Phototherapy Light for the Treatment of Seasonal Affective and Other Depressive Disorders

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.

Policy # 00101
Original Effective Date: 03/25/2002
Archived Date: 03/20/2013

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.

Services Are Eligible for Coverage
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 phototherapy for the treatment of seasonal affective or other depressive disorders to be eligible for coverage.

Background/Overview
Seasonal affective disorder (SAD) is defined as a history of major depressive episodes that recur regularly at a particular time of year, typically winter. Seasonal affective disorder is associated with decreases in ambient light exposure during the winter season; therefore, phototherapy, delivered by a light box or light visor, has been used as a treatment. Most commonly, white light is used at an intensity equaling that of a bright summer day—2,500 lux or higher.

Commercial light boxes are now available for treatment of SAD and other depressive disorders. The patient is typically instructed to remain a specified distance from the light box for a certain length of time, usually from 30 minutes to several hours. Phototherapy is given for a period of days to weeks, until a satisfactory antidepressive response is attained. The treatment can be repeated in the case of relapse following initial treatment. A portable light delivery device in the form of a light visor has also been developed to deliver an identical intensity of supplemental light for the same time period, allowing the patient to move around and perform normal activity during the treatment period. Another variant provides extraocular light via a pad that could be affixed to the bend of the knee, with the intent to correct disruptions in circadian rhythms.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Currently, no phototherapy device has final market approval from the FDA for the treatment of SAD or other depressive disorders. While light boxes or light visors cannot be marketed directly for the treatment for SAD or promoted for other health benefits, these devices are commercially available.
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Rationale/Source
A 1995 TEC Assessment concluded that phototherapy as a treatment for SAD did not meet the TEC criteria due to the lack of well-controlled trials that validated the effectiveness of phototherapy compared to placebo. The 1999 TEC Assessment proposed the following study selection criteria:

- The control group should be given an intervention intended to serve as a placebo control, and results compared with active phototherapy treatment.
- The study includes at least ten subjects in each treatment arm.
- The study uses a validated measure of depression severity as an outcome measure(s) (e.g., Hamilton rating scale or similar instrument).

Five controlled studies meeting these criteria were included in the 1999 Assessment, while three such studies have appeared between 1999 and 2002. The studies included in the 1999 Assessment reported no differences between groups on any outcome measure. The 1999 TEC Assessment reported that it was not possible to conclude that phototherapy is efficacious above placebo in decreasing the severity of depression in patients who have SAD. However, the results did not definitively demonstrate that phototherapy was ineffective.

Specific observations and conclusions of the 1999 TEC Assessment and 2002 policy update include the following:

- There is a high likelihood of a substantial placebo effect in any clinical study of depression. This emphasizes the necessity for demonstrating a significant difference between a credible placebo and the active treatment. The measure of efficacy for treatment must be the incremental benefit greater than the placebo response.
- There is substantial difficulty in constructing an adequate placebo in studies of SAD. While dim light is typically used as a placebo, dim light may offer some benefit, thus studies may underestimate the efficacy of phototherapy. An additional problem with dim light placebo is the difficulty in blinding active treatment from placebo, and the concern that the timing of light may be the crucial factor rather than the provision of light itself.

In 2005, a group of researchers representing the American Psychiatric Association reported on a meta-analysis of the efficacy of light therapy. A total of 173 studies were abstracted. Using predefined criteria for bright light therapy, placebo therapy and dawn simulation, and outcomes measures, the authors reported significant effect sizes for bright light treatment of seasonal affective disorder (0.84, CI 0.60 to 1.08), dawn simulation for seasonal affective disorder (0.73, CI 0.37-1.08), and bright light treatment of nonseasonal depression (0.53, CI 0.18 - 0.89). The authors conclude that these effects are comparable to those reported in many antidepressant pharmacotherapy trials. The authors point out that, compared to pharmacologic therapies, there has been minimal funding for light therapy, leading to various different definitions of bright light and different protocol used. In addition, it has been very difficult to devise an adequate placebo that is...
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either not detected by the patient or does not have an effect of its own. The previous TEC Assessment noted that the data available at that time were unable to confirm a treatment benefit, but also that they were inadequate to eliminate the possibility of a benefit. This meta-analysis attempted to clarify the issue by carefully selecting randomized trials based both on study design, predetermined criteria defining bright light, and a credible placebo. The results of this meta-analysis suggest that bright light is associated with a treatment benefit in patients with seasonal affective disorder.

References
2. 1995 TEC Assessments; Tab 3
3. 1999 TEC Assessments; Tab 4

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines (BCBSLAMPCG) are obtained from Current Procedural Terminology (CPT®), copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>HCPCS</td>
<td>A4634, E0203</td>
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<td>ICD-9 Diagnosis</td>
<td>All diagnoses</td>
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<tr>
<td>ICD-9 Procedure</td>
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Policy History
Original Effective Date: 03/25/2002
03/21/2002 Medical Policy Committee review
03/25/2002 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy.
03/09/2004 Medical Director review
03/16/2004 Medical Policy Committee review. Format revision. Individual policy formulated utilizing elements specific to seasonal affective disorder within general phototherapy medical policy.
03/29/2004 Managed Care Advisory Council approval
03/09/2006 Medical Director review
03/15/2006 Medical Policy Committee review. Format revision. FDA information added.
03/14/2007 Medical Director review
03/21/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
03/04/2009 Medical Director review
03/18/2009 Medical Policy Committee approval. No change to coverage.
03/05/2010 Medical Policy Committee review
03/19/2010 Medical Policy Implementation Committee approval. Coverage changed from Investigational to eligible for coverage.
03/03/2011 Medical Policy Committee review
03/16/2011 Medical Policy Implementation Committee approval. No change to coverage.
03/01/2012 Medical Policy Committee review
03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2013 Medical Policy Committee review. Recommend archiving
03/20/2013 Medical Policy Implementation Committee approval. Archived

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;
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.

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