



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Home Phototherapy for Hyperbilirubinemia**

**Effective Date .....4/15/2010**  
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**Coverage Policy Number .....0025**

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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

Coverage for home phototherapy devices is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of co-payments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for home phototherapy devices is available, the following conditions apply.

CIGNA covers the use of a home phototherapy unit in a newborn with neonatal jaundice when ALL of the following criteria are met:

- The infant is otherwise clinically appropriate for discharge from the hospital or, if already discharged, does not otherwise require readmission to the hospital.
- The infant appears healthy, active, and is feeding well.
- A primary liver disorder is not the cause of the elevated serum bilirubin.
- Arrangements have been made that include close visual follow-up by the primary care provider and/or an appropriately trained home health care nurse, as well as regular serum bilirubin determinations.

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## General Background

Hyperbilirubinemia, or neonatal jaundice, is a condition in which there is a higher-than-normal level of bilirubin in the blood. Newborns, especially premature infants, are unable to excrete bilirubin as fast as the body produces it, which results in jaundice. In most cases, hyperbilirubinemia causes no problems and treatment is not necessary. However, if left untreated, severe hyperbilirubinemia can lead to encephalopathy or kernicterus (i.e., permanent, bilirubin-related brain damage). Sick infants, lower birth weight infants, and lower gestation infants are at a greater risk of developing kernicterus at lower total serum bilirubin (TSB) levels. The level of bilirubin in the blood is monitored by ongoing assessment of the TSB or transcutaneous bilirubin (TcB).

Phototherapy, the use of light to eliminate bilirubin in the blood, is the most common form of treatment for jaundice. Bilirubin absorbs the blue light provided by phototherapy and converts to a water-soluble compound, permitting more rapid excretion in the urine. According to the American Academy of Pediatrics (2004), there is no standardized method for delivering phototherapy. The effectiveness of phototherapy depends upon the type of light source used (e.g., dose, spectral emission curve, depth of penetration), the distance between the light and the infant, the surface area treated, the characteristics of the infant's skin and tissue, the etiology of the jaundice, and the TSB level at the onset of the phototherapy. Home phototherapy is initiated when the infant's TSB reaches a level of clinical concern. Due to early postpartum discharge, many infants are at home when the TSB reaches its peak (i.e., ~96 hours) and jaundice becomes apparent. Home phototherapy is a generally safe treatment with minimal complications (e.g., dehydration and overheating).

Home phototherapy light sources include fluorescent tubes, fiberoptic lights, halogen lights, blue light-emitting diode, and gallium nitride light-emitting diodes. Special blue fluorescent bulbs (e.g., F20 T12/BB, TL52/20W) are more effective than regular blue tubes (e.g., F20T12/B) because they provide a blue-green spectrum, which most closely mimics the bilirubin absorption spectrum. The blue-green spectrum penetrates the skin more effectively and has the highest absorption rate by bilirubin. The most effective light sources are those in a narrow wavelength, 400–520 emission range (nm), with a peak center of  $460 \pm 10$  nm. The spectral irradiance (i.e., light intensity) determines the effectiveness of the treatment with higher doses typically, delivering greater results. "Conventional phototherapy" refers to the use of halogen or fluorescent lights (Vreman, et al., 2004; Watchko and Maisels, 2003).

Fiberoptic pads are an alternative to fluorescent tubes. An advantage of a fiberoptic blanket is the ability to wrap the infant with the blanket and, therefore, their eyes may not need to be covered. The disadvantage of fiberoptic pads is the inability to treat large areas of the skin due to the small size of the pads.

A newer light source is the gallium nitride light-emitting diode (LED). Not only is LED proposed to be more efficient and provide a longer life span, but it emits little heat, requires less power, and can be applied closer to the infant. LED provides a selected peak wavelength and allows the capability of delivering narrow bilirubin-specific band irradiances (Vreman, et al., 2004; Seidman, et al., 2003).

### U.S. Food and Drug Administration (FDA)

Light sources for the treatment of hyperbilirubinemia are approved by the FDA as Class II, 510(k) neonatal phototherapy units. FDA approved light sources that are appropriate for home use include: the BiliBlanket<sup>®</sup> Plus High Output Phototherapy System (Ohmeda Medical, Laurel, MD), neoBlue cozy<sup>™</sup> LED Phototherapy System (Natus Medical, Inc., San Carlos, CA), Wallaby<sup>™</sup> 3 Phototherapy System (Respironics GA Inc., Marietta, GA), and the BiliBed<sup>®</sup> Phototherapy Unit (Medela, Inc., McHenry, IL).

