Home Phototherapy for Neonatal Jaundice
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified. Claims related to home phototherapy for neonatal jaundice will be autoadjudicated to pay.

Policy # 00102
Original Effective Date: 03/25/2002
Archived Date: 02/21/2007

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May be Eligible for Coverage
Note: Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met

Based on review of available data, the Company may consider home phototherapy for neonatal jaundice to be eligible for coverage.

Patient Selection Criteria
The use of home phototherapy will be considered for coverage eligibility when all of the following criteria are met:

- Healthy infant at 35 weeks or more gestation with neonatal jaundice, and
- Total serum bilirubin (TSB) level of greater than 13 mg/dL but not requiring “intensive phototherapy,” and
- Pathologic jaundice has been ruled out.

When Services are Not Covered
The use of home phototherapy for neonatal jaundice when patient selection criteria are not met is considered not medically necessary.

Background/Overview
Home phototherapy is frequently used in the management of physiologic hyperbilirubinemia in the healthy term newborn. Phototherapy can be delivered using a special phototherapy lamp positioned over the baby’s bed; a fiberoptic system also can be used. For example a fiberoptic cable attached to a transparent flat mat can be placed in direct contact with the infant’s skin. Fiberoptic phototherapy may be preferred by some, since exposure during feeding is not interrupted and protective eye pads are not needed.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Phototherapeutic light, which is light in the blue region (425-475 nm [nanometers]), is transmitted from the illuminator to the blanket via the fiberoptic cable. The blanket is applied to the infant so as to maximize the infant’s contact with the blanket. However, blue lights prevent detection of cyanosis, so phototherapy using broad-spectrum white light is often preferred. Sometimes standard therapy and fiberoptic wrap therapy are used together. The FDA approves these devices under the 510(k) process.
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Rationale/Source
While fluorescent lamps have been the most commonly used method of phototherapy treatment of hyperbilirubinemia, fiberoptic systems have also become available. Comparative studies have suggested that the decline in TSB in those using the fiberoptic system may not be as rapid as those using conventional fluorescent lights – which in one study consisted of seven overhead lamps. Tan reported on a study of 165 term healthy infants and 105 preterm infants with nonhemolytic hyperbilirubinemia who were assigned to receive a fiberoptic blanket, overhead lamps, or a combination of the two. In term infants, the 24-hour TSB decline rate for fiberoptic, conventional, and combined therapy was 9.2%, 21.5%, and 29.9%, respectively. The decrease in efficacy of the fiberoptic system alone was thought to be related to the small size of the mat. In a subsequent 1997 study, Tan compared the efficacy of several different sizes of fiberoptic mats (standard, large, or two standard mats) and conventional phototherapy with 24 declines of 10.26%, 14%, 21%, and 19%, respectively. However, both of the above studies were done in the setting of the neonatal intensive care unit. In this setting, the speed of decline of the TSB might be clinically significant. However, the significance of the different rates of decline is uncertain in the home setting where, by definition, the infants do not need intensive phototherapy and monitoring.

The guidelines for the management of hyperbilirubinemia in the healthy term newborn published by the American Academy of Pediatrics (AAP) were reviewed. The AAP first published guidelines for the management of hyperbilirubinemia in 1994 which were reaffirmed in 2000. In 2004, the AAP updated these guidelines and provided new provisions for phototherapy including when home phototherapy would be appropriate and when phototherapy may be discontinued. The updated guidelines focus on infants 35 weeks or more in gestation and specify that TSB levels be assessed in relation to the age of the infant in hours and risk level. At 48 hours of age, intensive phototherapy should begin at TSB levels of 11mg/dL, 13mg/dL, or 15mg/dL, or above for high-, medium-, and low-risk infants respectively. At 72 hours of age, levels of TSB in infants requiring intensive phototherapy rise to 13mg/dL, 15mg/dL, and 18mg/dL for high-, medium-, and low-risk infants respectively.

The AAP indicates “intensive phototherapy” implies the use of high levels of irradiance in the 430-490-nm band (usually 30μW/cm² per nm or higher) delivered to as much of the infant’s surface area as possible.” Additionally, special blue fluorescent tubes or specially designed light-emitting diode lights which emit predominately blue-green spectrum light are noted to be most effective.

The AAP specifies that providing conventional phototherapy either in the hospital or at home is an “option” at TSB levels that are 2-3mg/dL below the intensive therapy levels but only in infants without risk factors. Infants with hyperbilirubinemia and any risk factors do not have the option for home phototherapy and require intensive phototherapy in the hospital setting. The AAP notes this is because home phototherapy devices may not provide levels of irradiance or surface-area exposure comparable to hospital devices. The risk factors for intensive phototherapy, as specified in the guidelines, are as follows:

- Isoimmune hemolytic disease;

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- G6PD deficiency;
- Asphyxia
- Significant lethargy;
- Temperature instability;
- Sepsis; and
- Acidosis

The previous AAP guidelines did not indicate when phototherapy should stop. The 2004 guidelines indicate there is no standard for when phototherapy may be discontinued since the cause of the hyperbilirubinemia and the age of the infant when phototherapy started must be taken into consideration. However, the guidelines also indicate phototherapy should be discontinued when TSB levels reach <13-14mg/dL.

References
3. Milliman CareGuidelines, Home Care; 10th Edition, Neonatal Jaundice; ORG: P-2265(HC) (Milliman CareGuidelines are copyright protected)

Policy History
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03/16/2004 Medical Policy Committee review
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12/07/2004 Medical Director review
01/31/2005 Managed Care Advisory Council approval
02/01/2006 Medical Director review
02/23/2006 Quality Care Advisory Council approval
07/07/2006 Format revision: including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/07/2007 Medical Director review. Recommend archiving policy.

Next Scheduled Review Date: Archived medical policy

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. in accordance with nationally accepted standards of medical practice;
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B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.