BLUE CROSS BLUE SHIELD OF MICHIGAN

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

Effective November 1, 2020

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

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions: Transcranial magnetic stimulation must be administered by an approved U.S. Food & 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 drug screen is obtained if indicated by history, current clinical evaluation, or a high degree of clinical suspicion.
3. A confirmed diagnosis of severe major depressive disorder (single or recurrent episode) measured by evidence-based scales such as Beck Depression Inventory (score 30-63), Zung Self-Rating Depression Scale (>70), PHQ-9 (>20), Hamilton Depression Rating Scale (>20), or Montgomery-Asberg Depression Rating Scale (MADRS) (score >34).
4. At least one of the following:
   - Current depressive episode treatment:
     Medication treatment resistance, evidenced by:
     - Lack of a clinically significant response to 4 trials of psychopharmacologic agents:
       - Two single agent trials of antidepressants from at least two different agent classes
       - Two augmentation trials with different classes of augmenting agents utilizing either (or both) of the agents used in the single agent trials

     NOTE: Each agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy.
     NOTE: 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 (ie, < 50% reduction of symptoms or scale improvement).
   - 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: persistent electrolyte imbalance, pancytopenia, severe weight loss, poorly

controlled metabolic syndrome or diabetes.
Examples of psychological side effects: suicidal-homicidal thinking/attempts, impulse dyscontrol.
Note: A trial of less than one week of a medication is not be considered a qualifying trial to establish intolerance.

- The patient has a history of response to rTMS in a previous depressive episode (and it has been at least 3 months since the prior episode)
- The patient is a candidate for electroconvulsive therapy; further, electroconvulsive therapy would not be clinically superior to transcranial magnetic stimulation (eg, in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized).

5. The patient failed 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 (eg, Becks Depression Inventory, Zung Self-Rating Depression Scale, PHQ-9, Hamilton Depression Rating Scale, or MADRS).
6. Conditions that must be met during the entire rTMS treatment:
   - A board-certified psychiatrist, trained in this therapy, must deliver the treatment
   - An attendant trained in BCLS, the management of complications (such as seizures), and the use of the equipment must be present
   - Adequate resuscitation equipment must be available (eg, 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.

Exclusions:

- All other behavioral health, neuropsychiatric or medical conditions (eg, 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