Clinical Policy Title: Home phototherapy for hyperbilirubinemia

Clinical Policy Number: 11.02.04

Effective Date: January 1, 2016
Initial Review Date: August 19, 2015
Most Recent Review Date: August 17, 2016
Next Review Date: August 2017

Related Policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of home phototherapy for hyperbilirubinemia to be clinically proven and, therefore, medically necessary when the following criteria are met:

- The infant is at least 35 weeks gestation and born over 2500 grams.
- The bilirubin level is < 20 mg/dl (term infants) or <18 mg/dl (pre-term infants).
- The infant’s elevated bilirubin is not due to any primary hepatic disorder
- The infant has no risk factors and is otherwise ready for discharge after appropriate lab tests.
- Arrangements have been made for a home visit within 48 hours of discharge.

Limitations:

All other uses of home phototherapy for hyperbilirubinemia are not medically necessary.

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

S9098 - Home visit, phototherapy services (e.g., Bili-Lite), including equipment rental, nursing services, blood draw, supplies and other services; per diem.
Alternative covered services:
None.

**Background**

Hyperbilirubinemia is a disorder affecting newborns, marked by an elevated level of bilirubin in the blood. This condition occurs when red blood cells break down, rendering newborns less able to excrete bilirubin. Hyperbilirubinemia causes jaundice, marked by a yellow color of the infant’s skin, eyes and other tissues. The infant also may be lethargic and feed poorly.

Hyperbilirubinemia is a common condition among newborns, affecting 60 percent of full-term births and 80 percent of premature births. It is diagnosed by measuring bilirubin levels, red blood cell counts, and blood type testing for Rh incompatibility (Coomb’s test). It typically is treatable, although it can cause seizures and brain damage, known as kernicterus.

A diagnosis of jaundice or with a bilirubin value of greater than expected from the American Academy of Pediatrics (AAP) Nomograms in the first 24 hours after delivery suggests a potentially serious form of the disease, and treatment should begin immediately (AAP, 1994). Diagnosis at least 24 hours after delivery which accounts for most cases, can result from various factors, such as infections or breast milk-related problems.

Criteria for when treatment of hyperbilirubinemia should commence varies by the infant’s age and bilirubin level. A subcommittee of the AAP made recommendations in 2004 for treatment, shown below (AAP, 2004). This statement updated a similar policy statement from the AAP in 1994 (AAP, 1994).

<table>
<thead>
<tr>
<th>Age of infant</th>
<th>Consider treatment</th>
<th>Recommend treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;24 hours</td>
<td>if rising rapidly</td>
<td>----</td>
</tr>
<tr>
<td>25-48 hours</td>
<td>&gt;12 mg/dL</td>
<td>&gt;15 mg/dL</td>
</tr>
<tr>
<td>49-72 hours</td>
<td>&gt;15 mg/dL</td>
<td>&gt;18 mg/dL</td>
</tr>
<tr>
<td>&gt;72 hours</td>
<td>&gt;17 mg/dL</td>
<td>&gt;20 mg/dL</td>
</tr>
</tbody>
</table>

The goal of hyperbilirubinemia therapy is to reduce bilirubin from dangerous levels. There are several forms of therapy; one common method is phototherapy, which involves a blue spectrum light. Treatment is continual, and includes exposure of all of the skin directly to the light.

Hyperbilirubinemia can be treated in the hospital setting or (since about 1980) at home under certain conditions. Treatment is typically halted when the serum bilirubin falls below 13 to 14 mg/dl of blood, usually after 1-3 days of therapy.

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on July 22, 2016. Search terms were “home phototherapy hyperbilirubinemia.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Hospital phototherapy for hyperbilirubinemia, which has been used since the 1950s, employs a fluorescent light. The infant is placed in an incubator, wearing only a diaper, and its eyes must be covered. When intensive phototherapy is required, a fiber optic light can be used. Home administration of phototherapy uses a less intensive method that emits a fiber optic light. A blanket or neck ring is used to direct the light below the infant’s head, and thus covering the eyes is not needed. In most cases, home administration is effective in reducing serum bilirubin levels, but a small proportion requires readmission to the hospital.

