

# Local Coverage Determination (LCD): Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37086)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

## LCD Information

## Document Information

**LCD ID**

L37086

**LCD Title**

Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

DL37086

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N/A

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N/A

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03/29/2018

**Notice Period End Date**

05/13/2018

## **CMS National Coverage Policy**

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act (SSA) §1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(D), and (E). Investigational or Experimental.

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

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.

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.

### **Indications for Coverage**

Noridian 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 direct supervision of a qualified physician (MD or DO) who has experience administering TMS therapy.

### **Initial Treatment**

Left Prefrontal rTMS of the brain is considered medically necessary for use in an adult who meets all four of the following criteria:

1. Has a confirmed diagnosis of severe major depressive disorder (MDD) single or recurrent episode; **and**
2. **One or more of the following:**

- 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; 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
- 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.

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.

## **AND**

3. 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**

4. 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).

NOTE: Please refer to the "Provider Qualification" section for qualified physician and direct supervision requirements.

Therapeutic repetitive transcranial magnetic stimulation 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 redetermination.

## **Retreatment**

Retreatment may be considered for patients who 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).

### **Coverage Limitations**

TMS therapy not ordered by a psychiatrist who has experience administering TMS therapy and furnished under direct supervision, by a qualified physician (MD or DO), 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.

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 will not be covered:

- 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, 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.

Retreatment that occurs 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.

All other uses of TMS therapy are investigational and/or experimental and are not covered.

Routine performance of motor threshold re-determination during rTMS therapy will be considered not reasonable and necessary. 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).

### **Place of Service (POS) Provider Qualifications**

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 familiar with this therapy and furnished under the direct supervision of a qualified physician (MD or DO) as follows:

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

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

Qualified Physicians (MD or DO) must possess evidence of knowledge, training and expertise to perform TMS services.

Qualified Physician and/or Prescribing Physician expectations are as follows:

The attending physician who prescribes a treatment course of TMS (psychiatrist), which involves a medical device, is ultimately responsible for the overall daily management of the TMS treatment team. It is expected that the prescribing physician (psychiatrist) establish the anticipated clinical treatment plan based on assessment of the patient's clinical history and review this treatment plan with the patient prior to beginning the course of treatment.

It is expected that the prescribing physician or another physician in the practice should perform the initial motor threshold determination and identify the appropriate coil location for subsequent treatments. Subsequent motor threshold determinations may be delegated by the attending physician to another, appropriately qualified physician or member of the clinical staff. In this circumstance, the qualified physician must be available on-site.

The qualified physician should review the clinical course of each daily treatment session to determine whether any modifications to the subsequent daily treatment should occur. It is expected that the qualified physician will provide appropriate documentation supporting the medical necessity of the services and that such documentation be made available upon request.

Conduction and oversight of daily treatment sessions may be delegated by the attending physician to another qualified physician or member of the clinical staff but must be furnished under direct physician supervision.

### **TMS Training Requirements for Qualified Physicians and Personnel**

Peer-to-peer and graduate medical education have an important role in physician and staff training. In addition to

industry sponsored training that is device specific, it is expected that TMS providers complete additional training either through a university affiliated or industry independent Continuous Medical Education (CME) program or through additional peer-to-peer direct supervision.

Providers with a strong foundation in TMS through their training or extensive TMS experience may be exempt from the above expectation (i.e. Psychiatrist).

It is also expected that the attending physician and all staff who are members of the TMS treatment team receive appropriate product training on the use of this technology. It is expected that at a minimum, the TMS team receive the detailed product training offered by the device manufacturer and maintain written documentation of training.

Non-physician operators should also undergo manufacturers' training prior to independently performing treatments. TMS is a medically complex treatment and, therefore, emergency medical services must be accessible at all times. The operator should provide updates, progress notes or both every day that should be monitored by the prescribing physician. The use of repeated ratings with mood scales to document depression changes is expected.

It is expected that all TMS clinical staff maintain appropriate training to support their role as first responders to potential medical emergencies.

It is expected that a TMS clinic establish formal standard operating procedures (SOPs) related to training and ongoing criteria to maintain procedural skills for all staff who are involved in the delivery of TMS in the office setting. Documentation of implementation and adherence to these procedures must be included and made available upon request.

For frequency limitations please refer to the Utilization Guidelines section below.

## **Summary of Evidence**

### **Levels of Evidence**

Levels of evidence were determined by placing the greatest emphasis on evidence obtained from randomized controlled trials and systematic reviews of randomized controlled trials. (Levels 1 and 2).

