HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Repetitive Transcranial Magnetic Stimulation (rTMS)
Policy Number:	MP-089-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	04/01/2019; 04/15/2018
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the behavioral health benefits of the Company's Medicaid products for medically necessary repetitive transcranial magnetic stimulation.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Repetitive Transcranial Magnetic Stimulation (rTMS) – A noninvasive treatment using pulsed magnetic fields to induce a localized region of the cerebral cortex. Repetitive TMS has been investigated as treatment for pharmacoresistant depression.

Depressive Symptoms Rating Scales – Standardized self-reported depression measurement instruments used for accurate evaluations of patient's depression status. These tools include but are not limited to:

- Geriatric Depression Scale (GDS)
- Personal Health Questionnaire (PHQ-9)
- Montgomery Asberg Depression Rating Scale (MADRS)
- Inventory for Depression Symptomatology Systems Review (IDS-SR)
- Beck Depression Scale (BDI)
- Hamilton Rating Scale for Depression (HAM-D)

Direct Supervision – Services and supplies must be furnished by the physician or by auxiliary personnel under the physician's direct supervision. When services are performed in the office setting, the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.

Qualified Physician – An MD or DO that must possess evidence of knowledge, training, and expertise to perform rTMS services.

Electroconvulsive Therapy – This is a procedure where a brief application of electric stimulus is used to produce a generalized seizure.

PROCEDURES

The following medical necessity criteria must be met:

1. Initial rTMS therapy
    A. The patient has a confirmed diagnosis of severe major depressive disorder, single or recurrent episode; AND
    B. The patient has a current baseline depression measurement score that has been documented indicating severe depression using an evidence-based validated rating scale (e.g., MADRS, BDI, HAM-D); AND
    C. The patient is 18 years of age or older; AND
    D. The patient must have failed four trials of psychopharmacologic agents, to include 2 different agent classes and 2 augmentation trials in the current depressive event; OR
    E. The patient's inability to tolerate therapeutic doses must be demonstrated by 4 trials of psychopharmacologic agents with distinct side effects; OR
    F. The current treatment episode must demonstrate that an adequate course of mono- or poly-drug therapy is provided under the supervision of a licensed psychiatrist. According to the APA practice guidelines for Major Depressive Disorder, adequate treatment with an antidepressant medication for at least 4 to 8 weeks is necessary before concluding that a patient is not responsive to a particular medication. For those patients who have shown a partial response, extending the anti-depressant medication trial for an additional 2 to 4 weeks may allow up to one-third of patients to respond more fully. Titration to full therapeutic doses may vary depending upon the development of side effects, the patient's age, and the presence of comorbidities.
    G. The patient has not responded to treatment with evidence-based psychotherapy, such as a formal trial of Cognitive Behavioral Therapy and/or Interpersonal Therapy; AND
    H. The patient is currently receiving or is a candidate for electroconvulsive therapy, and rTMS would be considered a less invasive equally effective treatment option; OR

I. The treatment must be performed with a device that has been specifically approved to deliver rTMS; AND
J. The treatment must be ordered by a psychiatrist (MD or DO) who has examined the patient and reviewed the medical record. AND
K. The patient must have been under the direct care of a psychiatrist for the entirety of their current depressive event and/or the past 90 days.
L. The therapy must be administered/ furnished by an adequately trained physician (MD or DO) or under the direct supervision of this physician;
M. The facility must have a CPR-trained attendant during the therapy; AND
N. The facility must have adequate resuscitation equipment (e.g., suction and oxygen); AND
O. The facility must be aware of the emergency services response time, which should be available within five minutes; AND
P. A treatment course is not to exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3 week taper. Each treatment session consists of rTMS to the left prefrontal dorso-lateral cortex area at around 120% motor threshold (10Hz, 4-second train duration, 26 second inter-train interval, between 3000 and 5000 pulses per session), using a figure-eight solid core coil. Treatment beyond the 30 sessions and 6 tapering sessions must be reviewed for medical necessity.
Q. The patient's medical record must contain documentation of the patient's clinical progress during rTMS. Treatment response is usually defined as a least a 50% drop from the baseline depression scores.

2. Repeat rTMS therapy

Repeat rTMS therapy may be considered for patients who met the guidelines for initial treatment and subsequently relapsed with depressive symptoms when:

A. The patient has a history of a positive response to rTMS in a previous depressive episode, with improvement of more than 50% in standard rating measurements for depressive symptoms; OR
B. The patient suffered a relapse after remission; OR
C. If the patient meets the relapse criteria, up to 30 visits for the acute phase of treatment is covered with an additional 6 tapering visits.