### Literature Review

Randomized controlled trials (Ebbesen, et al., 2007; Maisels, et al., 2007; Romagnoli, et al., 2006; Sarin, et al., 2006; Ebbesen, et al., 2003; Seidman, et al. 2003) and meta-analysis (Mills and Tudehope, 2001) support the safety and efficacy of phototherapy for the treatment of hyperbilirubinemia.

### Professional Societies/Organizations

The Canadian Pediatric Society (2007) supports the use of phototherapy to prevent severe hyperbilirubinemia in an infant with a moderately elevated TSB and as initial therapy in cases of severe hyperbilirubinemia. They

stated that the “consensus of the American Academy of Pediatrics’ Subcommittee on Hyperbilirubinemia was the most appropriate currently available standard”.

In 2004, the Subcommittee on Hyperbilirubinemia of the American Academy of Pediatrics published clinical practice guidelines on identifying and managing jaundice in newborns. The key elements in the guidelines recommended that clinicians:

- promote and support successful breastfeeding
- establish nursery protocols for the identification and evaluation of hyperbilirubinemia
- measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours
- recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants
- interpret all bilirubin levels according to the infant’s age in hours
- recognize that infants at less than 38 weeks’ gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring
- perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia
- provide parents with written and verbal information about newborn jaundice
- provide appropriate follow-up based on the time of discharge and the risk assessment
- treat newborns, when indicated, with phototherapy or exchange transfusion

Other recommendations included:

- A TcB and/or TSB measurement should be performed on every infant who is jaundiced in the first 24 hours after birth (Figure 1 and Table 1). The need for and timing of a repeat TcB or TSB measurement will depend on the zone in which the TSB falls (Figure 2), the age of the infant, and the evolution of the hyperbilirubinemia. Recommendations are for TSB measurements after the age of 24 hours (Figure 1 and Table 1).
- A TcB and/or TSB measurement should be performed if the jaundice appears excessive for the infant’s age. If there is any doubt about the degree of jaundice, the TSB or TcB should be measured. Visual estimation of bilirubin levels from the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
- All bilirubin levels should be interpreted according to the infant’s age in hours (Figure 2).
- The possible cause of jaundice should be sought in an infant receiving phototherapy or whose TSB level is rising rapidly (i.e., crossing percentiles [Figure 2]) and is not explained by the history and physical examination.
- Before discharge, every newborn should be assessed for the risk of developing severe hyperbilirubinemia. Such assessment is particularly important in infants who are discharged before the age of 72 hours.
- The AAP recommends two clinical options used individually or in combination for the systematic assessment of risk: pre-discharge measurement of the bilirubin level using TSB or TcB and/or assessment of clinical risk factors. Whether either or both options are used, appropriate follow-up after discharge is essential.
- All hospitals should provide written and verbal information for parents at the time of discharge, which should include an explanation of jaundice, the need to monitor infants for jaundice, and advice on how monitoring should be done.
- All infants should be examined by a qualified health care professional in the first few days after discharge to assess infant well-being and the presence or absence of jaundice. The timing and location of this assessment will be determined by the length of stay in the nursery, presence or absence of risk factors for hyperbilirubinemia (Table 2 and Figure 2), and risk of other neonatal problems.
- Follow-up should be provided as follows:
  - infant discharged before age 24 hours should be seen by age 72 hours
  - infant discharged between 24 and ≤ 48 hours should be seen by age 96 hours
  - Infant discharged between 48 and 72 hours should be seen by age 120 hours

- For some newborns discharged before 48 hours, two follow-up visits may be required, the first visit between 24 and 72 hours and the second between 72 and 120 hours. Clinical judgment should be used in determining follow-up. Earlier or more frequent follow-up should be provided for those who have risk factors for hyperbilirubinemia (Table 2), whereas those discharged with few or no risk factors can be seen after longer intervals.
- If appropriate follow-up cannot be ensured in the presence of elevated risk for developing severe hyperbilirubinemia, it may be necessary to delay discharge until either appropriate follow-up can be ensured or the period of greatest risk has passed (i.e., 72–96 hours).
- The follow-up assessment should include the infant's weight and percent change from birth weight, adequacy of intake, the pattern of voiding and stooling, and the presence or absence of jaundice. Clinical judgment should be used to determine the need for a bilirubin measurement. If there is any doubt about the degree of jaundice, the TSB or TcB level should be measured. Visual estimation of bilirubin levels can lead to errors, particularly in darkly pigmented infants.
- Recommendations for phototherapy and exchange transfusion treatment are given in the guidelines (Table 3 and Figures 3 and 4). If the TSB does not fall or continues to rise despite intensive phototherapy, it is very likely that hemolysis is occurring. The committee's recommendations for discontinuing phototherapy can be found in Appendix 2 in the original guideline document. In using the guidelines for phototherapy and exchange transfusion (Figures 3 and 4), the direct-reacting, or conjugated bilirubin level, should not be subtracted from the total.

