Transcranial Magnetic Stimulation (TMS)

DESCRIPTION

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain at various frequencies or stimulus intensities. When the device delivers a rapid repetitive stimulation, it is referred to as repetitive transcranial magnetic stimulation (rTMS). Conventional rTMS is a repetition of individual pulses at a pre-set interval (train of pulses), whereas theta-burst rTMS is a repetition of short bursts of pulses at a pre-set interval (train of bursts). Stimulation can either be delivered unilaterally, over the left or right dorsolateral prefrontal cortex, or bilaterally over both cortices. Bilateral stimulation may be done sequentially or simultaneously.

Repetitive transcranial magnetic stimulation has been evaluated for treatment-resistant major depression and is proposed to relieve symptoms by stimulating nerve cells in the brain believed to be associated with mood regulation. A treatment course is usually 36 treatment sessions, beginning with one session daily five times per week for six weeks and tapering to three sessions the next week, two sessions the next week, and then one session the following week. The treatment course may be repeated after a 3 month cessation period if needed. Clinical trials show that about 1/3 of individuals treated will experience a return of symptoms.

TMS devices (repetitive and single-pulse) are also being evaluated for other psychiatric/neurologic disorders (e.g., alcohol dependence, Alzheimer disease, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder, epilepsy, migraine).

POLICY

- Repetitive transcranial magnetic stimulation (rTMS) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Transcranial magnetic stimulation (TMS) for any other indication, including but not limited to migraine headaches and maintenance therapy, is considered ***investigational***.

MEDICAL APPROPRIATENESS

- Repetitive transcranial magnetic stimulation (rTMS) is considered **medically appropriate** if **ALL** of the following have been met:

    - Age 18 years or older
    - Confirmed diagnosis of severe Major Depressive Disorder (initial or recurrent episode) documented by a standardized-rating scale that reliably measures depressive symptoms (e.g., Hamilton Rating Scale for Depression, Beck Depression Inventory-II, or Clinically Useful Depression Outcome Scale).
    - Failure of a trial of psychotherapy
    - Documentation of **ANY ONE** of the following:
        - Failure of four (4) trials of psychopharmacologic agents for depression, including two (2) different agent classes and at least one of the treatment trials must have been administered as an adequate course of mono- or poly- drug therapy
        - Inability to tolerate a therapeutic dose of medications as evidenced by four (4) trials of psychopharmacologic agents with documented side effects
        - History of response to repetitive TMS in a previous depressive episode
        - Individual is a candidate for electroconvulsive therapy (ECT), and ECT would not be clinically superior to repetitive TMS

- Absence of **ALL** of the following:
  - Pregnancy
  - Ongoing substance abuse
  - Presence of acute or chronic psychotic symptoms/disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode
  - Neurologic conditions including but not limited to: epilepsy, history of seizure disorder with increased risk of future seizures, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, primary or secondary tumors in the central nervous system (CNS)
  - Presence of implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil (examples include, but are not limited to, cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents, bullet fragments)

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For conditions other than treatment-resistant major depression, the evidence is insufficient to determine if treatment with repetitive TMS leads to improved outcomes. Currently, FDA approved devices are indicated for adult use only (e.g. NeuroStar®, Brainsway™ H-Coil Deep TMS, Rapid Therapy System, Mag Vita TMS Therapy® system, Mag Vita TMS Therapy System with Theta Burst Stimulation, Neurosoft TMS).

SOURCES

BlueCross BlueShield Association. Evidence Positioning System (11:2019). *Transcranial magnetic stimulation as a treatment of depression and other psychiatric/neurologic disorders* (2.01.50). Retrieved May 1, 2020 from https://www.evidencepositioningsystem.com/. (50 articles and/or guidelines reviewed)

Carmi, L., Tendler, A., Bystritshy, A., Hollander, E., Blumberger, D.M., Daskalakis, J., et al. (2019). Efficacy and safety of deep transcranial magnetic stimulation for obsessive-compulsive disorder: A prospective multicenter randomized double-blind placebo-controlled trial. *The American Journal of Psychiatry,* 176 (11), 931-938. (Level 1 evidence)

CMS.gov: Centers for Medicare & Medicaid Services. Palmetto, GBA. (2020, January). Local Coverage Determination (LCD): *Repetitive transcranial magnetic stimulation (rTMS) in adults with treatment resistant major depressive disorder* (LCD: ID L34869). Retrieved May 1, 2020 from https://www.cms.gov.

