



MEDICARE COVERAGE SUMMARY: TRANSCRANIAL MAGNETIC STIMULATION

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Relevant Services

- Transcranial Magnetic Stimulation

Related Behavioral Health Policies & Guidelines

- Optum Transcranial Magnetic Stimulation Behavioral Clinical Policy

INSTRUCTIONS FOR USE

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum®¹. When deciding coverage, the member’s specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member’s benefits prior to using this guideline. Other clinical criteria may apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in *Clinical Criteria*.

This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

TRANSCRANIAL MAGNETIC STIMULATION

Transcranial magnetic stimulation (TMS) is a noninvasive method of brain stimulation. The technique involves placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire which produces a magnetic field that passes unimpeded through the brain. Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), repetitive TMS (rTMS) to specific cortical regions can either increase or decrease the excitability of the affected brain structures. The procedure is usually carried out in an outpatient setting and does not require anesthesia or analgesia (CMS L33398, L34641, L34522, L34998, L36469, L34269).

¹ Optum is a brand used by United Behavioral Health and its affiliates.

[Transcranial magnetic stimulation \(TMS\) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal current in the brain that temporarily modulates cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions. Repetitive TMS \(rTMS\) has been investigated as treatment for pharmacoresistant depression \(CMS L34869\).](#)

When used as an antidepressant therapy, TMS produces a clinical benefit without the systemic side effects attendant with standard oral medications. TMS does not have adverse effects on cognition. Unlike electroconvulsive therapy (ECT), rTMS does not induce amnesia or seizures (CMS L33398, L34641, L34522, [L34869](#), L34998, L36469, L34269).

APPLICABLE STATES

(CMS L33398)

- Connecticut
- Illinois
- Maine
- Massachusetts
- Minnesota
- New Hampshire
- New York
- Rhode Island
- Vermont
- Wisconsin

(CMS L34641)

- Alaska
- Alabama
- Arkansas
- Arizona
- Connecticut
- Florida
- Georgia
- Iowa
- Idaho
- Utah
- Virginia
- Virgin Islands
- Vermont
- Washington
- Wisconsin
- West Virginia
- Wyoming

[\(CMS L34869\)](#)

- [Alabama](#)
- [Georgia](#)
- [North Carolina](#)

- [South Carolina](#)
- [Tennessee](#)
- [Virginia](#)
- [West Virginia](#)

(CMS L34998)

- Arkansas
- Colorado
- Delaware
- District of Columbia
- Louisiana
- Maryland
- Mississippi
- New Jersey
- New Mexico
- Oklahoma
- Pennsylvania
- Texas

(CMS L36469)

- Kentucky
- Ohio

(CMS L34269)

- Alabama
- Georgia
- Tennessee

(CMS L34522)

- Florida
- Puerto Rico
- Virgin Islands

If services are delivered in another state, please apply the Optum Transcranial Magnetic Stimulation Behavioral Clinical Policy.

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

Indications (CMS L33398, L34641, L34522, L34269, L34998, L36469)

- TMS may be covered if prescribed and administered by a licensed physician who is knowledgeable in the use of Transcranial Magnetic Stimulation. TMS may be indicated for patients with DSM defined Major Depressive Disorder who have failed to benefit from initial treatment of their depression.
- Initial treatment left Prefrontal TMS of the brain is considered medically necessary for use in an adult who has a confirmed diagnosis of severe Major Depressive Disorder (MDD) single or recurrent episode; and
- 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 at an adequate course of mono- or poly-drug therapy; or
- Inability to tolerate psychopharmacologic agents as evidenced by trials of four such agents, from at least two different agent classes, with distinct side effects; or

- History of good response to TMS in a previous episode; or
- If patient is currently receiving electro-convulsive therapy, TMS may be considered reasonable and necessary as 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; and additional LCD specific indications below.
- The order for treatment (or retreatment) is written by a psychiatrist (MD or DO) who has examined the patient, and reviewed the record. The physician will have experience in administering TMS therapy. The treatment shall be given under direct supervision of this physician (physician present in the area, but does not necessarily personally provide the treatment).

