7.0 Other

7.102 Repetitive Transcranial Magnetic Stimulation (rTMS)

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. It is thought that this stimulates the part of the brain that involves mood control and can ease depression. This is a treatment that could be tried when other depression treatments have not worked. rTMS does not induce seizures or involve complete sedation with anesthesia like are involved with ECT. 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 patient. This analysis considers the diagnosis of the patient and the severity of the presenting illness, the patient'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.

Important: While level of care determinations are considered in the context of an individual's treatment history; Beacon Health Options never requires the attempt of a less intensive treatment as a criterion to authorize any service.

Criteria

Admission Criteria	**All** *of the following criteria are necessary for admission* 1. The individual must be18 years or older. 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. a. Depression is severe as defined and documented by a validated, self-administered, evidence-based monitoring tool (e.g. QID-SR16, PHQ-9,

	HAM-D or BDI, etc.). b. The diagnosis of MDD cannot be made in the context of current or past history of manic, mixed or hypomanic episode. 3. One of the following clinical criteria: a) Has resistance to treatment as evidenced by a lack of clinically significant response to 4 trials of psychopharmacologic agents in the current depressive episode from at least two different agent classes, at or above the minimum effective dose and duration, and trials of at least two evidence-based augmentation therapies; or b) Inability to tolerate psychopharmacologic agents as evidenced by four trials of psychopharmacologic agents with distinct side effects; or c) History of response to rTMS in a previous depressive episode as evidenced by a greater than 50% response in standard rating scales 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) and now has a relapse after remission and meets all other authorization criteria, OR d) History of previous response to electroconvulsive therapy (ECT), or inability to tolerate ECT, and rTMS is considered a less invasive treatment option. 4. During the current episode the member has had A trial of evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and minimum of twelve week duration without significant improvement in depressive symptoms as documented by standard rating scales that reliably measure depressive symptoms (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) 5. 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. 6. 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)
Psychosocial, Occupational, and Cultural and Linguistic Factors	*These factors, as detailed in the Introduction, may change the risk assessment and should be considered when making level of care decisions.*
Exclusion Criteria	**Any** *of the following criteria are sufficient for exclusion from this level of care*: 1. The individual has medical conditions or impairments that would prevent beneficial utilization of services. 2. The individual requires the 24-hour medical/nursing monitoring or procedures provided in a hospital setting. The safety and effectiveness of rTMS has not been established in the following patient populations or clinical conditions through a controlled clinical trial, therefore the following are exclusion criteria: 3. Patients who have a suicide plan or have recently attempted suicide during the current depressive episode. 4. Patients who do not meet current DSM or ICD criteria for major depressive disorder 5. Patients younger than 18 years of age or older than 70 years of age. 6. Patients with history recent history of active of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder. 7. Patients with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features.) 8. Patients 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. 9. 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, and magnetically activated (not amalgam) dental implants. 10. Patients with major depressive disorder who have failed to receive clinical benefit from ECT or VNS. 11. Presence of severe cardiovascular disease, unless cleared for rTMS by a

	cardiologist. 12. Patients who are pregnant or nursing. 13. rTMS is not indicated for maintenance treatment. An extensive review of the published peer reviewed medical literature found no double blind clinical trials looking at the efficacy of rTMS in preventing relapse in those patients who have responded. rTMS for maintenance treatment of major depressive disorder is experimental/investigational due to the lack of demonstrated efficacy in the published peer reviewed literature.
Discharge Criteria	**Any** *of the following criteria are sufficient for discharge from this level of care*: 1. The individual has achieved adequate stabilization of the depressive symptoms. 2. The individual no longer meets admission criteria, or meets criteria for a less or more intensive services. 3. The individual 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. 4. Worsening of depressive symptoms such as increased suicidal thoughts/behaviors or unusual behaviors. 5. Member has completed the acute course of 5 treatments per week for 6 weeks and up to 6 taper treatments over three weeks 6. Provider has failed to monitor, document, and/or report member response to treatment.