Croarkin, P. Nakonezny, P., Wall, C. Murphy, L. Sampson, S. Frye, M., et al. (2015). Transcranial magnetic stimulation potentiates glutamatergic neurotransmission in depressed adolescents. *Psychiatry Research: Neuroimaging*, 247, 25-33. (Level 3 evidence)

Janicak, P. and Dokucu, M. (2015). Transcranial magnetic stimulation for the treatment of major depression. *Neuropsychiatric Disease and Treatment,* 11, 1549–1560. (Level 2 evidence)

Kelly, M., Oliveira-Maia, A., Bernstein, M., Stern, A., Press, D., Pascual-Leone, A., et al. (2017). Initial response to transcranial magnetic stimulation treatment for depression predicts subsequent response. *Journal of Neuropsychiatry and Clinical Neuroscience*, 29, 179–182. (Level 4 evidence)

Lan, L., Zhang, X., Li, X., Rong, X., & Peng, Y. (2017). The efficacy of transcranial magnetic stimulation on migraine: a meta-analysis of randomized controlled trials. *The Journal of Headache and Pain,* 18, 86. (Level 2 evidence)

Mostofavi, S-A., Khaleghi, A., & Mohammadi, M.R. (2020). Noninvasive brain stimulation in alcohol craving: A systematic review and meta-analysis. *Progress in Neuro-psychopharmacology and Biological Psychiatry,* doi: 10.1016/j.pnpbp.2020.109938. Abstract retrieved May 1, 2020 from PubMed database.

National Institute for Health and Clinical Excellence (NICE). (2015, December). *Repetitive transcranial magnetic stimulation for depression.* Retrieved May 1, 2020 from http://www.nice.org.uk.

National Institute for Health and Clinical Excellence (NICE). (2014, January). *Transcranial magnetic stimulation for treating and preventing migraine.* Retrieved March 20, 2015 from http://www.nice.org.uk.

Rapinesi, C., Bersani, F., Kotzalidis, G., Imperatori, C., Casale, A., DiPietro, S., et al. (2015). Maintenance deep transcranial magnetic stimulation sessions are associated with reduced depressive relapses in patients with unipolar or bipolar depression. *Frontiers in Neuroscience,* Vol 6, Article 16. (Level 4 evidence)

Sahu, A.K., Sinha, V.K., & Goyal, N. (2019). Effect of adjunctive intermittent theta-burst repetitive transcranial magnetic stimulation as a prophylactic treatment in migraine patients: a double-blind sham-controlled study. *Indian Journal of Psychiatry,* 61 (2), 139-145. (Level 2 evidence)

U. S. Food and Drug Administration. (2008, December). Center for Devices and Radiological Health. *510(k) Premarket Notification Database. K083538 (NeuroStar®).* Retrieved September 12, 2014 from http://www.accessdata.fda.gov.

Winifred S. Hayes, Inc. Medical Technology Directory. (2019, March; last update search March 2020). *Transcranial magnetic stimulation for the treatment of obsessive-compulsive disorder.* Retrieved May 1, 2020 from www.Hayesinc.com/subscribers. (56 articles and/or guidelines reviewed)

Winifred S. Hayes, Inc. Medical Technology Directory. (2016, November; last update search March 2020). *High-frequency left repetitive transcranial magnetic stimulation for treatment-resistant major depressive disorder.* Retrieved May 1, 2020 from www.Hayesinc.com/subscribers. (78 articles and/or guidelines reviewed)

Winifred S. Hayes, Inc. Medical Technology Directory. (2016, December; last updated March 2020).*Comparative effectiveness review of high-frequency left repetitive transcranial magnetic stimulation versus other*

Approved Revision: Do Not Implement Until 4/2/21

neurostimulation approaches to treatment-resistant depression. Retrieved May 1, 2020 from www.Hayesinc.com/subscribers. (66 articles and/or guidelines reviewed)

EFFECTIVE DATE 4/2/2021

ID_BT