Department of Vermont Health Access—Transcranial Magnetic Stimulation Clinical Practice Guidelines

Introduction

This document is to be used as a guide for recommendations and best practice suggestions in the use of Transcranial Magnetic Stimulation (TMS) as a treatment approach for treatment-resistant Major Depressive Disorder. These guidelines are based on the Local Coverage Determination (L33398) document from the Centers for Medicare and Medicaid Service (CMS, 2018), TMS industry consensus treatment recommendations (McClintock, et.al., 2018), and the State of Vermont Department of Vermont Health Access (DVHA) Medical Policy for TMS. DVHA pre-authorizes the use of TMS for adult members when the approved clinical and medical necessity criteria are met. The DVHA coverage guidelines document can be found here: https://dvha.vermont.gov/providers/clinical-practice-guidelines.

Considerations

Transcranial Magnetic Stimulation (TMS) has been shown to be an effective treatment option for individuals diagnosed with Major Depressive Disorder who have not responded to first-line treatment approaches such as medication, and who meet the established clinical criteria outlined in this document. The U.S Federal Drug Administration first approved TMS for use in treating refractory Major Depressive Disorder in 2008. Although TMS continues to be studied for use in the treatment of other conditions and may hold some promise, the use of TMS for conditions other than the *acute phase* of Major Depressive Disorder that meets the outlined criteria, is considered *investigational* and *not medically necessary* by DVHA.

Transcranial Magnetic Stimulation

Transcranial Magnetic Stimulation (TMS) or Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive procedure that uses a coil device that is placed against the scalp and delivers rapidly alternating magnetic fields to electrically stimulate nerve cells in the brain and alleviate symptoms of depression. This treatment has been shown to be an effective tool for treating patients who have not responded to multiple trials of antidepressant medications, have not improved with evidence-based psychotherapy, or have been unable to tolerate those medications. The U.S. Federal Drug Administration has approved several devices for use in this treatment approach and regulated their use (see Federal Code of Regulations Title 21 CFR.882.5802 and 21 CFR 882.5805).

TMS is performed in daily sessions over several weeks and then tapered in decreasing frequency for several more weeks. Patients have been shown to tolerate this procedure without lasting adverse effects. The most common reported side effects include headache and scalp pain which typically resolve quickly. Possible but rare risks include seizure (<1%), transient hypomania, or transient hearing changes. There are contraindications for this treatment in patients with a history of seizure or active psychosis, as well as some patients with implanted medical devices such as

cochlear implants, pacemakers, and others. Careful screening of the potential candidate for TMS greatly reduces these possible risks. (Rossi, et.al, 2009)

Screening

Members being considered for referral for TMS must be carefully screened before they can be pre-authorized to receive TMS. They must have been found to meet criteria for *acute* Major Depressive Episode, according to the Diagnostic and Statistical Manual for Mental Disorders-Fifth Edition, or DSM-5. Furthermore, they must meet the criteria for "treatment resistance" as defined in the DVHA policy on TMS.

Members must be screened for conditions that may present an elevated risk of adverse effects, or possible contraindications. These include a history of seizures, acute or chronic psychosis, or other implanted medical devices that may be impacted by the electromagnetic intervention used in TMS.

Major Depressive Disorder

Acute Major Depressive Disorder (MDD) is a relatively common and sometimes debilitating condition that is characterized by a persistent depressed mood, and decreased interest and enjoyment in typically pleasurable activities. Other symptoms can include decreased energy and ability to concentrate, sleep disruptions, appetite changes, excessive guilt feelings, hopelessness and thoughts of suicide. These symptoms can range from mild to severe and represent a single or recurrent episode of MDD. A licensed clinician makes a clinical assessment in keeping with accepted diagnostic criteria and may employ a variety of empirically validated depression rating scales to determine severity, such as the Montgomery-Asberg Depression Rating Scale (MADRS), the Hamilton Depression Rating Scale (HAM-D), or the Beck Depression Inventory (BDI). Such scales are typically used to measure a patient's response to TMS, post-treatment. (APA, 2019)

