Transcranial Magnetic Stimulation (TMS)

Program Description

CBH considers TMS therapy reasonable and necessary when it is provided according to the accepted standards of FDA approval and medical practice, in a setting appropriate to the member's medical needs and condition, when it meets the member's medical need, and when it is ordered and provided by qualified personnel. It is expected that TMS therapy will be ordered by a psychiatrist familiar with this therapy and the patient's psychiatric and medical history and administered under the direct supervision of a qualified physician.

TMS treatment is provided using a device that is approved by FDA for the treatment of major depressive disorder (MDD) under certain conditions (see below). The TMS treatment order is written by a psychiatrist (MD or DO) who has examined the individual and reviewed the record. The psychiatrist must have experience in administering TMS therapy and the treatment must be given under direct supervision of this psychiatrist (i.e., he or she must be in the area and be immediately available).

TMS is reasonable and necessary for treatment of MDD for up to 30 visits over a seven-week period, followed by six tapered treatments for symptoms of MDD. The number of treatments is evaluated against member response and the published evidence-based literature.

Treatment must follow a scheduled plan for TMS sessions (specific number of sessions and frequency), assessment of efficacy, and a proposed tapering schedule. Contraindications include implanted devices or hardware in other locations, including but not limited to: cochlear implant, implanted defibrillator, pacemaker, vagus nerve stimulator, deep brain stimulator, cardiac clips/stents/staples/coils, medication pumps, or metal fragments. Special consideration/caution is required for members with epilepsy, history of seizures, psychosis, history of cerebrovascular disease, dementia, elevated intracranial pressure, head trauma, or tumor of the central nervous system.

An informed consent statement must be reviewed with the member and signed by both the member (or their representative) and the provider.

Authorization Criteria

A. The member is over the age of 18 and is not currently pregnant;

B. The member has a confirmed DSM-5 diagnosis of MDD, severe (single or recurrent episode) documented by standardized rating scales that reliably measure depressive symptoms;

AND

C. The member has a documented lack of clinically significant response to antidepressant medication treatment, evidenced by:

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1. Two single-agent trials of antidepressants from at least two different agent classes at adequate doses and duration (usually at least 6 weeks for each one),

   AND

2. Two augmentation trials with different classes of augmenting agents utilizing either (or both) of the agents used in the single-agent trials.

   - Extenuating circumstances that prohibit a second augmentation trial can be reviewed on a case-by-case basis.

NOTE: *Each antidepressant agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy. Trial criteria is six+ weeks of maximal FDA recommended dosing or maximal tolerated dose of medication with objectively measured evaluation at initiation and during the trial showing lack of treatment response (i.e., < 50% reduction of symptoms or scale improvement).*

OR

D. The member is unable to tolerate a therapeutic dose of at least two different antidepressant medications from different classes,

3. Intolerance is defined as severe somatic or psychological symptoms that cannot be modulated by any means including but not limited to additional medications to ameliorate side effects.

   a. Examples include severe and persistent fatigue, somnolence, insomnia, agitation, exacerbation of anxiety, nausea, diarrhea, vomiting, sweating, marked tremor, headaches, and/or cognitive dysfunction that are non-responsive to typical treatment regimens.

   b. Examples of psychological side effects include suicidal-homicidal thinking/attempts and dysregulated impulse control.

NOTE: *A trial of less than one week of a medication is not considered a qualifying trial to establish intolerance.*

AND

E. The member failed a trial of an evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms.

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Repeat treatment (retreatment) may be considered for members who meet **ALL** of the following:

A. The member met guidelines for initial treatment and subsequently developed relapse of symptoms;

B. The member responded to prior TMS treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for symptoms;

AND

C. Retreatment is not requested as maintenance therapy or continuous therapy. The time between treatment episodes should allow for assessment clinically and by a standardized rating scale to clearly document that the member responded and then relapsed, typically six months since the last TMS session.