REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS)

PURPOSE

Performance specifications are intended to enhance MassHealth Enrollee experience and outcomes by promoting transparency and consistency across Plans and providers. Performance specifications are expectations imposed on providers who contract for these specific and related services. Information contained in this document is based on publicly available documents, Plan expectations, your contract, and MassHealth guidance. This information should be and will look materially like any other MassHealth contracted Plan. Performance specifications, your provider manual, and other requirements can be found at providerexpress.com.

Providers contracted for this level of care or service are expected to comply with applicable regulations set forth in the Code of Massachusetts Regulations, and all requirements of these service-specific performance specifications. In addition, providers of all contracted services are held accountable to the General Performance Specifications. Where there are differences between the service-specific and General Performance Specifications, the service-specific specifications take precedence.

OVERVIEW

Effect of magnetic stimulation on brain function

1. rTMS temporarily modulates cerebral cortical function and changes the level of neuronal activity in key regions of the brain related to higher-level cognitive function.
2. A magnetic resonance-strength (MRI) pulse (between 1-20 Hz) is delivered to the brain.
3. Pulses are administered by passing currents through an electromagnetic coil placed adjacent to the scalp.
4. An electrical field is induced in the brain tissue targeted by the coil.
5. This results in altered activity of neurons in the targeted brain region.

Treatment location and procedure

1. rTMS is completed in an outpatient office setting.
2. It is a non-invasive procedure.
3. It does not require anesthesia.

Treatment indications

1. rTMS has had approval from the US Food and Drug Administration (FDA) since 2008 and the Agency for Health Care Research and Quality (AHRQ) since 2011 for the treatment of refractory major depressive disorder (MDD).
2. Refractory depression is defined as less than 50 percent response to medication and

psychotherapy trials, as detailed below in process specifications section.

3. rTMS is approved for re-administration in Enrollees who responded to it positively during a prior depressive episode.

Treatment contraindications

1. Non-refractory depression
2. Depressive syndromes that do not meet current DSM or corresponding ICD criteria for MDD
3. Maintenance treatment of depression
4. Psychiatric conditions other than unipolar depression, including but not limited, to active substance use disorder, post-traumatic stress disorder, obsessive compulsive disorder, bipolar disorder, and psychotic disorders, including major depression with psychosis
5. Enrollees with a recent suicide attempt or current suicide plan
6. Enrollees under 19 or over 70 years old
7. Presence of metallic devices, including, but not limited to, cochlear implants, aneurysm coils/clips, bullet fragments, pacemakers, ocular implants, facial tattoos with metallic ink, cardioverter defibrillators, metal plates, vagal nerve stimulators (VNS), deep brain stimulation devices, and stents
8. Presence of devices interrupted by rTMS signals including, but not limited to pacemakers, defibrillators, and VNS
9. Enrollees on medication that lowers the seizure threshold
10. Enrollees with medical conditions that lower the seizure threshold

Treatment duration/frequency

1. Treatment is administered for a maximum of six weeks or earlier if maximal benefit, as assessed by rating scales (discussed in process specifications below) has been attained.
2. Treatment is administered five (5) times per week.
3. The active treatment phase is followed by a three-week taper of x3, x2, and x1 treatments per week.

Side effects

1. Common: lightheadedness, temporary hearing loss, mild headaches
2. Rare: seizures

Use of medication and psychotherapy during rTMS administration

1. Medications can be continued but should not be changed during rTMS treatment.
2. Psychotherapy treatment can be provided, if indicated, with rTMS treatment.

Risk/benefit assessment consideration in decisions to administer rTMS

1. Severity of the current depressive episode
2. Treatment history for current and past depressive episodes
3. Anticipated side effects
4. Anticipated efficacy of rTMS

5. Anticipated speed of action
6. Potential benefits of alternative treatment approaches

SERVICE COMPONENTS

1. The rTMS device should be one that is FDA approved.

Training

1. A standard operating procedure (SOP) for all rTMS treatment components should be established for all Enrollees of the rTMS treatment team.
2. The SOP should include product training by the devise manufacturer for all Enrollees of the treatment team, consistent with standards established by the Clinical TMS Society (cTMSs).
3. Physician providers of rTMS should obtain documented annual continuing medical education in rTMS treatment.
4. The TMS physician assures that the delivered procedure is revised, where indicated, for consistency with updates to standards of practice and for device operation.
5. Device training should include a) the device's operation, b) rTMS coil placement, and c) coil targeting.
6. Side effect management training should include a) symptoms of treatment side effects, b) management of side effects, c) current first responder training in seizure management, and d) current basic life support (BLS) certification.
7. Non-physician clinician Enrollees of the rTMS treatment team should be certified in all areas listed above.