The 2004 AAP guideline recommends continuation of breastfeeding in infants with jaundice. However, some breastfeeding infants with elevated bilirubin being treated with phototherapy may also benefit by temporarily interrupting breastfeeding (Amato, 1985 and Osborn, 1985) until serum bilirubin levels return to normal.

Phototherapy for hyperbilirubinemia is a common method of treating the disease. However, only a modest amount of information exists to compare efficacy of this versus other therapies. The common understanding among experts is that treatments are highly effective in lowering serum bilirubin levels to normal within days, preventing further disease.

While phototherapy for hyperbilirubinemia has been administered at home for years, almost no evidence exists in the medical literature comparing efficacy of home versus hospital use. One study compared hospital-based to home-based phototherapy (62 and 55 infants). Average time needed to reduce serum bilirubin to normal levels was similar in each group (2.8 days), and no major complications or hospital readmissions were reported (Eggert, 1985). Another report found similar decreases in serum bilirubin, but a longer duration in therapy was needed for the home group (Slater, 1984).

A report of 260 infants undergoing home phototherapy over a three-year period found that average serum bilirubin at home fell from 14.19 to 10.97 mg/dL during therapy. While 17 of these patients (6%) required hospital readmission, no complications were reported, and patient satisfaction was 100% (Grabert, 1986).

After home phototherapy for hyperbilirubinemia became commonly-used after the 1980s, few articles on the efficacy of the treatment were published. Research conducted in Malaysia compared hospital-based to home-based phototherapy in 36 infants, matched for race, starting total serum bilirubin level, birth weight, and age of baby at phototherapy initiation. The average daily decrease in serum bilirubin
concentration was significantly greater in the home group than the hospital group (p<.05), and mean duration was significantly less (1.17 vs. 1.72 days, p<.01) in the home group. Each group reported complications in 4 of 18 patients (Zainab, 2004).

A Cochrane search from 2014 looked at Medline (1966-2013), CINAHL (1982-2013), and Embase (1988-2013), but could not uncover high quality evidence that supported or refuted use of home-based therapy for uncomplicated jaundice among newborns over 37 weeks gestation (Malwade, 2014). In addition, a Hayes Inc. search found no data comparing the efficacy of conventional and fiberoptic phototherapy in the home setting for hyperbilirubinemia.

Various phototherapy units can be used in the home setting for infants with elevated bilirubin levels. Any comparisons of efficacy of these models are limited. A review of 22 infants receiving home phototherapy with fiberoptic cummerbund, versus 26 infants with a conventional four-bul bililight found little difference in the average daily reduction in bilirubin, or in maternal satisfaction (Schuman, 1992).

One study compared outcomes for treatment of two groups of 52 jaundiced newborns. These include the high-threshold (phototherapy interrupted when total serum bilirubin decreased to >1 mg/dL below the limit requiring phototherapy), and low-threshold (> 3 mg/dL). Phototherapy duration and length of stay were shorter in the high-threshold group; percentages of infants in both groups needing additional phototherapy was the same (Barak, 2009).

One recent study compared the lightweight light-emitting diode phototherapy unit with the conventional blue light fluorescent phototherapy model. No significant difference was found between the average decline in bilirubin levels between the two (Yilmaz, 2015).

Policy updates:

A total of 10 peer-reviewed references were added to this policy, three (3) of which were cited in the summary of clinical evidence section.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, methods, recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yilmaz (2015)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Lightweight phototherapy vs. conventional blue light fluorescent phototherapy</td>
<td></td>
</tr>
<tr>
<td>Malwade (2014)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Home vs. hospital-based treatment for uncomplicated newborn jaundice</td>
<td></td>
</tr>
<tr>
<td>Woodgate (2011)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Effects of various treatments for infants with hyperbilirubinemia</td>
<td></td>
</tr>
<tr>
<td>Academy of Breast-feeding</td>
<td>Key points:</td>
</tr>
</tbody>
</table>

