Transcranial Magnetic Stimulation

Policy Number: BH803MCSTMS1223
Annual Review Date: December 12, 2023
Interim Review Date: April 18, 2023

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Introduction & Instructions for Use

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®.

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.

If there is an absence of any applicable Medicare statutes, regulations, National or Local Coverage Determinations offering guidance, Optum utilizes adopted external criteria as follows:

- Level of Care Utilization System (LOCUS):
    - Standardized level of care assessment tool developed by the American Association of Community Psychiatrists used to make determinations and placement decisions for adults ages eighteen and older.
- Child and Adolescent Level of Care/Service Intensity Utilization System (CALOCUS-CASII):
    - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry and the American Association of Community Psychiatrists used to make determinations and to provide level of service intensity recommendations for children and adolescents ages 6-18.
    - Access the CALOCUS-CASII Criteria here
- Early Childhood Service Intensity Instrument (ECSII):
    - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry used to make determinations and to provide level of service intensity recommendations for children ages 0-5.
    - Access the ECSII Criteria here
- Optum Supplemental Clinical Criteria: developed criteria based on “acceptable clinical literature”
    - Electroconvulsive Therapy (ECT)
    - National criteria used to make clinical determinations for ECT.
- National criteria that stem from evaluation of new services or treatments or new applications of existing services or treatments and are used to make coverage determinations regarding experimental and investigation services and treatments. Optum Behavioral Clinical Policies:
    - Complementary and Alternative Medicine (CAM) Treatments
    - Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT)
    - Neurofeedback
    - Transcranial Magnetic Stimulation
    - Wilderness Therapy
- *Optum utilizes The ASAM Criteria to supplement the Medicare National Coverage Determinations (NCDs 130.1-130.7) for Alcohol and Substance Abuse Treatment to ensure consistency in making medical necessity determinations.*
    - Access the ASAM Criteria *here*

Use of The ASAM Criteria to supplement the general provisions outlined under 42 CFR 422.101(b)(6)(i) provides clinical benefits that are highly likely to outweigh any clinical harms from delayed or decreased access to items or services.

Specifically, The ASAM Criteria are consulted when the NCDs do not fully address the type of treatment or appropriate treatment setting that will likely lead to improvement of the member’s condition. The ASAM Criteria are also consulted due to the comprehensive six-dimension analysis to determine if comorbid medical, mental health and substance related factors add to the evidence for services not offered in the NCDs.

These criteria represent current, widely used treatment guidelines developed by organizations representing clinical specialties, or Optum developed criteria based on “acceptable clinical literature” according to 422.101(b)(6)(i). Optum selects and uses clinical criteria that are consistent with generally accepted standards of care, including objective criteria that are based on sound clinical evidence. Optum uses the criteria to make standardized coverage determinations and to inform discussions

about evidence-based practices and discharge planning. The use of such criteria is highly likely to outweigh any clinical harms from delayed or decreased access to care.

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 conducted in an outpatient setting and does not require anesthesia or analgesia (CMS L33398, L34641, L37086, L37088).

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, L36469). 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, L34869, 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) (CMS L34869, L36469).

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 L34869, L36469, L37086, L37088).

Applicable States

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

Coverage, Indications, Limitations and/or Medical Necessity

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

Indications (CMS L33398, 2023)

- Repetitive transcranial magnetic stimulation (rTMS) is only considered medically necessary in adults who have a confirmed diagnosis of major depressive disorder (MDD), single or recurrent episode and meet the following criteria:
  - 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 must have experience in administering rTMS therapy and the treatment must be given under direct supervision of this physician (physician present in the area but does not necessarily personally provide the treatment).
  - NPPs providers may order treatment (or retreatment) if it is within the scope of practice of the NPP in the State they are licensed. It is expected that the NPP has examined the patient, reviewed the record and has experience administering TMS therapy. The treatment shall be given under direct supervision of this NPP.
- AND
- The rTMS 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.

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 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);
  - 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";
  - Deep TMS (d-TMS) is not considered reasonable and necessary for Obsessive Compulsive Disorder (OCD).
- 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.

Indications (CMS L34522, 2022)

- TMS of the brain for severe MDD, single or recurrent episode, is considered medically reasonable and necessary for up to six weeks when the following criteria are met:
  - The patient has a confirmed diagnosis of severe MDD as defined by the current DSM;
  - AND
  - The patient has demonstrated a failure of one or more trials of a pharmacological medication and/or demonstrates an intolerance to psychopharmacologic medications. Intolerance of a psychopharmacologic agent: Intolerable side effect(s) that are not expected to diminish or resolve with continued administration of the medication;
  - AND
  - The order for TMS procedure is written by a psychiatrist (MD or DO), who has examined the patient face to face and reviewed the record.