Level 3 includes systematic reviews of level 3 studies or controlled individual cases.

Level 4 includes case series.

Level 5 includes anecdotal evidence or non-human animal-based evidence

Levels of Evidence framework published by the University of Oxford Centre for Evidence-Based Medicine.

## **Analysis of Evidence (Rationale for Determination)**

### **Evidence in support of left prefrontal, fast rTMS.**

Multi-site randomized controlled trials (RCT) – Level 1

Three large, multisite, randomized sham-controlled trials included an aggregate sample of 703 adult patients with major depressive disorder (MDD) who had failed between 1 and 4 antidepressant trials.

Two of the studies were industry sponsored registration trials for the NeuroStar TMS Therapy System [O'Reardon, et al. (2007)] and the Brainsway Deep TMS device in 2013 [Levkovitz, et al. (2015)]. The third study was a National Institute of Mental Health (NIMH) - sponsored, multicenter study, which provided industry-independent evidence of TMS effects on depression [George, et al. (2010)]. This NIMH trial used an active, sham-controlled condition and the primary outcome focused on the clinically important endpoint of remission. All three trials were consistent in their evidence, establishing a statistically significant and clinically relevant benefit with TMS therapy compared to the sham condition.

### **Evidence for durability of acute treatment with rTMS**

The level of evidence for the durability of rTMS treatment is lower than the above. There is lack of uniformity of the population studied as some are on medication and some are not, follow up times vary and bias may be introduced by failure to account for what happened to those who dropped out of the studies. In a study by Dunner, et al, involving a one-year, multisite, naturalistic, observational cohort conducted in 120 patients who met criteria for response or remission after their acute TMS course, 62% continued to meet response criteria 12 months later [28]. The results of these studies in patients placed back on antidepressant medications demonstrates high (i.e.64–90%) durability for acute TMS benefits over a 3–12-month period, with a majority of patients who relapsed responding to additional TMS

sessions.

### **Evidence for continuation/maintenance studies:**

Data is scant and only a small number of patients were included to support continuation/maintenance therapy.

Maintenance is defined by the Clinical TMS Society as a course that begins after the end of C-TMS (continuation) and is intended to prevent recurrence of an episode (a new episode). The only published controlled trial to date of continuation TMS was performed in the Brainsway multicenter trial. MDD patients (N=212) were randomized to sham or active TMS during the acute 4-week treatment phase followed by a continuation phase of 2 treatments a week for an additional 12 weeks. At the end of the continuation phase (week 16), the difference in remission rates between TMS (31.8%) and sham (22.2%) were not significant ( $p=0.15$ ).

### **Provider and Staff Qualifications**

These are in keeping with the guidelines of the Clinical TMS Society recommendations.

### **Overall Conclusions Based on Summary of Evidence**

The efficacy and safety of TMS using a specific, defined treatment protocol in treatment resistant depression was confirmed in 3 trials as listed above and all three studies are consistent in their conclusion that support TMS as applied in routine clinical practice settings. There is some reasonable data to support retreatment but not maintenance or continuation treatments. Defining the number of treatment failures as one or two is consistent with longstanding evidence but often inconsistently applied across studies. According to recent assessments by the Agency for Healthcare Research and Quality, more consistent measures of improvement in responses are needed. Finally, several professional organizations have included TMS in their guidelines as recommended acute treatment for major depression, along with suggested qualifications of professionals involved in treatment.

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## **General Information**

### **Associated Information**

#### **Documentation Requirements**

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. 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.
3. 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.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.
5. The qualified physician must monitor and document the patient's clinical progress during treatment. The clinical

record must document that the qualified physician met with the patient face to face for the initial assessment and subsequent delivery and management and when there has been a change in either the clinical or mental status of the patient. The qualified 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.

## **Utilization Guidelines**

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

## **Sources of Information**

See Bibliography

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39. Other Contractor's LCDs

# Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R2	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)</li> </ul>
12/01/2019	R1	<p>12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> <li>Revisions Due To Code Removal</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

Article(s)

A57692 - Billing and Coding: Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder

A55902 - Response to Comments: Repetitive Transcranial Magnetic Stimulation for Major Depressive Disorder

LCD(s)

DL37086

- (MCD Archive Site)

### Related National Coverage Documents

N/A

### Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 11/13/2019 with effective dates 12/01/2019 - N/A

Updated on 03/14/2018 with effective dates 05/14/2018 - N/A

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## **Keywords**

N/A