3. Contraindications

A. The patient has been diagnosed with schizophrenia, schizophreniform disorder, or schizoaffective disorder
B. The patient has one of the following neurologic disorders: epilepsy, Parkinson's disease, multiple sclerosis, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, primary or secondary tumors in the central nervous system, or any other degenerative neurologic conditions.
C. The patient has active or inactive implants, including deep brain stimulators, cochlear implants, vagus nerve stimulators, implanted cardioverter defibrillator, pacemaker or metal aneurysm clips or coils, staples or stents.
D. Pregnancy or nursing
E. The patient who is acutely suicidal
F. Active current substance use

4. When repetitive transcranial magnetic stimulation services are not covered

A. rTMS is not medically necessary for all other psychiatric disorders or behavioral diagnoses not described in this policy;
B. Maintenance rTMS to prevent recurrence or relapse of major depressive disorder is not covered and considered not medically necessary;
C. Treatment with rTMS in patients who are non-compliant with prior therapies;
D. Failure of the provider to monitor and document the patient's response will result in a medical necessity denial of further care.
E. Patient-administered TMS or TMS administered outside a clinical office is not covered because there is lack of clinical evidence to support its use.

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

6. Place of Service
   The place of service for rTMS is the outpatient setting.

GOVERNING BODIES APPROVAL

The NeuroStar TMS Therapy system was approved by the FDA in 2008. The use of the system is approved for use in adults with major depressive disorder who have failed to achieve satisfactory results from one antidepressant trial at or above the minimally effective dose and duration. The therapy must be prescribed by a licensed psychiatrist.

In 2013, the Cerena™ TMS device (Eneura Therapeutics) received De Novo marketing clearance for the acute treatment of pain associated with migraine headache with aura. Warnings, precautions, and contraindications include the following:

- The device is only intended for use by patients experiencing the onset of pain associated with a migraine headache with aura.
- The device should not be used on headaches due to underlying pathology or trauma.
- The device should not be used for medication overuse headaches.
- Safety and effectiveness have not been established in pregnant women, children under the age of 18, and adults over the age of 65.

A number of devices for CES have received marketing clearance through the FDA 510(k) process. The Alpha-Stim® CES device (Electromedical Products International) received marketing clearance in 1992 for the treatment of anxiety, insomnia, and depression. The Brainsway Deep TMS System was cleared by the FDA in January 2013. The Rapid2 Therapy System was FDA-approved in May 2015, and the MagVita TMS Therapy System was approved in July 2015.

Additional information is available at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm

CMS
There is no National Coverage Determination regarding rTMS. There are several local coverage determinations all of which consider the service to be medically necessary when clinical guidelines are met.

There are multiple Local Coverage Determinations (LCDS) outlining the medical necessity criteria of rTMS therapy.

CODING REQUIREMENTS

Procedure Codes

CPT Codes	Description
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with deliver and management (diagnostic)

***Note**: One treatment planning service (90867) is allowed per course of treatment.*

Diagnosis Codes

ICD-10 Codes	Description
F32.2	Major depressive disorder, single episode, severe without psychotic features
F33.2	Major depressive disorder, recurrent, severe without psychotic features

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

It is estimated that nearly 14 million Americans will have experienced at least one episode of major depressive disorder (MDD). This condition is a common and debilitating disease that has been found to complicate the management and worsening of severity of several chronic conditions (Cassano, 2002). Of those affected, 20% to 40% are resistant to pharmacological antidepressant treatments, while another third show poor response (Fava, 2003). Several meta-analyses over the last several years have concluded that rTMS is an effective approach in the management of patients with treatment-resistant depression (Berlim et al., 2013, George et al., 2010).

The procedure for rTMS requires the placement of a small wire coil on the scalp which conducts an electric current. The current creates a magnetic field through the head. This current is thought to stimulate nerve cells in the region of the brain involved in mood regulation and depression. The procedure is performed in an office setting and does not require anesthesia. Sessions are usually 40 minutes in duration and administered on a daily basis for 2 to 6 weeks. The estimated cost of one series of rTMS is $10,000 to $15,000 compared to a treatment with ECT priced at $5,000.

In a September 2011 AHRQ report, "Nonpharmacologic Interventions for Treatment-Resistant Depression in Adults. Comparative Effectiveness Review," it was noted that rTMS was of benefit to patients relative to control groups receiving a sham procedure for all three outcomes (severity of depressive symptoms, response rate, remission rate), with high strength of evidence for severity of depressive symptoms and response rate, and moderate strength of evidence for remission rate. The report cited, relative to sham control, rTMS averaged a decrease in depressive severity measured by the Hamilton Rating Scale for Depression (HAM-D) of more than 5 points (a 3-point difference is considered clinically meaningful), a response rate three times greater, and a remission rates six times greater.

