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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Light Therapy, for Seasonal Affective Disorder (SAD)

- Bright Light Therapy
- Dawn Simulation Therapy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	See the Noridian Non-Covered Items for HCPC code E0203

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The term ‘seasonal affective disorder’ (SAD) was first introduced by Rosenthal and colleagues in 1984 who described a series of patients with a history or recurrent depressions that occurred in the fall or winter and spontaneously remitted in the following spring or summer. Two seasonal patterns of SAD have been described; the summer-onset SAD and the fall-onset SAD. The latter, also known as “winter depression”, is the most common pattern of the disorder. SAD affects about 5-6% of the population in the U.S. and its prevalence increases with latitude. This ranges from 1.4% in Florida to 9.7% in New Hampshire and 9.9% in Alaska. It is reported that SAD affects patients in their 20s, and that women are more likely than men to develop the disorder.

SAD was previously classified as a mood disorder in which people with normal mental health throughout most of the year experience depressive symptoms in the winter or summer. The Diagnostic and Statistical Manual of Mental Disorders DSM-IV and DSM-5 no longer classifies SAD as a unique mood disorder but describes it as a "specifier" or a subtype that can occur as part of unipolar major depression, bipolar I disorder, or bipolar II disorder. SAD is characterized by typical symptoms of major depression such as low mood, lack of drive, lack of concentration, and decrease in interest. In addition, patients exhibit more atypical depressive symptoms such as hypersomnia, increased appetite with carbohydrate craving, weight gain, irritability, and anger attacks. Symptoms usually resolve in the summer, and rarely progress to manic episodes of bipolar disorder.

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The exact mechanism of SAD is still under investigation, but it is hypothesized that it is related to natural seasonal variations in light levels. According to this hypothesis “the phase shift hypothesis” fewer daylight hours in the winter causes a circadian misalignment between the biological clock and solar cycle leading to disturbances in the melatonin levels and longer periods of its synthesis at night. Melatonin, also called circadian hormone, peeks in the darkness and promotes sleep. It is believed that its increased daytime levels contribute to the depressive symptoms of SAD. Other neurotransmitters under circadian control e.g. serotonin, norepinephrine, and dopamine are also believed to have a role in the SAD mood alterations. However, no studies have established a causal relationship between decreasing daylight and the winter SAD.

Three types of treatment are being used for patients with SAD: pharmacological therapy, cognitive behavioral therapy (CBT), and light therapy. Antidepressant medication is an accepted treatment for depression in general, and three SSRIs have shown favorable results with SAD. CBT may help reduce the risk of relapse of major depression, but only few small studies evaluated its effectiveness for SAD.

Light therapy using light boxes was introduced as a treatment for SAD when the disorder was first described in 1984, based on the phase shift hypothesis. Early studies examined the effect of bright white light on circadian rhythm. Other research investigated less intense light and showed that it may have a larger capacity to regulate the biological clock than higher intensity light. A small study showed that blue light with an intensity of about 460 m may have a significant effect on melatonin suppression and circadian phase shifting.

Currently there are a number of commercially available light therapy products. These include bright light boxes, lamps, light visors, and dawn simulators. Light boxes come in different shapes and sizes, and with varied features and intensities of light. There is no well-accepted standard protocol for light therapy. Commonly bright-light therapy (BLT) is applied using a light box containing fluorescent lamps, a reflector and a diffusing screen. For adequate treatment light intensities of 5,000-10,000 lux measured at the level of the eyes, and at a therapeutic distance of 60-80 cm from the light box is considered as a standard requirement. Patients do not need to look directly into the light source as long as the light meets the eye at an angle of 30-60o. Treatment is usually started with using a light intensity of 10,000 lux for 30 minutes. The duration of treatment may be increased in case of insufficient response or when using less powerful light boxes. It is reported that morning administration of BLT offers greater chance of remission, that compliance is the primary factor for success of the therapy, and that the therapeutic effect is demonstrated in 3-7 days and disappears shortly after the treatment is discontinued.

