Medical Necessity Guidelines:
Transcranial Magnetic Stimulation (rTMS)

Effective: November 9, 2016

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Applies to:
☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409
☒ Tufts Health Public Plans products
☒ Tufts Health Direct — Health Connector; Fax: 888.415.9055
☒ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055
☒ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607
☒ Tufts Health RITogether — A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒ Tufts Health Freedom Plan products; Fax: 617.972.9409

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW
Repetitive transcranial magnetic stimulation (rTMS) uses a specifically designed magnetic coil that is placed in contact with the scalp to generate rapidly alternating magnetic fields and produces electrical stimulation of superficial cortical neurons. The procedure takes approximately 40 minutes and is generally administered daily over a four to seven week period. The FDA approved rTMS in October 2008 for use in the treatment of treatment-refractory major depressive disorder based on the results of a multisite randomized controlled clinical trial using high frequency pulses over the left prefrontal cortex (HFL-TMS).

HFL-rTMS requires no anesthesia or sedation, has about a 5% discontinuation rate due to adverse effects (mostly headache or scalp pain), and has no systemic side effects. There are no long-term studies of rTMS.

Use the Repetitive Transcranial Magnetic Stimulation Request Form (Standard Form).

COVERAGE GUIDELINES
Tufts Health Plan has developed the following Guidelines for determining when rTMS is medically necessary. All five of the below must be met:

- The Member must have a diagnosis of Major Depression (single or recurrent episode) as defined by the most recent Diagnostic and Statistical Manual™ (DSM)
  AND
- The Member must demonstrate resistance to treatment as evidenced by ONE of the three following:
  1. BOTH OF THESE: a lack of clinically significant response in the depressive treatment episode, to four trials from at least two different agent classes, including at least one anti-depressant medication, administered at an adequate dose and duration of at least 4 weeks;
    AND
    Adequate trials of at least two (2) evidence-based augmentation therapies (at least four weeks in duration at adequate therapeutic doses);
    OR
  2. Inability to tolerate psychopharmacologic agents as evidenced by failed trials of four such agents with distinct, documented side effects;
    OR
  3. ONE OF THESE: A history of clinically significant response to rTMS in a previous depressive episode
    OR
    A history of clinically significant response to electroconvulsive therapy (ECT) in a previous or current MDD episode;
OR

The Member meets expert consensus guidelines for ECT but is unable to tolerate ECT, and rTMS is proposed as a less invasive alternative;

AND

- An unsuccessful trial has been undertaken, during the current depressive episode, 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;

- The rTMS treatment is delivered by a device that is FDA-approved or FDA-cleared for the treatment of MDD in a safe and effective manner. rTMS treatment should generally follow the protocol and parameters specified in the manufacturer’s user manual, with modifications only as supported by the published scientific evidence base;

- The order for treatment (or retreatment) will be written by a physician (MD or DO) who will examine the patient and review the record. The physician must have experience in administering rTMS therapy and must certify that the treatment will be given under direct supervision of this physician (i.e., he or she will be in the area and will be immediately available for each treatment).

AUTHORIZATION GUIDELINES

Thirty (30) visits over 7 weeks followed by six (6) taper treatments. Treatment planning service (90867) once per course of treatment.

LIMITATIONS

Tufts Health Plan will not cover rTMS under the following circumstances:

- For formats other than HFL-rTMS, as their use is considered experimental
- rTMS should not be used for Members who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head and located less than 30 cm from the rTMS magnetic coil, including but not limited to cochlear implants, implanted electrodes or stimulators, aneurysm clips or coil, or bullet fragments.
- In a setting other than a medical office or facility.
- The use of rTMS as a maintenance therapy to prevent relapse is not supported by controlled clinical trials and is therefore not considered medically necessary.

CODES

For the purposes of this guideline Tufts Health Plan will require the use of the diagnosis codes in Table 1 and the CPT procedure codes in Table 2.

The Member must have one of the following ICD-10 diagnoses to be considered for coverage.

Table 1: ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>F32.2</td>
<td>Major depressive disorder, single episode, severe without psychotic features</td>
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<tr>
<td>F33.2</td>
<td>Major depressive disorder, recurrent severe without psychotic features</td>
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Table 2: CPT Procedure Codes

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<thead>
<tr>
<th>CPT Procedure Code</th>
<th>Description</th>
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<tr>
<td>90867</td>
<td>Therapeutic repetitive Magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management</td>
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<tr>
<td>90868</td>
<td>Subsequent delivery and management, per session</td>
</tr>
<tr>
<td>90869</td>
<td>Subsequent motor threshold re-determination with delivery and management</td>
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REFERENCES
None

APPROVAL HISTORY
- September 20, 2012: Reviewed by the Mental Health Operations and Policy Committee
- March 1, 2013: Revised, added code descriptions from 2013 Current Procedural Terminology; revised: Thirty six (36) treatment visits (90868) over 13 weeks including taper visits at the end of treatment, if necessary.
- Revised: Subsequent motor threshold re-determination with delivery and management (90869), if needed, once per course of treatment; added: Not Covered for USFHP
- March 25, 2013: Added ICD-10 codes
- October 1, 2013: Reviewed by the Mental Health Operations and Policy Committee and renewed with the addition of “including at least one anti-depressant medication”.
- November 5, 2014: Reviewed and approved by the Mental Health Operations and Policy Committee with changes: remove fax number from Type of Review box.
- March 16, 2015: Added fax number back into "Applies to" Section.
- April 7, 2015: Reviewed by the Mental Health Operations and Policy Committee and updated to track with CMS Region 1 Local Coverage Determination;
- April 8, 2015 Approved by IMPAC and effective October 1, 2015.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- April 19, 2016: Fax number updated for Tufts Health Unify. Coding updated, ICD-9 CM codes removed.
- August 9, 2016 – Reviewed and approved by the Behavioral Health Operations and Policy Committee with no changes.
- October 27, 2016: Reviewed by the Behavioral Health Practitioner Advisory Committee and accepted with no changes.
- November 9, 2016: Reviewed and Approved by the Integrated Medical Policy Advisory Committee, with no changes.
- December 28, 2016: Coding updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member’s benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLink℠ Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.
Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.