Repetitive Transcranial Magnetic Stimulation (rTMS)
Performance Specifications

Providers contracted for this level of care or service are expected to comply with all the requirements of these service-specific performance specifications. Additionally, providers contracted for this service and all contracted services are held accountable to the General performance specifications. The requirements outlined within these service-specific performance specifications take precedence over those in the general performance specifications.

Repetitive Transcranial Magnetic Stimulation (rTMS) is a multisession treatment that uses magnetic fields to stimulate nerve cells associated with mood control and depression. rTMS is a noninvasive procedure and side effects are rare. 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 and is used to treat medication- resistant major depression; however, there is emerging evidence of its efficacy in treating PTSD. The treatment has been approved by the US Food and Drug Administration (FDA) since 2008 and the Agency for Healthcare Research and Quality (AHRQ) since 2011 for the treatment of refractory major depressive disorder (MDD) defined as less than a 50% response to medication and outpatient therapy trials. rTMS is approved for re-administration if a member has had a successful outcome on an initial trail of rTMS. The procedure takes place in an outpatient setting, is non-invasive and does not require anesthesia. The procedure is generally administered daily/ 5 days a week over a four to seven-week period but could be shorter depending on rating scale assessment results. Tapering occurs post active treatment phase and lasts approximately 3 weeks. Side effects include lightheadedness and mild headaches. Seizures constitute a rare side effect. Medications can be continued but should not be changed during treatment and Members are encouraged to continue with outpatient therapy. Providers and Members should conduct a risk/benefit assessment when determining if rTMS is an appropriate treatment. There are a number of treatment contraindications listed below.

Clinical Overview:

Risk Benefit Assessment, conducted between physician and the Member should include:

- Severity of the current depressive episode
- Treatment history for current and past depressive episodes including collateral history from current providers
- Anticipated speed of action, efficacy, and side effects
- Potential benefits of alternative treatment approaches
- The provider documents all risk/benefit elements assessment in the Members record including all contraindications

Treatment Contraindications:

- Non-refractory depression and depressive syndromes that do not meet current DSM criteria for MDD
- Maintenance treatment of depression
- Psychiatric and substance use diagnosis other than unipolar depression including active substance use disorder, obsessive compulsive disorder and psychotic disorders, including major depression with psychosis or Members with a recent suicide attempt or current suicide plan

- Members older than 70
- Presence of metallic devices, including 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, stents and presence of devices interrupted by rTMS signals including pacemakers' defibrillators and VNS
- Members with medical conditions or who are on medication (s) that lowers the seizure threshold

COMPONENTS OF SERVICE:

Training:

- All rTMS devices need to be FDA approved
- A standard operating procedure (SOP) should be developed, including product training by the manufacturer for all treatment components and available to all Members of the treatment team consistent with the standards established by the Clinical TMS Society
- Physicians who provide rTMS need to ensure that they have completed an annual training on the product (device operation, rTMS coil replacement or placement and coil targeting) and that any procedures delivered are consistent with updated standards of practice
- Side effect training should include symptom recognition, management, and treatment as well as first responder training in seizure management and basic life support
- Non-physician staff of the treatment team need to be certified in all of the requirements listed above

Administration:

- Prior to each treatment, the Member is assessed for new risk factors, or significant worsening of symptoms present at pre-TMS administration. After each treatment, individuals are assessed for any adverse effects that may occur during the recovery period
- The prescribing rTMS physician determines the placement of the magnetic coil placement by initially establishing the Members motor threshold (MT). Coil placement should be adjusted based on initial MT response and to subsequent treatment response during rTMS administration
- A neurology consultation is obtained if seizures develop after an rTMS administration
- The individual's clinical status and cognitive functioning, including assessment by depression rating scale, are completed following each rTMS session
- rTMS is not to be continued beyond six weeks and is then tapered over three weeks
- Decision about continuing rTMS is done in conjunction with ongoing follow up with the
- primary psychiatrist, other psychiatric providers, the primary care physician, the outpatient therapist, and any relevant specialists

Training Expectations

It is the expectation of CCA that all contracted providers will offer ongoing staff training in order to best serve the diverse identities and experiences of the CCA Member population. Staff training should be inclusive of, but not limited to:

- Social determinants of health (SDOH)
- Trauma-informed behavioral health and medical care (including, but not limited to, ways in

which the ACE study informs care delivery for Members, and trauma-specific treatment approaches)
- Best practices in delivering LGBTQIA+ inclusive and affirming— and, specifically, transgender inclusive and affirming— behavioral health and medical care
- Best practices in delivering culturally responsive, inclusive, and anti-racist behavioral health and medical care
- Best practices in health equity and inclusivity for Members of various racial, ethnic, and cultural backgrounds, as well as disabled Members, Members of various religious backgrounds, and Members with multiply marginalized identities
- Organizational strategies and resources for accessing interpreter services for Members who primarily communicate in languages other than English (including ASL)

Expectations of Transgender inclusive and affirming policies for non-overnight levels of care

It is the expectation of CCA that all contracted providers will provide inclusive and affirming care to our transgender/non-binary/gender diverse Members. For non-overnight levels of care this expectation is inclusive of, but not limited to:

- Consistently using the name and pronouns that the Member uses for themselves, even if this is not the name and/or pronoun set reflected in the Member's legal identification and/or CCA insurance card
- Ensuring that staff are regularly trained in best practices in delivering LGBTQIA+ inclusive and affirming— and, specifically, transgender inclusive and affirming— behavioral health and medical care
- Making determinations about access to any gender-based/gender separated service based on the gender with which the Member identifies, even if this is not the gender reflected in the Member's legal identification and/or CCA insurance card

STAFFING REQUIREMENTS:

- The provider complies with the staffing requirements of the applicable licensing body
- A rTMS provider is a physician or nurse practitioner who is licensed, trained, and qualified to order and administer rTMS.
- rTMS treatment requires an inter-disciplinary team that includes:
    - Board-certified physician in psychiatry or qualified nurse who has sufficient training in rTMS as outlined in the service component section
    - Consulting internist, neurologist, ob-gyn, radiologist, and other specialists as appropriate for the Member being treated
    - Member's non-rTMS treating psychiatrist if the rTMS-prescribing physician is not the Member's primary psychiatric prescriber, Member's PCP and psychotherapist

PROCESS SPECIFICATIONS:

ASSESSMENT, TREATMENT PLANNING, DOCUMENTATION:

- The initial assessment between the physician and the Member includes all of elements of the Risk/Benefit assessment listed above as well as all the elements of an initial psychiatric evaluation and a medical evaluation with a focus on major areas of risk including history of seizures or history of other neurological conditions

- Documentation of refractory depression based on the following criteria:
    - 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
    - Less than a 50 percent response to two trials of at least four weeks duration
    - Medication trials have included two different antidepressant classes as well as medication augmentation strategies
    - Lack of response to an evidence-based psychotherapeutic intervention for depression
- The provider conducts a full mental status assessment using the Mini-Mental Status Exam at a minimum, conducts a psychosocial screen for factors that affect the Members life are assessed and documents the results of these assessments in the Member's medical record
- The provider documents previous pharmacotherapy including each medication prescribed (current and past), dosage, duration of each trial, compliance, response, side effects, and response to augmentation strategies
- The provider ensures on-going collateral contact with all of the Members current providers
- The provider assesses any implanted metal devices that may affect the rTMS and completes a radiographic assessment if appropriate
- The provider documents Members informed consent or substituted judgement, if the Member cannot give consent, the provider documents this in the Members record. Informed consent needs to be presented and reviewed in a culturally sensitive manner and in the Members language of choice
- With consent, the Members family and/or other natural supports are included in the initial assessment and informed consent process
- The provider obtains a prior authorization from CCA completing the Repetitive Transcranial Magnetic Stimulation Request Form and faxing the form to 855-341-0720
- Best practices for care include collaboration with Commonwealth Care Alliance Care Team. With the approval from the Member and appropriate release of information, Providers are expected to contact the CCA Care Team using CCA's Provider Services Line 866-420-9332 to alert the Members Care Team that the Member is receiving services and to discuss any services that might help support the Member for seamless continuity of Care

Follow-up and Re-treatment:

- An assessment is completed by the prescribing rTMS physician following each rTMS to include:
- Clinical response based on clinical interview and follow-up results to initial screening instruments
- Adverse events (these should also be reported to appropriate monitoring agencies)
- Documentation of side-effects, and changes in treatment based on clinical response and/or side effects to each rTMS session
- Changes in pulse frequency and coil placement
- rTMS can be administered for refractory depression in Members who have had a positive response of > 50 percent to prior rTMS treatment
- Assessment for re-treatment should include documentation of the prior 50 percent response

- Assessment for re-treatment should consider re-treatment in light of the duration and level of response to the prior rTMS treatment

DISCHARGE, COLLABORATION WITH COMMUNITY BASED PROVIDERS & SERVICES:

- The rTMS treatment team collaborates with the Member's outpatient providers in the development of treatment and discharge plans including, but not limited to, follow-up with psychopharmacological prescribers and outpatient therapists
- Upon discharge, discharge paperwork and agency referrals are given to the Member, and when appropriate, the Member's family or guardian, and includes appointments, medication information and emergency/crises information. The discharge plan is documented in the Member's medical record

QUALITY MANAGEMENT:

- The facility and/or program will develop and maintain a quality management plan that is consistent and that utilizes appropriate measures to monitor, measure, and improve the activities and services it provides.
- The facility utilizes a continuous quality improvement process and will include outcome measures and satisfaction surveys, to measure and improve the quality of care and service delivered to Members, including their families.
- Providers are required to collect and measure outcome data and incorporate the data in treatment plans in the medical records and inform clinical programming.
- Clinical outcomes data must be made available to Commonwealth Care Alliance (CCA) upon request and must be consistent with CCA' s performance standards for this level of care for quality management and Network Management purposes.
- The success of the program and the care and well-being of members rely on a collaborative partnership with Commonwealth Care Alliance and its provider network.
- All reportable adverse incidents will be reported within one business day of their occurrence per policy and DMH licensing requirements. A reportable adverse incident is an occurrence that represents actual or potential harm to the well-being of a Member, or to others by action of a Member, who is receiving services, or has recently been discharged from services.
- The provider must report any adverse events that occur to the relevant authorities and CCA.
- The facility and/or program will adhere to all reporting requirements of DPH and/or DMH regarding Serious Reportable Events (SRE) and all related matters.

DOCUMENT UPDATES:

- December 2024: Revised template
- March 2026: Annual review