Roles and responsibilities

1. The physician who writes the order for rTMS hold the ultimate responsibility for overall daily management of the rTMS treatment team.
2. The initial treatment plan is completed by the prescribing physician.
3. Initial and subsequent motor threshold (MT) determinations should be performed by the prescribing physician.
4. Determination of coil location should be made by the prescribing physician.
5. The first three sessions should be completed by the prescribing physician.
6. Subsequent rTMS sessions may be delivered by a qualified (based on above training requirements) non-physician as long as the prescribing physician is on-site during administration by another qualified clinician.
7. After each rTMS session, the prescribing physician should assess potential adverse side effects through direct clinical assessment of the Enrollee.
8. After each rTMS session, the prescribing physician should assess whether modifications, including MT re-establishment, are indicated.

Administration of rTMS

1. The prescribing rTMS physician determines the placement of the magnetic coil placement.
2. The Enrollee's motor threshold (MT) is initially established to ensure the most accurate treatment location, magnetic field intensity, and to provide a head surface landmark to permit navigation to the treatment location.
3. The usual initial coil location is the left dorsolateral prefrontal cortex (L DLPFC) but can be modified based on Enrollee-specific factors or updates to the literature that meet rTMS medical necessity criteria (MNC).
4. The individual is monitored for side effects after recovering from the procedure.
5. Vital signs are checked before and after administration of the procedure.
6. Prior to each treatment, there is an assessment for new risk factors or significant worsening of those present at pre-TMS administration.
7. After each treatment, individuals are assessed for any adverse effects that may occur during the recovery period.
8. A neurology consultation is obtained if seizures develop after an rTMS administration.
9. Coil placement should be adjusted based on initial MT response and to subsequent treatment response during rTMS administration.
10. The individual's clinical status, including assessment by depression rating scale, is completed following each rTMS session.
11. The individual's cognitive function is monitored on an ongoing basis and, at a minimum, at the end of each course of treatment.
12. rTMS is not to be continued beyond six weeks and is then tapered over three weeks.
13. Decision about continuing rTMS is done in conjunction with ongoing follow up with the primary psychiatrist, other psychiatric providers, the primary care physician, and any relevant specialists.

STAFFING REQUIREMENTS

1. The provider complies with the staffing requirements of the applicable licensing body, the staffing requirements in the Plan service-specific performance specifications, and the credentialing criteria outlined in the Plan provider manual found at providerexpress.com.
2. rTMS treatment requires an inter-disciplinary team that includes:
    a) a Board-certified physician in psychiatry who has sufficient training in rTMS as outlined in the service component section;
    b) a consulting internist, neurologist, ob-gyn, radiologist, and other specialists as appropriate for the Enrollee being treated;
    c) the Enrollee's non-rTMS treating psychiatrist if the rTMS-prescribing physician is not the Enrollee's primary psychiatric prescriber;
    d) the Enrollee's primary care provider;
    e) the Enrollee's psychotherapist if this is not the rTMS-prescribing physician; and
    f) optional: a non-physician clinician qualified and supervised per the above section on

service components to deliver rTMS sessions four and beyond.

SERVICE, COMMUNITY AND OTHER LINKAGES

1. The rTMS treatment team collaborates with the Enrollee's outpatient providers in the development of treatment and discharge plans.

PROCESS SPECIFICATIONS

Assessment, Treatment Planning and Documentation

1. The provider ensures there is documentation in the Enrollee's health record that rTMS is being used for treating target symptoms in an individual with refractory major depression.

