



United Behavioral Health

Medicare Coverage Summary: Transcranial Magnetic Stimulation

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INTRODUCTION

Medicare Coverage Summaries are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members' recovery, resiliency, and wellbeing for Medicare behavioral health benefit plans managed by Optum®¹.

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. 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. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member's specific benefit, the member's specific benefit supersedes 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 non-invasive 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).

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, L37086, L37088).

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, L37086, L37088).

TMS parameters include cranial location, stimulation frequency, duration, and intensity. TMS is delivered in outpatient settings without anesthesia or analgesia. Typically for the treatment of depression, the coil is located over the left prefrontal cortex. The rTMS is performed daily (weekdays) for 6 weeks. There is no need for anesthesia or analgesia and there are no restrictions about activities before or after treatment (e.g. driving, working, operating heavy machinery). 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 (L37086, L37088).

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

Note: Part A services are typically inpatient. Part B services are typically outpatient.

(CMS L33398/A57528: All states Part A Inpatient Services and Part B Outpatient Services apply)

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

(CMS L34641/A57598: Part A Inpatient Services and Part B Outpatient Services vary, see each state)

- Alaska (Part A Inpatient Services)
- Alabama (Part A Inpatient Services)
- Arkansas (Part A Inpatient Services)
- Arizona (Part A Inpatient Services)
- California (Part A Inpatient Services)
- Colorado (Part A Inpatient Services)
- Connecticut (Part A Inpatient Services)
- Delaware (Part A Inpatient Services)
- Florida (Part A Inpatient Services)
- Georgia (Part A Inpatient Services)
- Hawaii (Part A Inpatient Services)
- Iowa (Part A Inpatient Services **and** Part B Outpatient Services)
- Idaho (Part A Inpatient Services)
- Illinois (Part A Inpatient Services)
- Indiana (Part A Inpatient Services **and** Part B Outpatient Services)
- Kansas (Part A Inpatient Services **and** Part B Outpatient Services)
- Kentucky (Part A Inpatient Services)
- Louisiana (Part A Inpatient Services)
- Massachusetts (Part A Inpatient Services)
- Maryland (Part A Inpatient Services)
- Maine (Part A Inpatient Services)
- Michigan (Part A Inpatient Services **and** Part B Outpatient Services)
- Missouri (Part A Inpatient Services **and** Part B Outpatient Services)

- Mississippi (Part A Inpatient Services)
- Montana (Part A Inpatient Services)
- North Carolina (Part A Inpatient Services)
- North Dakota (Part A Inpatient Services)
- Nebraska (Part A Inpatient Services **and** Part B Outpatient Services)
- New Hampshire (Part A Inpatient Services)
- New Jersey (Part A Inpatient Services)
- New Mexico (Part A Inpatient Services)
- Nevada (Part A Inpatient Services)
- Ohio (Part A Inpatient Services)
- Oklahoma (Part A Inpatient Services)
- Oregon (Part A Inpatient Services)
- Pennsylvania (Part A Inpatient Services)
- Rhode Island (Part A Inpatient Services)
- South Carolina (Part A Inpatient Services)
- South Dakota (Part A Inpatient Services)
- Tennessee (Part A Inpatient Services)
- Texas (Part A Inpatient Services)
- Utah (Part A Inpatient Services)
- Virginia (Part A Inpatient Services)
- Vermont (Part A Inpatient Services)
- Washington (Part A Inpatient Services)
- Wisconsin (Part A Inpatient Services)
- West Virginia (Part A Inpatient Services)
- Wyoming (Part A Inpatient Services)

(CMS L34869/A57813: All states Part B Outpatient Services)

- Alabama
- Georgia
- North Carolina
- South Carolina
- Tennessee
- Virginia
- West Virginia

(CMS L34998/A57072: All states Part A Inpatient Services and Part B Outpatient Services apply)

- Arkansas
- Colorado
- Delaware
- District of Columbia

- Louisiana
- Maryland
- Mississippi
- New Jersey
- New Mexico
- Oklahoma
- Pennsylvania
- Texas

(CMS L36469/A57047: All states Part A Inpatient Services and Part B Outpatient Services apply)

- Kentucky
- Ohio

(CMS L34522/A57647: All states & territories Part A Inpatient Services and Part B Outpatient Services apply)

- Florida
- Puerto Rico
- Virgin Islands

(CMS L37086/A57692: All states & territories Part A Inpatient Services and Part B Outpatient Services apply)

- California
- American Samoa
- Guam
- Hawaii
- Nevada
- Northern Mariana Islands

(CMS L37088/A57693: All states Part A Inpatient Services and Part B Outpatient Services apply)

- Alaska
- Arizona
- Idaho
- Montana
- North Dakota
- Oregon
- South Dakota
- Utah
- Washington

- Wyoming

If services are delivered in another state, please apply the Optum Level of Care Guidelines.

