Transcranial Magnetic Stimulation for Major Depressive Disorder Part A/B

FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L34522

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A/ B

LCD Title
Transcranial Magnetic Stimulation for Major Depressive Disorder

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physician examinations.

Title XVIII of the Social Security Act, section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.
Title XVIII of the Social Security Act, section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

**Primary Geographic Jurisdiction**

Florida
Puerto Rico/Virgin Islands

**Oversight Region**

Region I

**Original Determination Effective Date**

10/01/2014

**Original Determination Ending Date**

N/A

**Revision Effective Date**

N/A

**Revision Ending Date**

N/A

**Indications and Limitations of Coverage and/or Medical Necessity**

Transcranial magnetic stimulation (TMS) is a non-invasive, non-systemic treatment that uses Magnetic Resonance Imaging (MRI)-strength, pulsed, magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil is placed on the scalp that induces a focal current in the brain and temporary modulation of cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Depending on stimulation parameters, repetitive TMS to specific cortical regions can either decrease or increase the excitability of the targeted structures.

TMS offers a well-tolerated, non-pharmacologic alternative that does not require attendant anesthesia services and can be administered in an outpatient setting for patients with DSM-IV defined Major Depressive Disorder who have failed to benefit from initial treatment of their depression. When effective, TMS may prevent the need to utilize more complex pharmaceutical augmentation strategies (e.g., atypical antipsychotic medication), electroconvulsive therapy (ECT), and inpatient hospitalization at later stages of the illness.

When used as an antidepressant therapy, TMS produces a clinical benefit without the systemic side effects typical with oral medications, has no adverse effects on cognition, and unlike electroconvulsant therapy does not induce amnesia or seizures. TMS may be covered when prescribed and supervised by a licensed psychiatrist or neurologist who is knowledgeable in the use of transcranial magnetic stimulations. The Centers for Medicare & Medicaid Services (CMS) Online Manual System, Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.1 outlines that “reasonable and necessary” services are “ordered and/or furnished by qualified personnel. Services will be considered medically reasonable and necessary only if performed by appropriately trained providers.”
An appropriately trained provider (Psychiatrist or Neurologist) performing and supervising TMS is a professional provider who has:

1. Completed a fellowship or residency in psychiatry or neurology.
2. Completed and demonstrated proficiency in TMS device at a University based training course or a company sponsored training course.
3. Provides personal supervision for the initial individual motor threshold determinations, treatment parameter definition and TMS treatment course planning and documentation supportive of the level of supervision.
4. Subsequent delivery and management of TMS sessions may be performed by a psychiatrist or neurologist and/or an appropriately trained technician under the direct supervision of the professional provider (psychiatrist or neurologist) ensuring the patient has someone in attendance at all time during the TMS session.
5. During subsequent delivery and management of TMS sessions the providing psychiatrist or neurologist must meet face to face with the patient when there is a change in the individuals’ mental status and/or other significant change in clinical status.

TECHNICIANS PERFORMING TMS

A technician must be directly supervised by a professional provider (psychiatrist or neurologist) who has knowledge and demonstrated expertise in TMS and must meet the following criteria when performing TMS:

- The technician who is performing TMS must be trained in basic life support.
- The technician who is performing TMS must have knowledge and demonstrated expertise in TMS.
- The technician must be in continuous attendance in the procedural room.
- The technician must have the competencies to monitor patients for seizures and for providing seizure management.

Indications of Coverage:

Left prefrontal Transcranial magnetic stimulation (TMS) of the brain is considered medically necessary for use in an adult who meets 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:
   - The patient has demonstrated resistance to treatment with psychopharmacologic agents as evidenced by a lack of clinically significant response to four trials of such agents, in the current depressive episode, from at least two different agent classes. (At least one of the treatment trials must have been administered as an adequate course of mono- or poly-drug therapy; antidepressants involving standard therapeutic doses of at least 4 weeks duration); or
   - Inability to tolerate psychopharmacologic agents as evidenced by four trials of psychopharmacologic agents with distinct side effects; or
   - History of 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
   - 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.
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Coverage Limitations:

The following cautionary uses have not been proven in clinical studies and on post payment medical review of the records may be determined to be not medically necessary and denied.

- Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence);
- Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode;
- Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system (CNS);
- 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 with TMS).

Type of Bill Code

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

013x Hospital Outpatient
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
073x Clinic - Freestanding
077x Clinic - Federally Qualified Health Center (FQHC)
085x Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0900 Behavioral Health Treatment/Services-General Classification

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90867</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial including cortical mapping, motor threshold determination, delivery and management</td>
</tr>
<tr>
<td>90868</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session</td>
</tr>
<tr>
<td>90869</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management</td>
</tr>
</tbody>
</table>
ICD-10 Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F32.2</td>
<td>Major depressive disorder, single episode, severe without psychotic features</td>
</tr>
<tr>
<td>F33.2</td>
<td>Major depressive disorder, recurrent severe without psychotic features</td>
</tr>
</tbody>
</table>

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

All documentation must be maintained in the patient’s medical record and be made available upon request. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service). The record must include the physician responsible for and providing the care of the patient. The submitted medical record should support the covered indications as detailed above, as well as the use of the selected diagnosis code(s). The submitted CPT/HCPCS code should describe the service performed. The medical record documentation must support that the attending physician has met with the patient face to face for the initial assessment and for subsequent delivery and management, when there is a change in the individuals; mental status and/or other significant change in clinical status The attending physician must use evidence-based validated depression monitoring scales such as the Geriatric Depression Scale (GDS), the Personal Health Questionnaire Depression Scale (PHQ-9), the Beck Depression Scale (BDI) Hamilton Rating Scale for Depression (HAM-D), the Montgomery Asberg Depression Rating Scale (MADRS), the Quick Inventory of Depressive Symptomatology (QIDS) or the Inventory for Depressive Symptomatology Systems Review (IDS-SR) to monitor treatment response and the achievement of remission of symptoms.

The medical record must clearly show that the criteria listed under the “Indications and Limitations of Coverage and/or Medical Necessity” sections have been met, as well as, the appropriate diagnosis and response to treatment. When TMS is provided for cautionary uses the pre-procedure documentation should address these debated indications. The documented clinical judgment of the treating physician for cautionary indications is always a consideration in the determination of medical necessity, if clearly addressed in the pre-procedure record and if consistent with the episode of care for the patient as documented in the patient record.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

TMS is reasonable and necessary for up to 30 visits over a 7-week period followed by 6 tapered treatments.

Repeat acute treatment for relapse of depressive symptoms is considered medically necessary if the patient responded to prior treatments, specifically > 50% improvement in a standard rating scale for depressive symptoms (e.g., (GDS), PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score).
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If patient meets the relapse criteria, up to 30 visits for the acute phase treatment followed by an additional 6 visits for tapering is considered reasonable and necessary.

The use of TMS as a maintenance therapy is not supported by controlled clinical trial at this time and is therefore, considered not reasonable and necessary.

It is reasonable and necessary to report the treatment planning service (90867) once per course of treatment.

Sources of Information and Basis for Decision

AHRQ: Nonpharmacologic Interventions for Treatment-Resistant Depression in adults: A comparative effectiveness review-04/25/2012


Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments (2011)


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;60(5)5007-516


Other Medicare Contractors


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Start Date of Comment Period
N/A

End Date of Comment Period
N/A

Start Date of Notice Period
04/01/2014

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents
N/A

LCD Attachments
N/A

Document formatted: 08/16/2013 (KS/et) 10/14/2013 (DA/et) 05/19/2014 (DA/et)