Updated Discussion and Websites for Additional Information sections.
Reviewed	08/12/2021	MPTAC review. Updated Websites for Additional Information section.
Reviewed	08/13/2020	MPTAC review. Updated Discussion/General Information, References, Websites for Additional Information, and Index sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Website section.
Revised	09/13/2018	MPTAC review. Updated link to AAP guidelines in MN statement. Updated Discussion/General Information section.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated hyperlink in clinical indications section. Updated References section.
Reviewed	11/03/2016	MPTAC review. Updated References section.
Reviewed	11/05/2015	MPTAC review. Updated Reference section. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review.
Reviewed	11/14/2013	MPTAC review. References updated.
Revised	11/08/2012	MPTAC review. Added not medically necessary statement for when medically necessary criteria have not been met. Updated References section.
Reviewed	11/17/2011	MPTAC review. Coding and References updated.
Reviewed	11/18/2010	MPTAC review. References updated.
Reviewed	11/19/2009	MPTAC review. Removed Place of Service/Duration table. Updated Discussion/General Information and References.
Reviewed	11/20/2008	MPTAC review. References updated.
Reviewed	11/29/2007	MPTAC review. Description and references updated.
Reviewed	12/07/2006	MPTAC review.

Revised	12/01/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			None
WellPoint Health Networks, Inc.	12/02/2004		Home Phototherapy Devices for Neonatal Hyperbilirubinemia

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