The guidelines listed the following risk factors for development of severe hyperbilirubinemia in infants of 35 or more weeks' gestation (Figure 2):

- major risk factors
  - pre-discharge TSB or TcB level in the high-risk zone (Table 2)
  - jaundice observed in the first 24 hours
  - blood group incompatibility with positive direct antiglobulin test, other known hemolytic disease (e.g., G6PD deficiency), elevated end-tidal carbon monoxide corrected for ambient carbon monoxide (ETCO<sub>c</sub>)
  - gestational age of 35–36 weeks
  - previous sibling received phototherapy
  - cephalohematoma or significant bruising
  - exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive
  - East Asian race as defined by mother's description
- minor risk factors
  - pre-discharge TSB or TcB level in the high intermediate-risk zone
  - gestational age of 37–38 weeks
  - jaundice observed before discharge
  - previous sibling with jaundice
  - macrosomic infant of a diabetic mother
  - maternal age ≥ 25 years
  - male gender
- decreased risk factors (i.e., these factors are associated with decreased risk of significant jaundice, listed in order of decreasing importance)
  - TSB or TcB level in the low-risk zone (Figure 2)
  - gestational age ≥ 41 weeks
  - exclusive bottle feeding
  - black race
  - discharge from hospital after 72 hours

Home therapy should not be used in any infants with risk factors.

Appendix 2 of the guideline, included recommendations for using phototherapy effectively including light source, distance from the light, and surface area. Regarding home phototherapy, the AAP stated:

- Devices available for home phototherapy may not provide the same degree of irradiance or surface area exposure as those available in the hospital; therefore, home phototherapy should be used only in infants whose bilirubin levels are in the “optional phototherapy” range (Figure 3) and is not appropriate for infants with higher bilirubin concentrations.
- It is essential that serum bilirubin levels be monitored regularly.
- Prior to discharge, the newborn is assessed (predischARGE measurement of the bilirubin level using TSB or TcB and/or assessment of clinical risk factors) for the risk of developing severe hyperbilirubinemia.
- The hospital has provided written and verbal information for parents at the time of discharge, including an explanation of jaundice, the need to monitor infants for jaundice, and advice on how monitoring should be done.
- The infant is scheduled to be examined by a qualified health care professional according to the following schedule:
  - infant discharged before age 24 hours should be seen by age 72 hours
  - infant discharged between 24 and ≤ 48 hours should be seen by age 96 hours
  - infant discharged between 48 and 72 hours should be seen by age 120 hours
- This follow-up examination should include the infant’s weight and percent change from birth weight, adequacy of intake, the pattern of voiding and stooling, and the presence or absence of jaundice. Clinical judgment should be used to determine the need for a bilirubin measurement. If there is any doubt about the degree of jaundice, the TSB or TcB level should be measured.

### Summary

Professional societies and evidence in the published peer-reviewed scientific literature support the safety and efficacy of phototherapy for the treatment of hyperbilirubinemia. Home phototherapy is an established treatment option for healthy, active infants with hyperbilirubinemia who are feeding well, do not require hospitalization, and do not have a primary liver disorder causing the hyperbilirubinemia. Close follow-up, including regular serum bilirubin determinations, provided by the primary care giver and/or trained home health care nurses is recommended.

### Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

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

ICD-9-CM Diagnosis Codes	Description
773.4	Kernicterus due to isoimmunization
774.0	Perinatal jaundice from hereditary hemolytic anemias
774.1	Perinatal jaundice from other excessive hemolysis
774.2	Neonatal jaundice associated with preterm delivery
774.30	Neonatal jaundice due to delayed conjugation, cause unspecified
774.31	Neonatal jaundice due to delayed conjugation in diseases classified elsewhere
774.39	Other neonatal jaundice due to delayed conjugation from other causes
774.6	Unspecified fetal and neonatal jaundice

\*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	04/15/2008	0025	Home Phototherapy for Hyperbilirubinemia

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