First-line treatment options for MDD include pharmacotherapy and psychotherapies. Research has long shown that a combination of medication and psychotherapy can be very successful in treating MDD. There are several effective evidenced-based psychotherapies for MDD, including Cognitive Behavioral Therapy (CBT), Interpersonal Psychotherapy (IPT) and more. There are several classes of antidepressant medications and combinations of medications that have proven to be effective in alleviating symptoms, but not all medications work well for all patients. Some patients cannot tolerate these medications due to other medical conditions or sensitivities. When the above treatments fail, acute MDD can be considered "treatment resistant", and alternative therapies, such as TMS, may be explored. (APA, 2019) (The Department of Vermont Health Access Medical Policy for TMS clearly defines "treatment resistance" in their eligibility criteria.)

Qualified Providers

Providers of TMS services must be Board-certified psychiatrists who have training experience administering TMS Therapy. While they may employ trained technicians that assist them

delivering the treatment, the psychiatrist must be present in the area and immediately available. Currently there is no Vermont State licensure or certification for TMS providers. Training on the use of the equipment under FDA approved clinical guidelines is provided by the manufacturers.

Devices

TMS devices must be approved by the US FDA. DVHA requires that providers follow the protocol and parameters specified in the manufacturer's user manual specific to the device in which they are using. Use of modifications only as supported by the published evidence base are allowed.

Frequency

TMS requires a significant time commitment for the patient. DVHA Coverage Guidelines specify that treatment sessions (usually 30-40 minutes long) occur 5 days a week for 7 weeks, or 30 sessions. Then, treatments are tapered in decreasing frequency for 3 weeks (3 sessions/week, then 2/week, then 1/week). Additional transcranial magnetic stimulation treatment may be approved with medical justification from provider if criteria is met (reference below). Due to the time commitment outlined, providers should consider patients availability, physical proximity to treatment, transportation etc. (e.g. caring for others, living independently). As stated earlier in this document, the use of TMS for conditions other than the *acute phase* of Major Depressive Disorder that meets the outlined criteria, is considered *investigational* and *not medically necessary* by DVHA.

Specific Eligibility Criteria for TMS under DVHA Policy[1]:

Coverage Guidelines (from the DVHA Medical Policy for TMS)

Transcranial magnetic stimulation (TMS) of the brain is a Vermont Medicaid covered benefit for all eligible beneficiaries who meet the following criteria:

1. Has a confirmed diagnosis of severe major depressive disorder (MDD) (single or recurrent episode);
AND
2. **One or more** of the following:

- Resistance to treatment as evidenced by a lack of a clinically significant response to 4 trials of psychopharmacologic agents in the current depressive episode from at least 2 different agent classes, at or above the minimum effective dose and duration, and trials of at least 2 evidence-based augmentation therapies; **or**
- Inability to tolerate psychopharmacologic agents as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; **or**
- History of good response to TMS in a previous depressive episode (evidenced by a greater than 50% improvement in a standard rating scale for depression symptoms); **or**
- Is currently receiving or is a candidate for and has declined electroconvulsive therapy (ECT) and TMS is considered a less invasive treatment option;

AND
3. 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 (*Note:* See Definition section for Depression Rating Scales);
AND
4. TMS is administered by a U.S. Food and Drug Administration (FDA) cleared device for the treatment of MDD according to specified stimulation parameters, 30 sessions over a 7-week period 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;
AND
5. **None** of the following conditions or contraindications to TMS are present:

- Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence); **or**
- Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; **or**
- 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 (ICD), pacemaker, vagus nerve stimulator (VNS), 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 https://dvha.vermont.gov/for-providers/clinical-guidelines-tms-final-12-22-15.pdf/view?searchterm=tmswith TMS).

References:

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McClintock, et. al. (2018) *Consensus Recommendations for the Clinical Application of Repetitive Transcranial Magnetic Stimulation (rTMS) in the Treatment of Depression.* J. Clin. Psychiatry, 79(1):16cs10905. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5846193/

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[1] https://dvha.vermont.gov/for-providers/clinical-guidelines-tms-final-12-22-15.pdf/view?searchterm=tms