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

Note: Part A services are typically inpatient. Part B services are typically outpatient.

Indications (L34641)

- 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-IV defined Major Depressive Disorder who have failed to benefit from initial treatment of their depression.
 - 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:
 - Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to one trial of psychopharmacologic agents in the current depressive episode from at least two different agent classes. Each agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy; or
 - Inability to tolerate psychopharmacologic agents as evidenced by two 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 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
- 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).
 - 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.

Indications (CMS L33398)

- 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;

- 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).
- 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 L34522)

- Left Prefrontal rTMS of the brain is considered medically necessary for use in an adult who meets all four of the following criteria:
 - Has a confirmed diagnosis of severe major depressive disorder (MDD) single or recurrent episode;
 - AND
 - 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;

- 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.

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, L37086, L37088)

- Left Prefrontal rTMS of the brain is considered medically necessary for use in an adult who meets all four of the following criteria:
 - Has a confirmed diagnosis of severe major depressive disorder (MDD) single or recurrent episode;
 - AND
 - One or more of the following:
 - Resistance to treatment** with psychopharmacologic agents as evidenced by a lack of a clinically significant response to at least a single trial of psychopharmacologic agents in the current depressive episode; or
 - Inability to tolerate psychopharmacologic agents as evidenced by two trials of psychopharmacologic agents from two different agent classes; or
 - History of response to rTMS in a previous depressive episode (see "Retreatment(s)" below for previous response criteria); or
 - A history of response to ECT in a previous or current episode or an inability to tolerate ECT, or is a candidate for, but has declined ECT and rTMS is considered a less invasive treatment option.
- 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 (L34998).

Indications (CMS L36469)

- The treatment must be provided by use of a device approved by the FDA for the purpose of supplying Transcranial Magnetic Stimulation.
- Left Prefrontal rTMS of the brain is considered medically necessary for use in an adult who meets all four of the following criteria:
 - Has a confirmed diagnosis of severe major depressive disorder (MDD) single or recurrent episode;
AND
 - One or more of the following:
 - Resistance to treatment* with psychopharmacologic 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 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
 - The order for treatment (or retreatment) is written by a psychiatrist (MD or DO) who has examined the patient, and reviewed the record. The psychiatrist will have experience in administering TMS therapy. The treatment shall be given under direct supervision of this psychiatrist (physician present in the area and immediately available, but does not necessarily personally provide the treatment).
 - 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).
- 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.
- *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.

At this time there is insufficient published evidence to evaluate the safety and efficacy of this treatment in the context of maintenance therapy to prevent relapse in a patient who had a major depressive episode that remitted with prior treatment. Therefore, maintenance rTMS for the prevention of relapse of recurrent treatment resistant depression in the Medicare population is not considered to be reasonable and necessary (CMS L34869).

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);
- 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;
- 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.

Limitations (CMS L34998, L37086, L37088)

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 during rTMS therapy will be considered not reasonable and necessary.
 7. More than three motor threshold redeterminations in a rolling six-month period will be denied. Denied claims may be appealed with supporting documentation addressing the medical necessity (e.g. when there is a change in clinical status or medical regimen that is expected to alter cortical excitability) (CMS L37086, L37088).

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.

CLINICAL BEST PRACTICES

(CMS L33398/A57528)

- 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.
- Maintenance therapy is not covered.
- The TMS treatment planning service (CPT code 90867) 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.
- Maintenance therapy is considered experimental/investigational and therefore not medically necessary.

(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.
- 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 once per course of treatment.

(CMS L34998/A57072)

- 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) (CMS, A57072).
- 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.

*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: 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.

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

(CMS L34869, 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 (CMS, L36469).
- 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 L37086, L37088)

- 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 30 treatment sessions over a 7-week period followed by 6 treatment sessions for tapering 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.

- 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.
- Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management, is considered reasonable and necessary when there is a change in clinical status or medical regimen that is expected to alter cortical excitability. The medical record must clearly document the rationale for the performance of a motor threshold re-determination. Routine performance of motor threshold re-determination during rTMS therapy will be considered not reasonable and necessary.
- More than three motor threshold re-determinations in a rolling six- month period will be denied. Denied claims may be appealed with supporting documentation addressing the medical necessity (e.g. when there is a change in clinical status or medical regimen that is expected to alter cortical excitability or there is a demonstrated need for an episode of retreatment). The medical record must clearly document the rationale for the motor threshold re-determination.

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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
May, 2019	• Version 7
August, 2019	• Update to clarify Part A and Part B services per CMS LCDs
April, 2020	• Version 8: Annual Review