Initial rTMS assessment

1. The initial evaluation for rTMS administration is completed by the prescribing physician.
2. The prescribing physician meets the qualifications listed in the Service Component section.
3. The initial evaluation includes all standard elements of a physician psychiatric intake assessment, as well as those specific for rTMS as listed below.

rTMS-specific initial assessment elements

1. Collateral history from current providers including the primary care provider and current psychiatric providers
2. Documentation of refractory depression based on the following criterion:
    a) Baseline depression assessment on both clinical interview and on an evidence-based rating scale (PHQ-9, BDI, HAM-D, MADRS) meet the current DSM and the rating scales standard for major depressive disorder
    b) Less than a 50 percent response to two trials of at least four weeks duration
    c) Medication trials have included two different antidepressant classes as well as medication augmentation strategies
    d) Lack of response to an evidence-based psychotherapeutic intervention for depression
    e) Psychosocial and contextual factors related to the Enrollee's depression
    f) The anticipated number of treatment and taper sessions, with the possibility of modification based on response
    g) Recommended initial cortical coil placement
    h) Recommended initial pulse frequency
3. Collateral contact should be made with the Enrollee's primary care provider, other psychiatric providers, and family members who have input to provide regarding the Enrollee's condition.
4. Target symptoms are identified.
5. A full mental status assessment including, at a minimum, a Mini Mental Status Examination Score (such as Folstein or Montreal Cognitive Assessment (MoCA)) is performed and documented.
6. Past treatments are carefully reviewed and documented.

7. Documentation of previous pharmacotherapy includes each medication prescribed, dosage, duration of each trial, compliance, response, side effects, and response to augmentation strategies.
8. Pre-treatment medical evaluation includes an updated history and physical examination with a focus on major areas of risk including history of seizures or history of other neurological conditions.
9. There is an assessment of implanted metal or medical devices, such as defibrillators or a VNS, whose current is affected by rTMS administration.
10. The rTMS prescribing physician ensures an evaluation of concurrent medications the individual is taking.
11. The Enrollee's history of any common or rare side effects associated with rTMS is noted.
12. Radiographic studies should be completed, if indicated, based on the initial evaluation of the Enrollee.

Risk benefits assessment and informed consent

1. There is documentation of an assessment of the risks and potential benefits to the individual undergoing rTMS.
2. Risk documentation should include any medical or other factors likely to increase risk of seizures or other side effects associated with rTMS.
3. There is documentation that contra-indicated conditions listed in the rTMS Overview section are absent (e.g., metal implants).
4. There is documentation of the informed consent process and the Enrollee's capacity to provide consent.
5. There is documentation of substituted judgment if the individual is not able to give consent.
6. Informed consent includes full and appropriate information in a format that allows for an informed discussion.
7. The informed consent discussion includes explanation of the general risks of rTMS, risks specific to the individual and potential benefits to the individual.
8. Prior to the initial rTMS session, the Enrollee is provided a visual aide to address anticipated anxiety associated with limited head movement during the procedure.
9. Family members are included during initial intake and/or informed consent process, where indicated.

Follow-up assessment

1. Assessment is completed by the rTMS prescribing physician after each rTMS administration and/or visit.
2. In addition to the standard elements of the physician follow-up assessment and documentation, the following is included:
    a) Changes in pulse frequency and coil placement,
    b) Clinical response based on clinical interview and follow-up results to initial screening instruments,
    c) Adverse events (these should also be reported to appropriate monitoring agencies),

d) Documentation of side-effects, and
e) Documentation of changes in treatment based on clinical response and/or side effects to each rTMS session.

Assessment for re-treatment

1. rTMS can be administered for refractory depression in Enrollees who have had a positive response of > 50 percent to prior rTMS treatment.
2. Assessment for re-treatment should include documentation of the prior 50 percent response.
3. Assessment for re-treatment should consider re-treatment in light of the duration and level of response to the prior rTMS treatment.

Discharge Planning and Documentation

None

QUALITY MANAGEMENT

1. The provider will develop and maintain a quality management plan that is consistent with their contractual responsibilities to Optum, and which utilizes appropriate measures to monitor, measure, and improve the activities and services it provides.
2. A continuous quality improvement process is utilized and may include outcome measures and satisfaction surveys to measure and improve the quality of care and services delivered to Enrollees, including youth and their families.
3. Clinical outcomes data must be made available to Optum upon request and must be consistent with the performance specifications of this service.
4. Providers must report any adverse incidents and other reportable events that occur to the relevant authorities.