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, 2017
Next Review Date: August 2018

Policy contains:
- Treatment for hyperbilirubinemia (jaundice).
- Criteria for home phototherapy for jaundice.

Related policies:
None.

ABOUT THIS POLICY: Keystone First VIP Choice has developed clinical policies to assist with making coverage determinations. Keystone First VIP Choice’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 VIP Choice 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 VIP Choice’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 VIP Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First VIP Choice will update its clinical policies as necessary. Keystone First VIP Choice’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First VIP Choice 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 2,500 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.

Alternative covered services:
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.

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.

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 the 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 of infants require readmission to the hospital. A study of 126 infants whose bilirubin was at least 17 ml/dL showed that compared to placebo, phototherapy reduced bilirubin levels significantly (Martinez, 1993).

The American Academy of Pediatrics (AAP) recommends universal screening of all newborns using total serum bilirubin or transcutaneous bilirubin, or screening of high-risk newborns (AAP, 2004). These methods are helpful in identifying infants whose bilirubin level is likely to exceed the 95th percentile (Maisels, 2009a). However, the U.S. Preventive Services Task Force is opposed to universal screening, citing a lack of evidence that this approach improves outcomes (USPSTF, 2009), which has been documented since (Darling, 2017). An update to the AAP guideline recommends a more structured approach to managing and follow up of hyperbilirubinemia, according to risk factors (Maisels, 2009b).

A diagnosis of jaundice or with a bilirubin value greater than expected from the 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>

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 – 14 mg/dl of blood, usually after 1 – 3 days of therapy.

**Searches**

Keystone First VIP Choice 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 13, 2017. 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**

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, little 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 systematic review of 42 studies, and a Cochrane review found no studies that compared outcomes in these two settings (Woodgate, 2011; Malwade, 2014). On study assessed 50 patients given home phototherapy or conventional blue-light fluorescent phototherapy (CFP) to treat hyperbilirubinemia in neonates. The average rate of decrease in bilirubin levels was not significantly greater (0.20 to 0.17 mg/dL/hours) after 24 hours, indicating that home based therapy is as effective as conventional therapy (Yilmaz, 2015).

A study that compared hospital-based to home-based phototherapy (62 and 55 infants) found that 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).

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 versus 1.72 days, P < .01) in the home group. Each group reported complications in 4 of 18 patients (Zainab, 2004).

After home phototherapy for hyperbilirubinemia became commonly used after the 1980s, a few non-
controlled articles on the efficacy of the treatment were published. 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 percent) required hospital readmission, no complications were reported, and patient satisfaction was 100 percent (Grabert, 1986).

A Cochrane search from 2014 could not uncover high quality evidence that supported or refuted use of home-based therapy for uncomplicated jaundice among newborns over 37 weeks of gestation (Malwade, 2014). In addition, a Hayes Inc. search found no data comparing the efficacy of conventional and fiber optic phototherapy in the home setting for hyperbilirubinemia (Hayes, 2016).

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 a fiber optic cummerbund, versus 26 infants with a conventional four-bulb light found little difference in the average daily reduction in bilirubin or in maternal satisfaction (Schuman, 1992).

There are various models of home phototherapy units available for use, raising the question of potential differences in accuracy between models. One review found that the BiliChek unit consistently documented a negative bias compared with serum bilirubin values; the bias increased as the serum bilirubin level rises. If a value of 14 mg/dL or less obtained using the BiliChek had been used as the cutoff for termination of phototherapy, 45% of newborns would have had therapy terminated prematurely (Reyes, 2008).

**Policy updates:**

Four peer-reviewed references were added to this policy in 2017.

**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</td>
<td>• Fifty newborns with hyperbilirubinemia given each type of therapy.</td>
</tr>
<tr>
<td>versus conventional blue light</td>
<td>• Reduction of bilirubin slightly greater for lightweight therapy.</td>
</tr>
<tr>
<td>fluorescent phototherapy</td>
<td></td>
</tr>
<tr>
<td>Malwade (2014)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Home versus hospital-based</td>
<td>• Meta-analysis using Medline, Cinahl, and Embase.</td>
</tr>
<tr>
<td>treatment for uncomplicated</td>
<td>• No studies met criteria comparing home- and hospital-based therapy.</td>
</tr>
<tr>
<td>newborn jaundice</td>
<td></td>
</tr>
<tr>
<td>American Academy of Pediatrics</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
Newborns with hyperbilirubinemia should be treated with phototherapy or exchange transfusion. Many infants can be managed as outpatients; those with phototherapy can receive supplements of formula or expressed breast milk.

**Key points:**
- Average days on hospital phototherapy (0.81); average days home phototherapy (2.44).
- Average serum bilirubin at home during therapy fell from 14.19 to 10.97 mg/dL.
- No complications, 17 re-hospitalizations, 100% patient satisfaction.

**Key points:**
- Infants with hyperbilirubinemia treated at home (n=62) and the hospital (n=55).
- Average days decrease in serum bilirubin to normal levels was similar (2.8 days).
- No reports of major complications or hospital readmission.
- Savings of $18,000 in 62 infants treated at home versus hospital.

**Key points:**
- Infants with hyperbilirubinemia treated at home (n=33) and the hospital (n=25).
- Average days decrease in serum bilirubin was similar in the two groups.
- Duration of phototherapy at home was longer.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


Reyes CA, Stednitz DR, Hahn C, Mutchie KD, McCullough SR, Kronberg K. Evaluation of the biliChek


**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>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0202</td>
<td>Phototherapy (bilirubin) light with photometer</td>
<td></td>
</tr>
<tr>
<td>HCPCS Level II Code</td>
<td>Description</td>
<td>Comment</td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<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>