Indications (CMS L33398)

- The TMS treatment is delivered by a device that is FDA-approved or –cleared for the treatment of MDD in a safe and effective manner. TMS treatment should generally follow the protocol and parameters specified in the manufacturer’s user manual, with modifications only as supported by the published scientific evidence base.

Indications (CMS L34869)

- TMS may be covered if prescribed and administered by a licensed physician who is knowledgeable in the use of repetitive transcranial magnetic stimulation. Outpatient rTMS may be indicated for patients with DSM-V defined Major Depressive Disorder who have failed to benefit from initial treatment of their depression.
- Treatment must be provided by use of a device approved by the FDA for purpose of supplying Transcranial Magnetic Stimulation.
- It is expected that the services would be performed as indicated by current medical literature and standards of practice. Services performed in excess of established parameters may be subject to review for medical necessity.
- TMS is reasonable and necessary up to 20 visits over a 4 week period followed by five visits for tapering for those in remission; for those who show at least a 25% improvement by means of the standard tests for depression, the therapy may be continued for an additional 2 weeks (an additional 10 visits) with an additional 6 visits for tapering.
- Initial Treatment
 - Left prefrontal rTMS of the brain is considered medically necessary for use in an adult who has a confirmed diagnosis of severe Major Depressive Disorder (MDD) single or recurrent episode, and one or more of the following are present:
 - Resistance to treatment with psychopharmacological agents as evidenced by a lack of a clinically significant response to four trials of psychopharmacologic agents in the current depressive episode from at least two different agent classes. At least one of the treatment trials must have been administered at an adequate course of mono- or poly-drug therapy; or
 - Inability to tolerate psychopharmacologic agents as evidenced by four trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects; or
 - History of response to rTMS in a previous depressive episode; or
 - If patient is currently receiving electro-convulsive therapy, rTMS may be considered reasonable and necessary as a less invasive treatment options.
 - 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.
 - The order for treatment (or retreatment) is written by a psychiatrist (MD or DO) who has examined the patient and reviewed the record. The physician will have experience in administering TMS therapy. The treatment shall be given under direct supervision of this physician (physician present in the area, but does not personally provide the treatment).

- Retreatment

- Retreatment may be considered for patients who met the guideline for initial treatment and subsequently developed relapse of depressive symptoms in the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms (e.g., Geriatric Depression Scale (GDS), Patient Health Questionnaire Depression Scale (PHQ-9), Beck Depression Inventory (BDI), Hamilton Rating Scale for Depression (HAM-D), Montgomery-Asberg Depression Rating Scale (MADRS), Quick Inventory of Depressive Symptomatology (QIDS), or Inventory of Depressive Symptomatology-Systems Review (IDS-SR).

Indications (CMS L34998)

- Retreatment(s) may be considered medically reasonable and necessary for patients who meet all of the following criteria:
 - Patients must have met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms as evidenced by a 50% worsening in the prior best response using the same rating scale (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR scores).
 - Patients must have responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR scores).
 - *Resistance to treatment is defined by a failure to achieve a 50% reduction in depressive symptoms, in accordance with objective measures such as Geriatric Depression Scale (GDS), the Personal Health Questionnaire Depression Scale (PHQ-9), the Beck Depression Inventory (BDI), the Montgomery Asberg Depression Rating Scale (MADRS), the Quick Inventory of Depressive Symptomatology (QIDS), the Inventory for Depressive Symptomatology Systems Review (IDS-SR) or Hamilton Rating Scale for Depression (HAM-D), from a pharmacologic trial where the medication is administered at both an adequate dose and for an adequate period of time consistent with accepted standards of care. A dose will be considered adequate when the medication is administered consistent with the FDA label. Where starting dosage is lower than maximum recommended dosage, the dose of any medication will be considered adequate when an initial response failure is followed by titrating the dosage upwards towards the maximum recommended dosage. Where such titration does not occur, the record must document the rationale for the decision not to increase the dose. Duration of therapy will be considered adequate, when a particular medication is administered for a length of time consistent with expectations for expected response times for that medication or class of medications as defined in the medical literature supporting the efficacy of that medication or medication class and by the standard of care.
- **Psychopharmacologic agent side effects will be considered intolerable, when those side effects are of a nature where they are not expected to diminish or resolve with continued administration of the drug.