- Note: TMS is delivered daily in an outpatient setting without anesthesia or analgesia for up to six weeks and there are no restrictions related to activities before or after treatment (e.g., driving, working, operating heavy machinery).

Limitations (CMS L34522)

- The following is considered an ABSOLUTE CONTRAINDICATION:
  - The presence of a medically implanted magnetic-sensitive device or other implanted metal items including, but not limited to, a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, vagus nerve stimulator (VNS), metal aneurysm clips/coils, staples, or stents, that are located less than or equal to 30 cm from the TMS magnetic coil.
- The following are considered RELATIVE CONTRAINDICATIONS:
  - The presence of a seizure disorder or any history of seizures (except those induced by Electroconvulsive therapy [ECT] or isolated febrile seizures in infancy without subsequent treatment or recurrence).
  - The presence of acute or chronic psychotic symptoms or disorders in the current depressive episode.
  - The presence of any neurological conditions including epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system.
- The following is considered not medically reasonable and necessary:
  - All other uses of TMS, including the use of TMS for OCD.

- Provider Qualifications
  - Services will be considered medically reasonable and necessary when all aspects of care are within the scope of practice of the provider's professional licensure, when performed according to the supervision requirements per state scope of practice laws, and when all procedures are performed by appropriately trained providers in the appropriate setting.

Indications (L34641, 2022)

- 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.

Limitations (CMS L34641)

- 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.

Indications (CMS L34869, 2022)

- 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-5 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 meets #1 and #2 of the following criteria:
      - 1. Has a confirmed diagnosis of severe MDD single or recurrent episode; and
      - 2. One or more of the following:
        - Resistance to treatment with psychopharmacological agents as evidenced by a lack of a clinically significant response to 2 trials of psychopharmacologic agents in the current depressive episode from at least 2 different agent classes. At least 1 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 2 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 personally provide the treatment).
- TMS for Obsessive Compulsive Disorder (OCD) may be covered if prescribed and administered by a licensed physician who is knowledgeable in the use of rTMS. Outpatient rTMS may be indicated for patients with DSM-5 defined OCD who have failed to benefit from initial treatment of their OCD.
  - Initial Treatment: rTMS of the brain is considered medically necessary for use in an adult who meets #1 and #2 of the following criteria:
    - 1. Has a confirmed diagnosis of OCD as per DSM-5 criteria; and
    - 2. One or more of the following:
      - Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to a trial of 2 distinct psychopharmacologic agents, administered for a minimum of 8 weeks; or

- Inability to tolerate psychopharmacologic agents as evidenced by trials of psychopharmacologic agents from 2 distinct psychopharmacologic agents; or
- History of response to TMS for OCD in the past that was clinically meaningful; or
- If patient is currently receiving antipsychotics, opioids, benzodiazepines, glutamatergic agents or other agents which could be considered investigational or risky treatments, TMS may be considered reasonable and necessary as a safer treatment option;
- AND
- A trial of an evidence-based psychotherapy known to be effective in the treatment of OCD for a minimum of 8 weeks duration without significant improvement in OCD symptoms as documented by standardized rating scales that reliably measure OCD 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 and will prescribe an evidence-based OCD TMS protocol. 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 Brainsway Deep TMS System is 1 TMS System for OCD, however any TMS system that has received FDA clearance for treatment of OCD may be utilized.

Limitations (CMS 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).
  - 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). Retreatment for OCD may be considered for patients who met the guidelines for initial treatment and experienced at least a 30% reduction in the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score, as long as the improvement persisted for at least 1 month after the prior treatments ended.
  - All other uses of Transcranial Magnetic are experimental and are not covered.

Utilization Guidelines (L34869)

- The treatment must be provided by use of a device approved by the FDA for the purpose of supplying TMS for treatment resistant MDD if treatment resistant MDD is the diagnosis. If the device is used for treatment of OCD it must be FDA approved for that diagnosis.
- 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 for treatment resistant MDD 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.

- Retreatment for treatment resistant MDD 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 treatment for OCD must be provided by a device cleared by the FDA for the purpose of TMS for OCD.
- 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 OCD for a minimum of 29 visits over a 6 week period. Extensions in 2 to 4 week increments will be cleared based on clinical need with evidence of response from the first 29 sessions. If patients cannot come in 5 days a week, treatments may be administered 3 days a week over a longer period of time.
- Retreatment for OCD may be considered for patients who met the guidelines for initial treatment and experienced at least a 30% reduction in the Y-BOCS score, as long as the improvement persisted for at least 1 month after the prior treatments ended. A repeat treatment program is allowed as above.