Gaynes, et al. (2014) published a systematic review and meta-analysis of 18 good- to fair-quality studies. The definition of treatment resistant depression (TRD) used by the authors was two or more prior antidepressant failures following adequate dose and duration (at least four weeks). Studies with up to 20% of patients with bipolar disorder were also included. It was found that compared to sham therapy, TMS is beneficial in producing a greater decrease in depression severity and averaging a clinically meaningful decrease on the Hamilton Depression Rating Scale. The average remission rates were 30% and five times more likely to achieve remission with treatment compared to sham. The authors indicated that no information about maintenance therapy was found following completion of TMS and that longer trials or follow-up periods would be helpful to determine whether treatment responses are maintained.

In December 2015, the National Institute for Health and Care Excellence (NICE), published revised guidelines for rTMS for depression. The guidelines state that rTMS shows no safety concerns and that the short efficacy evidence is adequate, however, the clinical response is variable. The research showed consistent positive outcomes, but there were difficulties in assessing the effect size from the available clinical trials.

The U.S. Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI) prepared an evidence brief on factors that optimize therapy with rTMS for treatment-resistant depression (2014). Patients who have not responded to multiple antidepressants (Ads) should be offered ECT with or without psychotherapy, and rTMS should be available to TRD patients. The guidelines recommend against the use of vagus nerve stimulation (VNS) and deep brain stimulation (DBS).

The American Psychiatric Association (APA) states that ECT is considered to be the most effective therapy for patients who have not responded to psychotherapy and/or adequately prescribed AD medications. Other factors that the APA says may increase the need for ECT are functional impairment, numerous medical trials, psychotic or catatonic features, urgent need for response (as when patients are suicidal or refusing food), and patient preference for ECT or a previous positive response to ECT. Light therapy is also presented as an option. The APA guidelines also state that rTMS may be considered, although there is less evidence to support this modality compared with ECT. Vagus nerve stimulation (VNS) may be considered an option for patients who have not responded to ≥ 4 trials of AD treatments, including ECT.

On February 6, 2018, Hayes performed an annual review on TMS to enhance pharmacotherapy for depression. There was no change in the conclusion of the original review from 2014 in which Hayes rated TMS treatment in this situation and a 'C' rating was maintained. It was stated that there is evidence of strong placebo effect with TMS, therefore, the benefit of TMS over sham stimulation may be too small to consider clinically meaningful.

On November 2, 2018 Hayes reported on an annual review on high-frequency left repetitive transcranial magnetic stimulation (HFL-rTMS) for treatment-resistant major depressive disorder. There was no change

in the November 2016 'C' rating for use of this therapy as monotherapy or an add-on therapy for moderate to severe major depressive disorder in adult patients with a prior failure of ≥1 antidepressant trials. In addition, a 'D2' rating was assigned for the use of HFL-rTMS as a maintenance therapy to prevent relapse in patients who had a major depressive episode that remitted with treatment, due to paucity of evidence.

Hayes (2017) updated a review on the effectiveness of left repetitive TMS versus other neurostimulation approaches to treatment-resistant depression. A total of 10 randomized controlled trials were analyzed for the efficacy and safety of high-frequency rTMS with ECT or bilateral rTMS. This was accomplished by evaluating the changes in depression symptom scores with changes in rates of response and remission. Overall, it was found that there is a low quality body of evidence suggesting that high frequency rTMS may offer comparable therapeutic benefit relative to ECT and bilateral rTMS for relief of treatment-resistant depression. There was insufficient evidence regarding the comparative effectiveness of high frequency rTMS relative to ECT alone. High frequency rTMS poses no significant risks over ECT and bilateral rTMS therapies from a safety perspective.

Hayes assigned a C rating for the use of high frequency left repetitive transcranial magnetic stimulation compared with electroconvulsive therapy in adult patients with treatment-resistant major depressive disorder. The use of high frequency rTMS compared with bilateral rTMS in adult patients with treatment-resistant major depressive disorder was also assigned a C rating. A rating of D2 was applied to the use of high frequency rTMS combined with ECT compared to ECT alone in adult patients with treatment-resistant major depressive disorder.