Indications (CMS L36469)

- Resistance to treatment is defined by a failure to achieve a 50% reduction in depressive symptoms, in accordance with objective measures such as PHQ-9 and/or HAM-D, from a pharmacologic trial where the medication is administered at the recommended adult dose, per the FDA label, for a period of not less than 6 weeks.
- Psychopharmacologic agent side effects will be considered intolerable, when those side effects are of a nature where they are not expected to diminish or resolve with continued administration of the drug.

Limitations (CMS L33398)

The benefits of TMS use must be carefully considered against the risk of potential side effect in patients with any of the following:

- Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy or childhood without subsequent treatment or recurrence). Additional consideration should be given for individuals on medications which may lower the seizure threshold or with conditions rendering the patient more prone to seizures, such as alcoholism;
- Presence of vagus nerve stimulators leads in the carotid sheath;
- Presence of an implanted medical device located <30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, or vagus nerve stimulators

TMS is not considered reasonable and necessary for any of the following:

- Presence of psychotic symptoms in the current depressive episode;
- Acute or chronic psychotic disorder such as schizophrenia, schizophreniform disorder, or schizoaffective disorder;
- Neurologic 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;
- Persons with conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head which are non-removable and within 30 cm of the TMS magnetic coil. Examples include cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils stents, and bullet fragments. (Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS.)
- Maintenance therapy is not currently supported by evidence from clinical trials and therefore, is considered not reasonable and necessary.
- All other conditions not included in the above list of "Indications."

Limitations (CMS L34641, L34869)

The benefits of TMS use must be carefully considered against the risk of potential side effects in patients with any of the following:

- Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence); or
- Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
- Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system, or
- Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS magnetic coil or other implanted metal items including, but not limited to a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, Vagus nerve stimulator (VNS), or metal aneurysm clips or coils, staples or stents. (Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS).

All other uses of Transcranial Magnetic are experimental and are not covered.

Retreatment may be considered for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms.

Limitations (CMS L34522)

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).

Limitations (CMS L34998)

1. The treatment must be provided by use of a device approved by the FDA for the purpose of supplying Transcranial Magnetic Stimulation.
2. TMS therapy not ordered by a psychiatrist and furnished under direct supervision of a qualified physician (MD or DO) will be considered not medically reasonable and necessary and not subject to coverage.
3. The benefits of TMS use must be carefully considered against the risk of potential side effects in patients. The use of TMS in patients with any of the following is considered not medically reasonable and necessary and therefore will be denied:
 - Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence) or any condition or treatment that may lower the seizure threshold; or
 - Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
 - Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system; or
 - Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS magnetic coil or other implanted metal items including, but not limited to a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, Vagus nerve stimulator (VNS), or metal aneurysm clips or coils, staples or stents (Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS).
4. All other uses of TMS, including "maintenance therapy", "continuous therapy", "rescue therapy", and "extended active therapy" are considered investigational and experimental as they are not supported by controlled clinical trials and they are considered not reasonable and necessary. This non coverage is extended to any other terminology that may be given to a treatment episode that does not meet the defined requirements noted and defined as initial treatment or retreatment.
5. Retreatment(s) that occur in close temporal proximity to a previous episode of treatment may be considered maintenance therapy or continuous therapy and not reasonable and necessary. It is expected that the time between treatment episodes should allow for assessment, both clinically and by one or more standard rating scales, to clearly document that the patient responded and then relapsed. The number of retreatments is not limited at this time. However, frequent reporting of services may trigger focused medical reviews.
6. Routine performance of motor threshold re-determination (CPT 90869) during rTMS therapy will be considered not reasonable and necessary and may invite medical review.

