



PHOTOTHERAPY (LIGHT BOX OR VISOR) FOR TREATMENT OF SEASONAL AFFECTIVE DISORDER (SAD)
PSY301.005

COVERAGE:

Phototherapy (Light Box or Visor) for Treatment of Seasonal Affective Disorder (SAD) or other conditions **is not eligible for coverage** as this therapy is considered **investigational**.

DESCRIPTION:

Phototherapy (Light Box or Visor) for Treatment of Seasonal Affective Disorder (SAD) is a white light delivery device, used to reduce the severity of depression in patients who have SAD. Most commonly, the white light is used at an intensity equaling that of a bright summer day - 2500 lux or higher. These light box units are known as Sun Boxes.

These phototherapy devices are commercially available specifically for the treatment of SAD. The patient is instructed to remain a specified distance from the light box for a certain length of time, usually from 30 minutes to several hours. The therapy is given for a period of days or up to weeks, until a satisfactory anti-depressive response is attained. The treatment can be repeated in case of relapse following the initial treatment.

A portable light delivery device (light visor) has been developed to deliver an identical intensity of supplemental light for the same time period, allowing the patient to move around and perform normal activities during the treatment period. A bright bedside lamp on a timer to go on 2 hours before arising, outdoor activity, exercise, and antidepressants can accomplish the same effect. Psychotherapy may also be useful.

SAD is defined as a history of major depressive episodes that recur regularly at a particular time of year, typically during winter. SAD is associated with decreases in ambient light exposure during the winter season. SAD is known as "winter depression" and is characterized by recurrent episodes of depression, hypersomnia, augmented appetite with carbohydrate craving, and weight gain that begins in the autumn and continue through the winter months.

The FDA states that approval is required for phototherapy devices. Currently, no phototherapy device has final market approval for the treatment of SAD.

RATIONALE:

This policy is based on a 1999 TEC assessment that updated a 1995 assessment. The 1995 TEC assessment concluded that phototherapy, as a treatment of SAD did not meet the TEC criteria due to the lack of well-controlled trials to validate the effectiveness of phototherapy compared to placebo. The 1999 TEC assessment focused on additional

randomized studies published since 1995 and reached the same conclusion. Specific observations and conclusions of the 1999 TEC assessment include:

- 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 an 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, it 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.
- Since the 1995 TEC assessment, 5 additional placebo controlled trials of phototherapy have been published. These newer studies fail to demonstrate the efficacy of phototherapy beyond placebo. Two of the five trials report no differences between groups on any outcome measure. In two other trials, the results are mixed, with reported of benefit for the phototherapy group on a few of the outcome measures examined. In the last trial, phototherapy was found to be superior to a low-density negative ion generator, but there was no difference between phototherapy and a high-density negative ion generator. Thus, the TEC assessment reported that it was not possible to conclude that phototherapy is more efficacious than placebo in decreasing the severity of depression in patients who have SAD. Nevertheless, the results do not definitively demonstrate that phototherapy is ineffective.

According to the FDA web site, searched in March 2000, there has not been a pre-market approval or investigational device exemption made for a phototherapy light box or light visor/mask.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general policies and procedures.

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