Transcranial magnetic stimulation for depression
BlueCross BlueShield Association

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
This Assessment will review the available evidence to determine if TMS therapy is effective for the treatment of depression.

Authors' conclusions
The randomized clinical trial of TMS does not show definitive evidence of efficacy for its primary endpoint at 4 weeks. Not all outcomes show efficacy, and the analysis is sensitive to alternative methods of analysis. Another limitation of this and other studies of TMS is lack of rigorous evaluation beyond the period of treatment. Although short-term studies are consistent with changes in depression scores due to TMS, the clinical significance and durability of the effect are not well characterized. One meta-analysis indicated no difference in effect between patients with treatment-resistant and nontreatment-resistant depression. The randomized, clinical trial showed a greater effect in patients with only one prior treatment failure, with possibly minimal or no effect in patients with greater than one prior treatment failure.

The indication for which TMS received approval, one prior failure of an adequate antidepressant course, is unusual. A change in antidepressant therapy is usually indicated at this point and has been shown to have a success rate similar to the first course. The current body of evidence cannot determine in a rigorous way whether TMS would be as effective as a second course of antidepressant therapy. Other important gaps in current knowledge include whether TMS is effective as an adjunctive treatment to second-line drug therapy, the durability of TMS treatment, and the effectiveness of retreatment. A clinical trial sponsored by the National Institute of Mental Health has recruited subjects for another clinical trial of TMS. However, this trial also appears to have only a short duration (3 weeks) in which the participants are randomized to TMS or sham before crossovers or alternative treatments are offered.

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether TMS for the treatment of depression meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

Devices for transcranial stimulation have received clearance by the U.S. Food and Drug Administration (FDA) for diagnostic uses. One device, NeoPulse (Neuronetics, Atlanta, GA) received approval in Canada and Israel as a therapy for depression. Although initially examined by the U.S. Food and Drug Administration (FDA) under a traditional 510(k) application, the NeoPulse, now known as NeuroStar® TMS, received 510(k) clearance for marketing as a "de novo" device assessed as low risk, no predicate device) in 2008. NeuroStar® TMS is indicated for the treatment of patients with depression who have failed one 6-week course of antidepressant medication.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

An important limitation of the evidence is lack of information beyond the acute period of treatment. Most of the clinical trials evaluate the outcomes at the point of the last TMS treatment, between 1 and 4 weeks. Very few studies evaluated patients beyond this time period. Although meta-analyses are consistent with short-term antidepressant effects, the clinical significance of the effect is uncertain. The large clinical trial of TMS reviewed in this assessment...
did not unequivocally demonstrate efficacy, as the principal endpoint was not statistically significant at 4 weeks, and some results were sensitive to the methods of analysis. The patients in whom TMS is indicated are usually treated with a second course of antidepressant therapy. The clinical trial, which was sham controlled without active treatment, cannot determine whether TMS would be more or less successful than this standard treatment.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

The available evidence does not permit conclusions regarding the effect of TMS on health outcomes or compared with alternatives. Comparison to alternatives using other observational studies may not be valid due to unmeasured differences in severity of depression between studies and other differences in studies.

5. The improvement must be attainable outside the investigational settings.

It has not yet been demonstrated whether TMS improves health outcomes in the investigational setting. Therefore, it cannot be demonstrated whether improvement is attainable outside the investigational settings.

For the above reasons, transcranial magnetic stimulation for the treatment of depression does not meet the TEC criteria.

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