Limitations (CMS L36469)

The benefits of TMS use must be carefully considered against the risk of potential side effects in patients with any of the following:

- Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence); or
- Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
- Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system, or
- Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS magnetic coil or other implanted metal items including, but not limited to a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, Vagus nerve stimulator (VNS), or metal aneurysm clips or coils, staples or stents.
- Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS.

Retreatment

Retreatment may be considered for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms. (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR scores).

All other uses of Transcranial Magnetic Stimulation, including "maintenance therapy" are experimental and are not covered.

Limitations (CMS L34269)

1. rTMS is considered not reasonable and necessary when used as a treatment modality for patients with psychotic symptoms.
2. Use of rTMS is not indicated in patients with:
 - A. Seizure disorder, or
 - B. A vagus nerve stimulator, or
 - C. An implanted medical device or metal in close proximity to the brain.

CLINICAL BEST PRACTICES

(CMS L33398)

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

It is expected that the services would be performed as indicated by current medical literature and standards of practice. Services performed in excess of established parameters may be subject to review for medical necessity.

Retreatment may be considered for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms or if there were a relapse after remission [e.g., (GDS), PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score]. A repeat treatment program is allowed as above.

The TMS treatment planning service may be reported once per treatment episode.

(CMS L34641)

The treatment must be provided by use of a device approved by the FDA for the purpose of supplying Transcranial Magnetic Stimulation.

It is expected that the services would be performed as indicated by current medical literature and standards of practice. Services performed in excess of established parameters may be subject to review for medical necessity.

TMS is reasonable and necessary for up to 20 visits over a 4 week period followed by five visits for tapering for those in remission; for those who show at least a 25% improvement by means of the standard tests for depression, the therapy may be continued for an additional 2 weeks (an addition 10 visits) with an additional 6 visits for tapering.

Retreatment may be considered for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms or if there were a relapse after remission (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score.) A repeat treatment program is allowed as above.

(CMS L34522)

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).

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.

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

(CMS L34998)

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

TMS is reasonable and necessary for up to 30 treatment sessions over a 6-7 week period followed by 6 treatment sessions for tapering over a 3 week period for those in remission. Further treatment of an episode of depression beyond this, for patients who have not achieved at least a 50% reduction in symptoms will be considered not medically reasonable and necessary and not subject to coverage. It is expected that CPT code 90867 be reported only once per patient (for the initial planning).

Retreatment program(s) may be considered as outlined above for patients who meet the covered indication guidelines. The number of retreatments is not limited at this time. However, frequent reporting of services may trigger focused medical reviews.

It is expected that the services would be performed as indicated by current medical literature and standards of practice. Services performed in excess of established parameters may be subject to review for medical necessity.

Medicare considers TMS therapy reasonable and necessary when it is furnished in accordance with the accepted standards of medical practice, when it is furnished in a setting appropriate to the patient's medical needs and condition, when it meets but does not exceed the patient's medical need and when it is ordered and furnished by qualified personnel.

It is expected that TMS therapy will be ordered by a psychiatrist and furnished under the direct supervision of a qualified physician (MD or DO) as follows:

- Direct Supervision – To be covered incident to the services of a physician, services and supplies must be furnished by the physician or by auxiliary personnel under the physician's direct supervision. In the office setting, this means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

*Note: For additional information on the CMS requirements for direct physician supervision, please refer to CMS IOM Pub. 100-02, Chapter 15, Section 60 for services and supplies furnished incident to a physician's professional service.

