MEDICARE COVERAGE SUMMARY: TRANSCRANIAL MAGNETIC STIMULATION

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INTRODUCTION

Medicare Coverage Summaries synopsize guidance provided in CMS' *National Coverage Determinations* (NCDs) and *Local Coverage Determinations* (LCDs), and are used to make medical necessity determinations for Medicare behavioral health benefits managed by Optum and U.S. Behavioral Health Plan, California (doing business as OptumHealth Behavioral Solutions of California ("Optum-CA")).

In the event that CMS does not provide a NCD or a LCD for a particular State, jurisdiction, condition or service, Optum's *Level of Care Guidelines* should be used for medical necessity decisions along with the member's benefit plan.

Before using this guideline, please check the member's specific benefit plan requirements and any federal or state mandates, if applicable.

TRANSCRANIAL MAGNETIC STIMULATION

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

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.

APPLICABLE STATES

Medicare provides guidance on the coverage of Transcranial Magnetic Stimulation in all states and territories with the exception of California Hawaii and Nevada. The Optum Level of Care Guidelines should be applied when making coverage decisions in these states.

Indications for Coverage

TMS may be covered if prescribed and administered by a licensed physician who is knowledgeable in the use of Transcranial Magnetic Stimulation. Outpatient TMS 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 TMS is considered reasonable and necessary for members diagnosed with Major Depressive Disorder in addition to at least **ONE** of the following:

- Resistance to treatment as evidenced by a lack of clinically significant response to four trials of pharmacologic agents in the current depressive episode, from at least two different agent classes. One of the following is also required for the following states:
    - In **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming** it is required that**:**
        - At least one of the treatment trials was administered at an adequate course of mono- or poly–drug therapy.
- Inability to tolerate four agents from two different agent classes of with distinct side effects.
- A history of good response to TMS in a previous episode.
    - In **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming** response history is evidence of a greater than 50% improvement in symptoms on a standardized rating scale such as:
        - The Geriatric Depression Scale (GDS)
        - Personal Health Questionnaire Depression Scale (PHQ-9)
        - Beck Depression Scale (BDI)
        - Hamilton Rating Scale for Depression (HAM-D)
        - Montgomery Asberg Depression Rating Scale (MADRS)
        - Quick Inventory of Depressive Symptomatology (QIDS)
        - Inventory for Depressive Symptomatology Systems Review (IDS-SR)
- TMS as a less invasive treatment option to Electroconvulsive Therapy (ECT):
    - The member is currently receiving ECT in **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming** and TMS is desired as a less invasive treatment option.
    - The member has declined ECT in **Florida, Puerto Rico and Virgin Islands** in favor of TMS as a less invasive treatment option.
    - In **Illinois, Minnesota, Wisconsin, Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont** there is a history of good response to ECT in a previous or in the current episode, or there is an inability to tolerate ECT, and TMS is considered a less invasive treatment option.
- Additional state-specific requirements:
    - In **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming** there must also be 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.

- In **Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania** TMS is delivered by a device that is FDA approved or cleared for the treatment of MDD in a safe and effective manner. TMS should follow the protocol and parameters specified in the manufacturer's user manual, with modifications only as supported by the published scientific evidence base.
- In **Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania** the order for treatment and retreatment is written by a physician (MD or DO) who has examined the patient and reviewed the record. The physician must have experience administering TMS therapy and the treatment must be given under the supervision of this physician.

Administration and Documentation

- If there is active suicidality, additional review may be warranted to evaluate whether TMS is the most appropriate treatment, or whether a more intensive treatment is indicated.
- TMS is reasonable and necessary for up to 30 visits (up to 5 times per week) over a 6-7-week period with a two week taper (6 taper treatments).
  - In **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming** 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 according to standardized rating scales, TMS may continue for an additional 2 weeks (10 visits) with an additional 6 visits for tapering.
- 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 with the use of standard rating 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.
- 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 attending physician must monitor and document the patient's clinical progress during treatment with the use of the above evidence-based rating scales.
- The medical record documentation must support the medical necessity of the services.

Exclusions

TMS is not covered in the following circumstances and is considered Not Reasonable and Necessary:

- There is a presence of psychotic symptoms in the current depressive episode.
- There is a presence of conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head which are non-removable and within 30cm of the TMS magnetic coil.
  - Examples include: cochlear implants, implanted electrodes/stimulators, aneurysm clips or coil, stents, and bullet fragments.
- The member has been diagnosed with Schizophrenia, Schizophreniform Disorder, or Schizoaffective Disorder.
- There are neurological conditions that include Epilepsy, Parkinson's disease, Multiple Sclerosis, Cerebrovascular disease, Dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, primary or secondary tumors in the central nervous system, or any other degenerative neurologic condition.
- Used as a maintenance therapy. TMS as a maintenance therapy is not supported by controlled clinical trials at this time and is not considered reasonable and necessary in **Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Mississippi, Minnesota, Missouri, Montana, North Dakota, North Carolina, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South**

Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia and Wyoming.

- There is active substance use is excluded specifically in Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania.

REFERENCES

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HISTORY/REVISION INFORMATION

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June, 2014	• Version 1
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