Medical Necessity National Criteria Set 6.602.02 Repetitive Transcranial Magnetic Stimulation

Description of Services: Repetitive Transcranial Magnetic Stimulation (rTMS) is a noninvasive method of brain stimulation. In rTMS, an electromagnetic coil is positioned against the individual's scalp near his or her forehead. A Magnetic Resonance Imaging (MRI)-strength, pulsed, magnetic fields then induce an electric current in a localized region of the cerebral cortex, which induces a focal current in the brain and temporary modulation of cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Depending on stimulation parameters, repetitive TMS to specific cortical regions can either decrease or increase the excitability of the targeted structures. rTMS does not induce seizures or involve complete sedation with anesthesia in contrast to the Electroconvulsive Therapy (ECT). The Food and Drug Administration (FDA) approval for this treatment modality was sought for patients with treatment resistant depression. Additionally, the population for which efficacy has been shown in the literature is that with treatment resistant depression. Generally speaking, in accordance with the literature, individuals would be considered to have treatment resistant depression if their current episode of depression was not responsive to two trials of medication in different classes for adequate duration and with treatment adherence. rTMS is usually administered four to six times per week and for six weeks or less. It is typically performed in an outpatient office. rTMS is not considered proven for maintenance treatment. The decision to recommend the use of rTMS derives from a risk/benefit analysis for the specific member. This analysis considers the diagnosis of the member and the severity of the presenting illness, the member's treatment history, any potential risks, anticipated adverse side effects and the expected efficacy. Licensure and credentialing requirements specific to facilities and individual practitioners do apply and are found in our provider manual/credentialing information.

Admission Criteria	Continued Stay Criteria	Discharge Criteria
All of the following criteria must be met: 1) The member must be at least 18 years of age. 2) The individual demonstrates behavioral symptoms consistent with unipolar Major Depression Disorder (MDD), severe degree without psychotic features, either single episode, or recurrent, as described in the most current version of the DSM, or corresponding ICD, and must carry this diagnosis. 3) Depression is severe as defined and documented by a validated, self-administered, evidence-based monitoring tool (i.e. Inventory of Depressive Symptomatology Self-Report, Quick Inventory of Depressive Symptomology (QID), Patient Health Questionnaire (PHQ-9), Hamilton Depression Rating Scale (HAM-D) or Beck Depression Scale (BDI), etc.). 4) The diagnosis of MDD cannot be made in the context of current or past history of manic, mixed or hypomanic episode. 5) The member has no active (within the past year) substance use or eating disorders. 6) The member must exhibit treatment-resistant depression in the current treatment episode with all of the following: a) Lack of clinically significant response (less than 50% of depressive symptoms); b) Documented symptoms on a valid, evidence-based	**All of the following criteria must be met:** 1) The member continues to meet admission criteria; 2) An alternative treatment would not be more appropriate to address the members ongoing symptoms; 3) The member is in agreement to continue rTMS treatment and has been adherent with treatment plan; 4) Treatment is still necessary to reduce symptoms and improve functioning; 5) There is evidence of objective progress in relation to specific symptoms, or treatment plan has been modified to address a lack of progress; 6) Treatment is to continue within the authorization period only when continued significant clinical benefit is achieved (evidenced by scales referenced throughout this document) and treatment outweighs any adverse effects;	**Any one of the following criteria:** 1) The member has achieved adequate stabilization of the depressive symptoms; 2) Member withdraws consent for treatment; 3) The member no longer meets authorization criteria and/or meets criteria for another level of care, either more or less intensive; 4) The member is not making progress toward treatment goals, as demonstrated by the absence of any documented meaningful (i.e., durable and generalized) measurable improvement (e.g. validated rating scale and behavioral description) and there is no reasonable expectation of progress; or 5) The member experiences a worsening of depressive symptoms such as increased suicidal

monitoring tool; c) Medication adherence; and d) Lack of response to at least 2 psychopharmacologic trials in the current episode of treatment at the minimum dose and from 2 different medication classes. 7) rTMS is administered by a US Food and Drug Administration (FDA) cleared device for the treatment of MDD in a safe and effective manner according to the manufacturer's user manual and specified stimulation parameters. 8) The order for treatment is written by a physician who has examined the Member and reviewed the record, has experience in administering rTMS therapy and directly supervises the procedure (on site and immediately available). 9) The member must not meet any of the exclusionary criteria below. **The following criteria may apply:** History of response to TMS in a previous depressive episode as evidenced by a greater than 50% response in standard rating scale for depression (e.g., Geriatric Depression Scale (GDS), Personal Health Questionnaire Depression Scale (PHQ-9), Beck Depression Scale (BDI), Hamilton Rating Scale for Depression (HAM-D), Montgomery Asberg Depression Rating Scale (MADRS), Quick Inventory of Depressive Symptomatology (QIDS), or the Inventory for Depressive Symptomatology Systems Review (IDS-SR) **Exclusionary Criteria :** ***Any*** *of the following criteria are sufficient for exclusion from this level of care:* 1) The member has medical conditions or impairments that would prevent beneficial utilization of services; 2) The member requires the 24-hour medical/nursing monitoring or procedures provided in a hospital setting.	7) There is documented coordination with family and community supports as appropriate; and 8) Medication assessment has been completed when appropriate and medication trials have been initiated or ruled out.	thoughts/behaviors or unusual behaviors.

3) The safety and effectiveness of rTMS has not been established in the following member populations or clinical conditions through a controlled clinical trial, therefore the following are exclusion criteria; 4) Members who have a suicide plan or have recently attempted suicide; 5) Members who do not meet current DSM criteria for major depressive disorder; 6) Members younger than 18 years of age or older than 70 years of age; 7) Members with recent history of active of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder; 8) Members with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features; 9) Members with neurological conditions that include epilepsy, cerebrovascular disease, dementia, Parkinson's disease, multiple sclerosis, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS. 10) The presence of vagus nerve stimulator leads in the carotid sheath; 11) The presence of metal or conductive device in their head or body that is contraindicated with rTMS. For example, metals that are within 30cm of the magnetic coil and include, but are not limited to, cochlear implant, metal aneurysm coil or clips, bullet fragments, pacemakers, ocular implants, facial tattoos with metallic ink, implanted cardioverter defibrillator, metal plates, vagus nerve stimulator, deep brain stimulation devices and stents; 12) Members with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators; 13) rTMS is not indicated for maintenance treatment. There is insufficient evidence to support the efficacy of maintenance therapy with rTMS; or		

14) rTMS for maintenance treatment of major depressive disorder is experimental / investigational due to the lack of demonstrated efficacy in the published peer reviewed literature.		