- Qualified Physicians (MD or DO) must possess evidence of knowledge, training, and expertise to perform TMS services.
- Qualified Physician and/or Prescribing Physician expectations are as follows:
 - The attending physician who prescribes a treatment course of TMS (psychiatrist), which involves a medical device, is ultimately responsible for the overall daily management of the TMS treatment team. It is expected that the prescribing physician (psychiatrist) establish the anticipated clinical treatment plan based on assessment of the patient's clinical history and review this treatment plan with the patient prior to beginning the course of treatment.
 - It is expected that the prescribing physician or another physician in the practice should perform the initial motor threshold determination and identify the appropriate coil location for subsequent treatments. Subsequent motor threshold determinations may be delegated by the attending physician to another, appropriately qualified physician or member of the clinical staff. In this circumstance, the qualified physician must be available on-site.
 - The qualified physician should review the clinical course of each daily treatment session to determine whether any modifications to the subsequent daily treatment should occur. It is expected that the qualified physician will provide appropriate documentation supporting the medical necessity of the services and that such documentation be made available upon request.
 - Conduction and oversight of daily treatment sessions may be delegated by the attending physician to another qualified physician or member of the clinical staff, but must be furnished under direct physician supervision.
- TMS Training Requirements for Qualified Physicians and Personnel
 - Peer-to-peer and graduate medical education have an important role in physician and staff training. In addition to industry sponsored training that is device specific, it is expected that TMS providers complete additional training either through a university affiliated or industry independent Continuous Medical Education (CME) program or through additional peer-to-peer direct supervision.

- Providers with a strong foundation in TMS through their training or extensive TMS experience may be exempt from the above expectation (i.e. Psychiatrist).
- It is also expected that the attending physician and all staff who are members of the TMS treatment team receive appropriate product training on the use of this technology. It is expected that at a minimum, the TMS team receive the detailed product training offered by the device manufacturer and maintain written documentation of training.
- Non-physician operators should also undergo manufacturers' training prior to independently performing treatments. TMS is a medically complex treatment, and therefore emergency medical services must be accessible at all times. The operator should provide updates, progress notes or both every day that should be monitored by the prescribing physician. The use of repeated ratings with mood scales to document depression changes is expected.
- It is expected that all TMS clinical staff maintain appropriate training to support their role as first responders to potential medical emergencies.
- It is expected that a TMS clinic establish formal standard operating procedures (SOPs) related to training and ongoing criteria to maintain procedural skills for all staff who are involved in the delivery of TMS in the office setting. Documentation of implementation and adherence to these procedures must be included and made available upon request.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862 (a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
 - Furnished in a setting appropriate to the patient's medical needs and condition.
 - Ordered and furnished by qualified personnel.
 - One that meets, but does not exceed, the patient's medical needs.
 - At least as beneficial as an existing and available medically appropriate alternative.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

(CMS L34269)

rTMS can be used up to 5 times per week over a 6 week period with a 2 week taper only with improvement in treatment response.

Repeat acute treatment for relapse of depressive symptoms is considered medically necessary if the patient responded to prior treatments.

Treatment planning with initial visit should be done only once per course of treatment.

(CMS L36469)

The treatment must be provided by use of a device approved by the FDA for the purpose of supplying Transcranial Magnetic Stimulation.

It is expected that the services would be performed as indicated by current medical literature and standards of practice. Services performed in excess of established parameters may be subject to review for medical necessity.

TMS is reasonable and necessary for up to 20 visits over a 4 week period followed by five visits for tapering for those in remission. For those who show at least a 25% improvement by means of the standard tests for depression, the therapy may be continued for an additional 2 weeks (an additional 10 visits) with an additional 6 visits for tapering. Further treatment of an episode of depression beyond this, for patients who have not achieved at least a 50% reduction in symptoms will be considered not medically reasonable and necessary and not subject to coverage.

Retreatment may be considered for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms or if there were a relapse after remission (e.g., (GDS), PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score. A repeat treatment program is allowed as above.

REFERENCES

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- 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. December 1, 2015. Retrieved from www.cms.gov
- Centers for Medicare and Medicaid Services, Local Coverage Determination. Transcranial Magnetic Stimulation for Major Depressive Disorder (L34522). First Coast Service Options, Inc. Florida; Puerto Rico; Virgin Islands. October 1, 2015. Retrieved from www.cms.gov
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HISTORY/REVISION INFORMATION

Date	Action/Description
June, 2014	• Version 1
October, 2014	• Version 1-Revised
March, 2015	• Version 2
August, 2015	• Version 2-Revised
April, 2016	• Version 3
May, 2017	• Version 4
January, 2018	• Version 5
April, 2018	• Version 6