CLINICAL MEDICAL POLICY	
Policy Name:	Repetitive Transcranial Magnetic Stimulation
Policy Number:	MP-101-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2025; 08/01/2024; 08/01/2023; 09/01/2022; 08/20/2021; 08/10/2020; 11/18/2019
Effective Date:	12/01/2025; 09/01/2024; 09/01/2023; 10/01/2022; 09/20/2021; 09/07/2020; 11/18/2019
Next Annual Review:	07/2026
Revision Date:	07/16/2025; 07/17/2024; 07/19/2023; 07/20/2022; 07/21/2021; 07/15/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Policy History

Date	Activity
12/01/2025	Provider Effective date
07/16/2025	QI/UM Committee review
07/16/2025	Annual Review: No change to Experimental/Investigational determination. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2024	Provider Effective date
07/17/2024	QI/UM Committee review
07/17/2024	Annual Review: No change to E/I determination. Updated 'Reference Sources' and 'Summary of Literature' section.
09/01/2023	Provider Effective date
07/19/2023	QI/UM Committee review
07/19/2023	Annual Review: No changes to E/I determination. Updated 'Summary of Literature' and 'Reference Sources' sections.
10/01/2022	Provider Effective date
07/20/2022	QI/UM Committee review
07/20/2022	Annual Review: No changes to E/I determination. Added TAG determination information. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/20/2021	Provider Effective Date
07/21/2021	QI/UM Committee Review

07/21/2021	Annual Review: Updated Summary of Literature and Reference sections.
09/07/2020	Provider effective date
07/15/2020	QI/UM Committee Review
07/15/2020	Annual Review: No change in E/I coverage determination; removed all hyperlinks and updated Summary of Literature and Reference sections.
11/18/2019	Provider effective date
09/06/2019	PARP approval
08/21/2019	QI/UM Committee review
08/15/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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 Wholecare℠ does not provide coverage under the benefits of the Company's Medicaid products for repetitive transcranial magnetic stimulation in the treatment of depression. The therapy is considered experimental and investigation, therefore, not medically necessary.

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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

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 pharmaco-resistant 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

1. The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:
   - Option #1: Approved - Will be added to the Fee Schedule
   - Option #2: Approved as Medically Effective - Will require Program Exception
   - Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
   - Option #4: Denied - Experimental/Investigational

As of May 2011, the TAG workgroup assigned repetitive transcranial magnetic stimulation (rTMS) an Option # 4, specifically for CPT codes 90867and 90868.

2. rTMS in the treatment of depression is considered experimental and investigational. There is currently insufficient peer-reviewed medical literature to support coverage.

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

4. Place of Service
   The proper place of service for rTMS is in 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.

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).

Repetitive transcranial magnetic stimulation (rTMS) uses a magnet to activate the brain. First developed in 1985, rTMS has been studied as a treatment for depression, psychosis, anxiety, and other disorders. rTMS can be targeted to a specific site in the brain. Scientists believe that focusing on a specific site in the brain reduces the chance for side effects. In 2008, rTMS was approved by the FDA for use in patients with MDD who do not respond to at least one antidepressant medications and who might otherwise be considered for electroconvulsive therapy. A typical rTMS session lasts 30 to 60 minutes and does not require anesthesia. During the procedure:

- An electromagnetic coil is held against the forehead near an area of the brain that is thought to be involved in mood regulation.
- Then, short electromagnetic pulses are administered through the coil. The magnetic pulses easily pass through the skull, and causes small electrical currents that stimulate nerve cells in the targeted brain region (NIMH, 2016).

The National Institute for Health and Care Excellence (NICE) has published 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. 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) (QUERI, 2014).

A study examining the current state of neuromodulation therapies being used to treat depression, including rTMS, ECT and others has been published by the American Psychiatric Association (APA). The publication reveals that for many decades, psychiatric treatment has been primarily focused on the development of medications and the development of psychotherapies. A third type of approach gaining attention in recent years is based in the concept that psychiatric dysfunction results from abnormal communication within a network of brain regions that regulate mood, thought, and behavior. Technological advances in the past couple of decades have also led to development of noninvasive neuromodulation approaches. One of these neuromodulation approaches is rTMS. Much research is underway looking at potential improvement in rTMS devices and protocols for treatment of depression. The authors note that the three primary types of treatment — medication, psychotherapy and neuromodulation — are complimentary not mutually exclusive, and the combination of neuromodulation treatments with other modalities to improve outcomes is an area for future study (APA, 2021).

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.

AHRQ has published a summary of comparative findings on nonpharmacologic treatment of adult treatment-resistant depression. The report stated that there is large volume of evidence for ECT and rTMS, however, the direct comparative evidence about these treatment is quite limited. The conclusion is that research on nonpharmacologic interventions in a TRD population is in its infancy. Many clinical questions about efficacy and effectiveness remain unanswered. The summary 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.

Coding Requirements

Non-covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

CPT Code	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)

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract

Reference Sources

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