Light boxes are designed to be safe and effective but are not regulated as devices by the Food and Drug Administration (FDA). A number of side effects of light therapy for SAD have been reported but are generally mild and/or transient. These include headache, nausea, agitation, eye strain and blurred vision. Evening light therapy may lead to sleep disturbances. Suicidality, menstrual irregularity, and hypomania in bipolar patients have also been reported. Retinal degeneration after prolonged exposure to intensive light has been noticed in rodents but was not confirmed in humans. However, it is recommended that caution must be used with patients at higher risk of retinal damage or those who need photosensitizing medication.

Medical Technology Assessment Committee (MTAC)

Light Therapy in the Treatment of Seasonal Affective Disorder (SAD)

06/02/2008: MTAC REVIEW

Evidence Conclusion: There is evidence from a meta-analysis of placebo-controlled RCTs (Golden et al., 2005) that bright light therapy and dawn simulation are both effective for treating SAD in non-geriatric adults. Strength of the meta-analysis was that the investigators used strict criteria to ensure that studies had a valid placebo control. Limitations are that studies tended to be small (all had <100 participants) and the minimum treatment duration was 4 days. Moreover, studies had different treatment protocols and thus conclusions cannot be drawn about the effectiveness of a particular approach to light therapy (e.g. lux, frequency of sessions, length of treatment). There is currently no generally accepted protocol for light therapy. When the two RCTs in the meta-analysis with the longest treatment durations and largest sample sizes were examined closely, bright light therapy did not clearly appear to be effective. Avery et al. (2001) did not find that bright light was significantly superior to placebo. Eastman et al. (2005) did not find a significant benefit to light therapy versus placebo for the outcomes change in SIGH-SAD score and response rate. They did find a significant benefit when examining the proportion of participants classified as near complete or complete responders. All of the studies on dawn simulation in the Golden et al. meta-analysis were conducted by the same research group. As the authors pointed out, the evidence would be strengthened if their findings could be replicated by different researchers in other locations. The largest study, Avery et al., (2001) found that dawn simulation was superior to both bright light and placebo for remission of SAD. The RCTs identified that compared light therapy to medication or cognitive-behavioral therapy did not have true placebo control groups and thus, intervention effectiveness beyond the placebo effect cannot be

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determined. The Rohan et al. 2007 study found a lower post-treatment SAD score in patients receiving light therapy, CBT or their combination compared to a wait-list control. However, being on a wait-list could have a 'reverse placebo effect' since patients are not expecting to improve before receiving treatment. The Lam et al. (2006) studies did not find significant differences in response rates in groups assigned to light therapy or fluoxetine treatment.
Conclusion: A valid placebo group is important in RCTs of light therapy for SAD. A meta-analysis of placebo-controlled RCTs found a significant benefit of bright light and dawn simulation therapy. The meta-analysis was limited because studies tended to be small and of short duration. The largest RCTs in the meta-analysis did not find a significant benefit to bright light therapy. The evidence on dawn simulation is limited because all studies were done by the same research group and it is not known whether findings are generalizable. RCTs comparing light therapy to antidepressant treatment or psychotherapy did not include true placebo groups.
Articles: The ideal study would be a randomized controlled trial (RCT) or meta-analysis of RCTs that include a placebo or sham intervention. Studies comparing light therapy to medication therapy and/or psychotherapy should also have a placebo group. There was a protocol for a Cochrane review on light therapy for SAD. The protocol was published in 2003, and its status remains unchanged in Cochrane Library 2008, Issue 2. An estimated date for completion of the review is not available. One published meta-analysis was identified (Golden et al., 2005). The Golden study searched the literature to July 2003 and included only placebo-controlled studies. Golden et al. and the two RCTs in the meta-analysis with the largest sample sizes per treatment group and the longest trial duration (Avery et al., 2001; Eastman et al., 1998) were critically appraised. No large placebo-controlled RCTs published after the Golden meta-analysis was identified. There was one newer RCT comparing light therapy to fluoxetine treatment (Lam et al., 2006) and another comparing light therapy to cognitive-behavioral therapy (Rohan et al. 2007). These two new RCTs were also critically appraised. References for studies reviewed are as follows:
Golden RN, Gaynes BN, Ekstrom RD et al. The efficacy of light therapy in the treatment of mood disorders: A review and meta-analysis of the evidence. Am J Psychiatry 2005; 162: 656-662. See Evidence Table**.** Avery DH, Eder DN, Bolte MA et al. Dawn simulation and bright light in the treatment of SAD: A controlled study. Biol Psychiatr 2001; 50: 205-216. See Evidence Table**.** Eastman CI, Young MA, Fogg LF et al. Bright light treatment of winter depression. Arch Gen Psychiatr 1998; 55: 883-889. See Evidence Table**.** Lam RW, Levitt AJ, Levitan RD et al. The Can-SAD study: A randomized controlled trial of the effectiveness of light therapy and fluoxetine in patients with winter seasonal affective disorder. Am J Psychiatry 2006; 163: 805-812. See Evidence Table**.** Rohan KJ et al. A randomized controlled trial of cognitive-behavioral therapy, light therapy and their combination for seasonal affective disorder. J Consult Clin Psych 2007; 75: 489-500. See Evidence Table.