A	**Established benefit.** Published evidence shows conclusively that safety and impact on health outcomes are comparable to or better than standard treatment/testing. Long-term safety and impact on health outcomes have been established, and other important questions concerning application of the technology have been answered. Drugs, biologics, and devices with an A rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
B	**Some proven benefit.** Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
C	**Potential but unproven benefit.** Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.
D1	**No proven benefit and/or not safe.** Published evidence shows that the technology does not improve health outcomes or patient management for the reviewed application(s) or is unsafe.
D2	**Insufficient evidence.** There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

On February 9, 2018 a technology assessment on the definition of treatment-resistant depression in the Medicare population was published by the Agency for Healthcare research and Quality (AHRQ). The project was undertaken to review the current definitions of treatment-resistant depression (TRD), to assess how closely current TRD treatment studies fit the most common definition and to suggest how to improve TRD treatment research. The following was reported:

- TRD is commonly defined as failure of treatment to produce a response or remission for patients after two or more treatment attempts of adequate dose and duration, but no clear consensus exists about the definition;
- TRD definitions in treatment studies do not closely match the definition above (only 17% of the studies matched);
- To improve TRD treatment research, experts need to standardize the number of prior treatment failures and to specify the adequacy of both dose and duration. Also, there is a need to identify the core outcome measures to be used in research.

POLICY SOURCE(S)

American Psychiatric Association. Practice Guideline for the treatment of patients with major depressive disorder. 3rd edition. Accessed on February 6, 2018.

Gaynes BN, Lloyd SW, Lux L, et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: a systematic review and meta-analysis. J Clin Psychiatry. 2014; 75(5):477-489. Accessed on February 5, 2018.

National Institute for Health and Care Excellence (NICE). Repetitive transcranial magnetic stimulation for depression. 16 December 2015. Accessed on February 5, 2018.

Fava M. Diagnosis and definition of treatment-resistant depression. Biol Psychiatry. 2003; 53:649-659. Accessed on February 5, 2018.

Berlim MT, Van den Eynde F, Daskalakis ZJ. High-frequency repetitive transcranial magnetic stimulation accelerates and enhances the clinical response to antidepressants in major depression: a meta-analysis of randomized, double-blind, and sham-controlled trials. J Clin Psychiatry. 2013; 74: e 122-e129. Abstract accessed on February 5, 2018.

George MS, Lisanby SH, Avery D, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: a sham-controlled randomized trial. Arch Gen Psychiatry. 2010; 67: 507-516. Abstract accessed on February 5, 2018.

Neuronetics. NeuroStar Healthcare Professionals Page. 2017. Accessed on February 5, 2018.

U.S. Department of Veterans Affairs. Veterans Health Administration, Quality Enhancement Research Initiative. Evidence Brief: Factors that optimize therapy with repetitive transcranial magnetic stimulation for treatment-resistant depression. Supplemental Materials. September 2014. Accessed on February 5, 2018.

Centers for Medicare and Medicaid, Local Coverage Determination. Transcranial Magnetic Stimulation (TMS) (L34641). Wisconsin Physicians Service Insurance Corporation. Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia, Wyoming. Accessed on February 6, 2018.

Centers for Medicare and Medicaid Services, Local Coverage Determination. Transcranial Magnetic Stimulation (TMS) for the Treatment of Depression (L34998). Novitas Solutions, Inc. Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania. Accessed on February 6, 2018.

Centers for Medicare and Medicaid, Local Coverage Determination. Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L36469). CGS Administrators. Kentucky and Ohio. Accessed on February 6, 2018.

Hayes, Inc, Medical Technology Directory. Comparative effectiveness of high-frequency left repetitive transcranial magnetic stimulation versus other neurostimulation approaches to treatment-resistant depression. Annual review November 21 2017. Accessed on February 6, 2018.

Hayes, Inc. Medical Technology Directory. Transcranial magnetic stimulation (TMS) to enhance pharmacotherapy for depression. Annual review February 6. 2018. Accessed on February 18, 2019.

Hayes, Inc. High-frequency right repetitive transcranial stimulation for treatment-resistant major depressive disorder. Annual Review November 2, 2018. Accessed on February 18, 2019.

Agency for Healthcare Research and Quality (AHRQ). Technology Assessment, Definition of treatment-resistant depression in the Medicare population. Project ID: PSYT0816; February 9, 2018. Accessed on February 22, 2018.

Policy History

Date	Activity
02/05/2018	Initial policy developed
03/13/2018	QI/UM Committee approval
04/18/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
05/15/2018	Provider effective date
03/12/2019	Annual Review: Added 'or nursing' with the pregnancy condition, active current substance abuse and patients who are acutely suicidal under the Contraindications section; updated Summary of Literature and Reference sections; removed hyperlinks from listed references.
03/12/2019	QI/UM Committee
05/06/2019	Provider effective date