- Fifty newborns with hyperbilirubinemia given each type of therapy.
- Reduction of bilirubin slightly greater for lightweight therapy.
- Meta analysis using Medline, Cinahl, and Embase.
- No studies met criteria comparing home- and hospital-based therapy.
- Meta analysis using Medline, Cinahl, and Embase.
- Forty-two controlled trials included.
- Data limitations made it often difficult to compare types of therapies.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, methods, recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Phototherapy best done in hospital.&lt;br&gt; • Home phototherapy is possible, but discouraged (especially for infants with risk factors).</td>
</tr>
<tr>
<td>Hayes Inc. (2007)</td>
<td>Phototherapy blanket versus standard phototherapy&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td><strong>Key points:</strong>&lt;br&gt; • Search of Medline and Embase.&lt;br&gt; • Insufficient data comparing efficacy of conventional and fiberoptic phototherapy in the home setting.</td>
</tr>
<tr>
<td></td>
<td><strong>Key points:</strong>&lt;br&gt; • Update of 1994 AAP practice guideline.&lt;br&gt; • Newborns with hyperbilirubinemia should be treated with phototherapy or exchange transfusion.&lt;br&gt; • Many infants can be managed as outpatients; those with phototherapy can receive supplements of formula or expressed breast milk.</td>
</tr>
<tr>
<td>AHRQ (2002)</td>
<td>Effects of bilirubin on neurodevelopmental outcomes&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td><strong>Key points:</strong>&lt;br&gt; • Meta analysis of 138 articles from Medline search.&lt;br&gt; • Phototherapy combined with substitution of formula for breast feeding was found to be most effective in reducing bilirubin.</td>
</tr>
<tr>
<td>Grabert (1986)</td>
<td>Review of experience with home phototherapy&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td><strong>Key Points:</strong>&lt;br&gt; • Home phototherapy group experience with 260 newborns, April 1982-February 1985.&lt;br&gt; • Average days on hospital phototherapy (0.81), average days home phototherapy (2.44).&lt;br&gt; • Average serum bilirubin at home during therapy fell from 14.19 to 10.97 mg/dL.&lt;br&gt; • No complications, 17 re-hospitalizations, 100% patient satisfaction.</td>
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<tr>
<td>Eggert (1985)</td>
<td>Hospital vs. home phototherapy for infants with hyperbilirubinemia&lt;br&gt;</td>
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<td><strong>Key Points:</strong>&lt;br&gt; • Infants with hyperbilirubinemia treated at home (n=62) and the hospital (n=55).&lt;br&gt; • Average days decrease in serum bilirubin to normal levels was similar (2.8 days).&lt;br&gt; • No reports of major complications or hospital readmission.&lt;br&gt; Savings of $18,000 in 62 infants treated at home vs. hospital.</td>
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<td>Slater (1984)</td>
<td>Hospital vs. home phototherapy for infants with hyperbilirubinemia&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td><strong>Key Points:</strong>&lt;br&gt; • Infants with hyperbilirubinemia treated at home (n=33) and the hospital (n=25).&lt;br&gt; • Average days decrease in serum bilirubin was similar in the two groups.&lt;br&gt; • Duration of phototherapy at home was longer.</td>
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</tbody>
</table>

**Glossary**

**Bilirubin** — a substance found in bile produced from breakdown of old red blood cells.

**Hyperbilirubinemia** — a condition found in many newborns marked by a high concentration of bilirubin, measured in the blood.

**Jaundice** — yellow discoloration in a newborn’s eyes and skin.
**Home Phototherapy** — (for hyperbilirubinemia) a blanket or neck ring that emits fiber optic light to reduce bilirubin levels in the blood.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical Trials:**


**CMS National Coverage Determinations (NCDs)**

No NCDs identified at the writing of this policy.

**Local Coverage Determinations (LCDs)**

No LCDs identified at the writing of this policy.

**Commonly submitted codes**
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

<table>
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<th>CPT Code</th>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>P59.0</td>
<td>Neonatal jaundice associated with preterm deliver</td>
<td></td>
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<tr>
<td>P59.9</td>
<td>Neonatal jaundice NOS</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
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<tbody>
<tr>
<td>E0202</td>
<td>Phototherapy (bilirubin) light with photometer</td>
<td></td>
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<tr>
<td>S9098</td>
<td>Home visit, phototherapy services (e.g., Bili-Lite), including equipment rental, nursing services, blood draw, supplies and other services; per diem</td>
<td></td>
</tr>
</tbody>
</table>