Indications (CMS L34998, 2022)

- TMS of the brain for severe MDD, single or recurrent episode, is considered medically reasonable and necessary for up to six weeks when the following criteria are met:
  - The patient has a confirmed diagnosis of severe MDD as defined by the current DSM;
  - AND
  - The patient has demonstrated a failure of one or more trials of a pharmacological medication and/or demonstrates an intolerance to psychopharmacologic medications as defined in the definition section above;
  - AND
  - The order for TMS procedure is written by a psychiatrist (MD or DO), who has examined the patient face to face and reviewed the record.

- Note: TMS is delivered daily in an outpatient setting without anesthesia or analgesia for up to six weeks and there are no restrictions related to activities before or after treatment (e.g., driving, working, operating heavy machinery).

Limitations (CMS L34998)

- The following is considered an ABSOLUTE CONTRAINDICATION:
  - The presence of a medically implanted magnetic-sensitive device or other implanted metal items including, but not limited to, a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, vagus nerve stimulator (VNS), metal aneurysm clips/coils, staples, or stents, that are located less than or equal to 30 cm from the TMS magnetic coil.
- The following are considered RELATIVE CONTRAINDICATIONS:
  - The presence of a seizure disorder or any history of seizures (except those induced by Electroconvulsive therapy [ECT] or isolated febrile seizures in infancy without subsequent treatment or recurrence).
  - The presence of acute or chronic psychotic symptoms or disorders in the current depressive episode.
  - The presence of any neurological conditions including epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system.
- The following is considered not medically reasonable and necessary:
  - All other uses of TMS, including the use of TMS for OCD.

- Provider Qualifications
  - Services will be considered medically reasonable and necessary when all aspects of care are within the scope of practice of the provider's professional licensure, when performed according to the supervision requirements per state scope of practice laws, and when all procedures are performed by appropriately trained providers in the appropriate setting.

Indications (CMS L36469, 2023)

- 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, and furnished under, the direct supervision of a psychiatrist who has experience administering TMS therapy.

- TMS therapy not ordered by and furnished under direct supervision, by a psychiatrist will be considered not medically reasonable and necessary and not subject to coverage.
- The treatment must be provided by use of a device approved by the FDA for the purpose of supplying Transcranial Magnetic Stimulation (A57047, 2023).
- 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 two 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 (A57047, 2023).
- *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 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, including TMS for the Treatment of Obsessive-Compulsive Disorder (OCD).

Indications (CMS L37086; L37088, 2023)

- TMS may be covered if prescribed and administered by a licensed physician under direct supervision who is trained and experienced 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.
- 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 a single 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 two different agent classes; 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 less invasive treatment option.
- 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 a qualified physician (physician present in the area and immediately available but does not necessarily personally provide the treatment).
- 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.
  - All other uses of TMS therapy are considered investigational or experimental and remain non-covered services.

Limitations (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.
- 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 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.
- All other uses of Transcranial Magnetic Stimulation are considered investigational and experimental and are not allowed reimbursement.

Clinical Best Practices

(CMS L33398/A57528)

- All documentation must be maintained in the patient's medical record and available to the contractor upon request.
- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- The medical record documentation must support the medical necessity of the services as directed in the related LCD.
- The attending physician must monitor and document the patient's clinical progress during treatment. 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.
- 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/A57598)

- All documentation must be maintained in the patient's medical record and available to the contractor upon request. The medical record documentation must support the medical necessity of the services as directed in this policy.
- The attending physician must monitor and document the patient's clinical progress during treatment. 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 Inventory (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 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 L36469/A57047)

- 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.
- The attending physician must monitor and document the patient's clinical progress during treatment. 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.

(CMS L37086/A57692, L37088/A57693)

- The attending physician must monitor and document the patient's clinical progress during treatment. 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.
- 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 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.
- 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 was 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 non-covered as not medically reasonable and necessary.

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Revision History

Date	Summary of Changes
April, 2020	• Annual Review
October, 2020	• Interium Review: Update to L33398 Limitations section regarding Deep TMS and OCD.
October, 2021	• Annual Review
April, 2022	• Interim Review: Update to L34869
November, 2022	• Annual Review
January, 2023	• Interim Review: Updates to L34522 and L34998
April 18, 2023	• Interim Review: Update to L33398, “Indications” section.
December 12, 2023	• Annual Review • Added language to Introduction & Instructions for Use section per CMS Final Rule 2024 requirements; updated References section