The use of light therapy in the treatment of Seasonal Affective Disorder (SAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/21/2015: MTAC REVIEW
Light Therapy for SAD
Evidence Conclusion: The ideal study for examining the effect of bright light therapy for SAD would be a double-blind randomized controlled trial that compares light therapy to a placebo or sham intervention. Studies comparing light therapy to pharmacological therapy or psychotherapy should also have a placebo group since there is limited evidence from placebo-controlled trials on the effectiveness of antidepressants or cognitive behavioral therapy on SAD. *Light therapy versus placebo* Martensson et al's meta-analysis, 2015 (Evidence table 1), pooled the results of 8 RCTs that compared light therapy to placebo (low negative air ions, dim red light, and dawn simulator placebo) to determine the effect bright white light (BWL) therapy on SAD. The authors performed two separate sets of meta-analyses; the first analyzed the results week-by-week, and the second analyzed the final results only. The pooled results suggest that BWL had a moderate effect on SAD symptoms compared to the controls (standardized mean difference [SMD] -0.54 (95% CI -0.95, -0.03), and that it reached statistical significance at week two and week three of treatment. The authors concluded that the BWL therapy seems to be effective, but they questioned the validity of the results due to the heterogeneity of the studies, lack of an appropriate placebo or sham light therapy control group, and other methodological limitations including the small sizes, short duration, and complex design of the trials. The results of Martensson et al's meta-analysis show a smaller effect size than that found in the Golden et al's meta-analysis reviewed earlier in MTAC (effect size 0.84, 95% CI 0.60, 1.08). As noted in the 2008 MTAC report, Golden et al's meta-analysis had the advantage of using strict criteria to ensure that studies had a valid placebo control, but was limited by the inclusion of very small studies with large treatment effect, short treatment durations, and the use different treatment protocols, which makes it difficult to draw any conclusion on the effectiveness of a particular approach to light therapy. When the two RCTs in the meta-analysis with the longest treatment durations and largest sample sizes were examined closely, bright light therapy did not clearly appear to be effective. *Light therapy versus antidepressants* In a Cochrane review on second-generation antidepressants for SAD, Thaler, et al (2011), pooled the results of two small trials (total N=136 participants) that

