I. POLICY/Criteria

A. Coverage criteria (all of the following must be met):
   1. Patient is 18 years of age or older.
   2. Patient meets the definition of unipolar major depression as defined by the DSM-5 criteria.
   3. Patient demonstrates resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to 4 trials of such agents, in the current depressive episode, from at least 2 different agent classes.
   4. The current treatment episode must demonstrate an adequate course of mono- or poly-drug therapy provided under the supervision of a psychiatrist. APA practice guidelines for Major Depressive Disorder state adequate treatment with an antidepressant medication for at least 4 to 8 weeks is necessary before concluding that a patient is not responsive or only partially responsive to a particular medication. For patients who have shown a partial response, extending the anti-depressant medication trial (i.e., 2 – 4 weeks) may allow up to one-third of patients to respond more fully. Titration to full therapeutic doses may vary depending on the development of side effects, the patient’s age and the presence of co-morbid illness.
   5. Patient has been under the direct care of a psychiatrist for the entirety of their current depressive episode and/or the past 90 days. The TMS treatment itself must be under the direct supervision of a psychiatrist.
   6. Patient has moderate to severe depression as defined by use of one of the following validated, evidence-based depression monitoring tools: HAM-D, MADRS or QIDS, IDS-SR.
   7. If patient is a candidate for electro convulsive therapy, rTMS may be authorized as a less invasive treatment option.

B. Absolute contraindications
   1. Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence)
   2. Space occupying brain lesion
   3. Evidence of increased intracranial pressure
4. Presence of intracranial devices (e.g. CSF shunts, aneurysm clips, cochlear/otologic implants, deep brain stimulation leads)
5. Vagus nerve stimulator leads (with or without IPG)
6. Facial tattoos with metallic ink
7. Carotid or cerebral stents
8. Ferromagnetic ocular implants
9. Magnetically activated dental implants
10. Pellets, bullets or metallic fragments < 30 cm from coil

C. Relative Contraindications
1. Dementia and other degenerative neurologic conditions, e.g. Parkinson's Disease, multiple sclerosis;
2. Unstable medical conditions;
3. Chronic or acute psychotic disorder, e.g. schizophrenia, schizophreniform disorder, schizoaffective disorder
4. Serious co-morbid psychiatric conditions, e.g. psychotic depression, active substance abuse;
5. History of cerebrovascular accident
6. Implantable automatic defibrillator of cardiac pacemaker
7. History of significant head injury (loss of consciousness > 5 min and/or hospitalization)

D. Limitations and exclusions
1. Treatment for patients non-compliant with prior therapies is not covered
2. Failure to monitor and document patient response will result in denial of further coverage.
3. If the above coverage criteria are met, Priority Health will cover an initial six weeks of therapy, up to 30 visits and 6 taper treatments.
4. Maintenance therapy with TMS is not considered medically necessary because no clinical trials have been done to demonstrate the clinical benefit nor have clinical trials been done to document the optimal frequency or duration of maintenance therapy.
5. Repeat acute treatment for relapse of depressive symptoms is considered medically necessary if the patient responded to prior treatment, specifically ≥50% improvement in score by use of a validated, evidence-based depression monitoring tool, such as HAM-D, MADRS or QIDS. If the patient meets these criteria Priority Health will authorize an additional 30 visits for acute phase treatment followed by additional six visits for tapering therapy.

E. Provider requirements
The treating psychiatrist and facility must meet the following criteria:
1. The psychiatrist will be onsite and available for direct supervision during the procedure.
2. The psychiatrist and any other person performing the procedure will have successfully completed NeuroStar’s TMS Therapy System training or an equivalent training, and submit documentation of such training.

3. Psychiatrist, any other person performing the procedure and facility will comply with all operating instructions and guidelines contained in the then-current NeuroStar TMS Therapy System User Manual and supplements/updates thereto.

4. Provider uses one of the following validated, evidence-based depression monitoring tools: HAM-D, MADRS, IDS-SR or QIDS for monitoring treatment response and remission.

5. Provider submits an updated copy of the administered HAM – D, MADRS, IDS-SR or QIDS demonstrating moderate to severe depression during the current depressive episode with the initial authorization request.

6. Provider submits an updated copy of the administered HAM-D, MADRS, IDS-SR or QIDS upon completion of the treatment episode and 6 months post treatment episode (pending member is still under the care of the provider).

This policy is based on review and recommendations of Priority Health’s Technology Assessment Committee in December 2008 and Behavioral Health Committee in December 2009.

Note: Not covered by Medicaid, Healthy Michigan Plan, requests for services must be coordinated with CMH.

II. MEDICAL NECESSITY REVIEW

☒ Required  ☐ Not Required  ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

❖ HMO/EPO: This policy applies to insured HMO/EPO plans.
❖ POS: This policy applies to insured POS plans.
❖ PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
❖ ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
❖ INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
IV. DESCRIPTION

Repetitive transcranial magnetic stimulation (rTMS) is a noninvasive technique that is being investigated as a treatment for major depression. Brief pulses of magnetic energy are applied to the scalp via a large electromagnetic coil to generate low levels of electrical current in underlying brain tissue. The goal of TMS is to stimulate areas of the brain involved in mood regulation in order to lessen the duration or severity of depressive episodes.

More than 75 studies and 8 metaanalyses have been published evaluating the efficacy of TMS. General findings include: TMS therapeutically effective, but the magnitude of clinical effect in question; active TMS significantly superior to sham in short-term acute treatment of treatment resistant depression (TRD) with clinically significant results; treatment is well-tolerated, few dropouts due to adverse effects; response and remission rates are low, unknown if effect is sustained. Limitations include: short treatment durations (1-2 weeks) in published studies; and response and remission rates low compared to most medication studies of TRD. (Daskalakis, et.al. and Lam et. al.). The Lam, et. al. metaanalyses calculated the number needed to treat (NNT) as 6 for the defined response rate, 7 for the defined remission rate.

V. CODING INFORMATION

The procedure is covered by the Plan when the above criteria is met and is billed by the licensed psychiatrist with the following codes:

ICD-10 Codes that may apply:
F32.2 Major depressive disorder, single episode, severe without psychotic features
F32.3 Major depressive disorder, single episode, severe with psychotic features
F33.2 Major depressive disorder, recurrent severe without psychotic features
F33.3 Major depressive disorder, recurrent, severe with psychotic symptoms

CPT/HCPCS Codes:
Not covered for Priority Health Medicaid
Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management

Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session

Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

Revenue Codes:
0940 Other Therapeutic Services - General

VI. REFERENCES


FDA @ http://www.fda.gov/cdrh/pdf6/K061053.pdf (November 21, 2008)

Local Coverage Determination (LCD) for TRANSCRANIAL MAGNETIC Stimulation (L32038) @ http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32038&ContrId=64&ver=8&ContrVer=1&CoverageSelection=Both&ArticleType=All&PcicyType=Final&s=Michigan&Keyword=transcranial+magnetic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA& (Retrieved January 18, 2012 & December 11, 2015).


Hayes, Inc. Transcranial Magnetic Stimulation for Treatment Resistant Depression, March 2014 and update March 2015

AMA CPT Copyright Statement:
All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member’s plan in effect as of the date services are rendered. Priority Health’s medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health’s medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name “Priority Health” and the term “plan” mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.