

BLUE CROSS BLUE SHIELD OF MICHIGAN

**Clinical Criteria utilized by
New Directions Behavioral Health
for
repetitive transcranial magnetic stimulation
pre-authorizations**

Effective November 1, 2019

**BCBSM Clinical Criteria utilized by
New Directions Behavioral Health
for repetitive transcranial magnetic stimulation
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Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

Note: Transcranial magnetic stimulation must be administered by an approved U.S. Food and Drug Administration (FDA) cleared device for the treatment of major depressive disorder (MDD) according to specified stimulation parameters, 5 days a week for 6 weeks (total of 30 sessions), followed by a 3 week taper of 3 TMS treatments in 1 week, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

Must meet all:

1. The member is 18 to 70 years of age (includes ages 18 and 70).
2. A urine drug screen is obtained if indicated by current clinical, history or a high degree of clinical suspicion.
3. Has a confirmed diagnosis of severe major depressive disorder (single or recurrent episodes) without psychosis measured by evidence based scales such as Beck Depression Inventory (score 30-63), Zung Self-Rating Depression Scale (>70), PHQ-9 (>20), or Hamilton Depression Rating Scale(>20)
4. At least one of the following:
 - Medication treatment resistance during the current depressive episode evidenced by each of the following:
 - Lack of a clinically significant response to 4 trials of psychopharmacologic agents. Trial criteria is 6 weeks of maximal FDA recommended dosing or maximal tolerated dose of medication with objectively measured evaluation at initiation and during the trial showing no evidence of response (i.e., < 50% reduction of symptoms-or scale improvement). At least two trials should be augmentation trials and two may be with single agents.
 - Two single agent trials of antidepressants of different classes
 - Two augmentation agent trials with different classes of augmenting agents utilizing either (or both) of the agents in the above single agent trials
 - The patient is unable to tolerate a therapeutic dose of medications. Intolerance is defined as: severe somatic or psychological symptoms that cannot be modulated by any means including but not limited to: additional medications to ameliorate side effects. Examples of somatic side effects include persistent electrolyte imbalance, pancytopenia, severe weight loss, poorly controlled metabolic syndrome or diabetes, as a result of the

medication. Examples of psychological side effects of the medication would be suicidal-homicidal thinking/attempts, impulse dyscontrol.

Note: A trial of less than one week of a specific medication would not be considered a qualifying trial to establish intolerance.

- Electroconvulsive therapy would not be clinically superior to transcranial magnetic stimulation (e.g., in cases with psychosis, acute suicidal risk, catatonia or lifethreatening inanition rTMS should NOT be utilized)

5. A trial 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 (e.g., Becks Depression Inventory, Zung Self-Rating Depression Scale, PHQ-9, or Hamilton Depression Rating Scale)

6. The following conditions are continuously present in the rTMS treatment setting during treatment:

- Treatment must be rendered by a board-certified psychiatrist, trained in this therapy
- An attendant trained in BCLS and the management of complications such as seizures, as well as the use of the equipment must be present at all times
- Presence of adequate resuscitation equipment including, for example, suction and oxygen
- The facility must maintain awareness of response times of emergency services (either fire/ambulance or “code team”), which should be available within five minutes. These relationships are reviewed on at least a one year basis and include mock drills

Requests for repeat rTMS therapy in patients who have attained remission subsequent to initial rTMS therapy and experienced relapse will be reviewed for individual consideration.

Exclusions:

- All other behavioral health, neuropsychiatric or medical conditions (e.g., anxiety disorders, mood disorders, schizophrenia, Alzheimer’s, dysphagia, seizures)
- Pregnancy
- Maintenance treatment
- Presence of psychosis in the current episode
- Seizure disorder or any history of seizure, except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence
- Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 centimeters from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents

Note: Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS.

- If the patient (or, when indicated) the legal guardian is unable to understand the risk and benefits of rTMS and provide informed consent
- Presence of a medical or co-morbid psychiatric contraindication to rTMS
- Patient lacks a suitable environmental, or social and/or professional support system for post-treatment recovery
- There is not a reasonable expectation that the patient will be able to adhere to postprocedure recommendations

Note: Caution should be exercised in any situation where the patient's seizure threshold may be decreased. Examples include:

- Presence in the bloodstream of a variety of agents, including but not limited to tricyclic antidepressants, clozapine, antivirals, theophylline, amphetamines, PCP, MDMA, alcohol, cocaine as these present a significant risk
- Presence of the following agents, including but not limited to SSRIs, SNRIs, bupropion, some antipsychotics, chloroquine, some antibiotics, some chemotherapeutic agents as they present a RELATIVE risk and should be considered when making risk-benefit assessments
- Withdrawal from alcohol, benzodiazepines, barbiturates and chloral hydrate also present a strong relative hazard