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compared light therapy to fluoxetine and found no significant difference between the two therapies in response or remission of SAD. The trials were small, with limitations and high dropout rates, and the overall response rate (>50% improvement on 24-item HAM-D SIGH-SAD) was 68/100 in the light therapy group and 67/100 in the fluoxetine group. The authors concluded that the overall quality of evidence is a low and insufficient to draw any conclusion on the use of second-generation antidepressants for SAD. The only available RCT of fluoxetine vs. placebo showed a nonsignificant effect in favor of fluoxetine, and the two small trials that compared fluoxetine to light therapy showed no significant differences between the two therapies in the treatment of SAD. *Light therapy versus cognitive behavioral therapy (evidence table 2)* In a recent RCT, Rohan et al, 2015, compared the treatment outcomes of light therapy versus cognitive behavioral therapy for SAD. The trial randomised 177 participants to receive light therapy (using 23x15.5x3.25 in. SunRay that emits 10,000 lux of cool-white fluorescent light) immediately upon awakening, or to receive cognitive behavioral therapy (CBT-SAD) for 6 weeks. The primary endpoints of the trial were the change in depression severity SIGH-SAD during 6 weeks of therapy, and remission status after treatment. Overall, the results showed improvement in SAD symptoms in the two study groups with no significant differences between them at 6 weeks of treatment. There was no long-term follow-up to examine recurrence rates with each therapy. The trial was a relatively small, single center, RCT conducted mainly among white women. The participants were not blinded to the treatment allocation, which is a potential source of bias, and according to the authors, the primary investigator was the developer of CBT-SAD which is another potential source of bias. More importantly, light therapy was compared to CBT-SAD which has not been thoroughly investigated as a treatment for SAD. Ideally the trial would include a sham light therapy and /or a placebo group to determine the placebo effect of each of the two therapies.
Conclusion: There is insufficient evidence to determine the effectiveness of light therapy for the treatment of SAD. Several national and international guidelines recommend light therapy for SAD giving it a level 1 evidence (Canadian guideline, 2009) or level 2 evidence (AAFP, 2013), others like the British NICE guideline (2009) and the World Federation of Societies of Biological Psychiatry (WFSBP, 2013) are uncertain about the evidence supporting light therapy for SAD.
Articles: The literature search for studies on light therapy for SAD published after the last MTAC review revealed a recent systematic review with meta-analyses on bright light therapy for depression including SAD, a Cochrane review on second-generation antidepressants for SAD, a randomized controlled trial of CBT vs. light therapy for SAD, a crossover RCT investigating the rapid effects of light therapy on SAD, and a retrospective study investigating the appropriate duration of light therapy. The search also identified three small to relatively small RCTs that compared standard bright light vs. dawn simulation, low-intensity blue-enriched white light, or negative air ions, as well as a more recent trial on different intensities of transcranial bright light treatment delivered via the ear canals for SAD. The meta-analysis and the RCT comparing bright light therapy to CBT were selected for critical appraisal. The pooled results of studies comparing antidepressants vs. light therapy in the Cochrane review were included. Mårtensson B, Pettersson A, Berglund L, et al. Bright white light therapy in depression: A critical review of the evidence. *J Affect Disord*. 2015 Aug 15; 182:1-7. See Evidence Table 1**.** Rohan KJ, Mahon JN, Evans M, et al. Randomized Trial of Cognitive-Behavioral Therapy versus Light Therapy for Seasonal Affective Disorder: Acute Outcomes. *Am J Psychiatry*. 2015 Sep 1; 172(9):862-869. See Evidence Table 2.

The use of light therapy in the treatment of Seasonal Affective Disorder (SAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW
Light Therapy for SAD
Conclusion:

- The search identified one study which is a follow-up of one of the studies assessed in the last review in 2015. The study is of low quality and suggests that CBT may be comparable to LT in terms of recurrence and remission status at next winter. In addition, CBT might be more effective than light therapy two winters later. Studies with higher quality are needed to draw firm conclusions on light therapy and unipolar depression with seasonal pattern in the long-term. There is insufficient (high-quality) evidence for or against the use of light therapy in patients with unipolar major depression with seasonal pattern in the long-term.
- There is insufficient evidence for or against the effectiveness of light therapy as preventive treatment for patients with a history of SAD.

Articles: The search yielded 242 items; but one RCT and one meta-analysis were retained.

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Applicable Codes

Considered not covered:

HCPC Codes	Description
E0203	Therapeutic lightbox, minimum 10,000 lux, table top model
A4634	Replacement bulb for therapeutic light box, tabletop model

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/16/2008	05/03/2011[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012 [MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	08/06/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/20/2015	Changed Medicare link
01/06/2016	MPC approved to retain a policy of insufficient evidence
08/06/2019	Added July 8, 2019 MTAC review

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