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Transcranial Magnetic Stimulation Policy

Transcranial Magnetic Stimulation (TMS) or (rTMS) High-Frequency Left Repetitive Transcranial Magnetic Stimulation (HFL-TMS) Low-Frequency Right Repetitive Transcranial Magnetic Stimulation (LFR-TMS)

Indication/Usage:

Transcranial magnetic stimulation (TMS) is a noninvasive technique used as a treatment for major depressive disorder (MDD). Brief repetitive pulses of magnetic energy are applied to the scalp via an electromagnetic coil to generate low levels of electrical current in the underlying brain tissue. The goal of TMS is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes. TMS may be used to enhance pharmacotherapy or in lieu of a new medication. TMS was developed as a physiologically similar but potentially more acceptable alternative to electroconvulsive therapy (ECT). TMS is not invasive, does not induce seizures, and is

not associated with stigma. It can also be performed in an outpatient setting as it does not require anesthesia.

TMS works by passing electrical energy through an electromagnetic stimulation coil that is positioned on the scalp above the target cortical center. Pulsed electrical current generates a magnetic field that travels through the skull and induces low-level electric currents in underlying tissue locally in the brain. This is in contrast to ECT's direct application of electrical current to induce a global seizure. (TMS, 2/6/18).

Conventional TMS involves either high-frequency (> 5 and up to 10 hertz (HZ)) stimulation applied to the left dorsolateral prefrontal cortex (DLPFC) or low-frequency stimulation (< 1 Hz) applied to the right DLPFC. These protocols are referred to as HFL-TMS and LFR-TMS. A full course of TMS usually involves 1 session a day, 5 days a week, for 6 weeks. Each session takes approximately 40 minutes. Additional sessions (up to 36) may extend an acute course of care to 6 weeks.

Medical Indications for Authorization Commercial Members

1. SummaCare considers TMS of the brain medically necessary for use in an adult who meets the following criteria:

    - Age 18 years or older
    - A confirmed diagnosis of major depressive disorder and ALL of the following:
    - Failure of two or more trials of antidepressant medications from two separate classes of antidepressant medications. A failed trial is defines as:
        - Use of an antidepressant medication, at adequate therapeutic doses for at least four weeks with no significant reduction in depressive symptoms.
        - Use of an antidepressant medication with documented intolerance/medical contraindication.
    - An adequate trial of an evidence-based psychotherapy known to be effective in the treatment of major depressive disorder, without significant improvement in depressive symptoms.
    - The TMS is administered using a U.S. Food and Drug Administration cleared device and utilized in accordance with the FDA labeled indications.
    - Treatment consists of a maximum of 36 sessions.

2. SummaCare considers TMS re-treatment (rTMS) medically necessary for members with depression relapse who meet ALL of the following criteria:

    - The member meets initiation criteria
    - The member has relapsed following TMS despite other treatment
    - The member had previously had at least a 50% reduction in depressive symptoms with TMS

Medicare Members

Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

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

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

CGS 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, 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.

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 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.

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 effect 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 this psychiatrist (physician present in the area and immediately available but does not necessarily personally provide the treatment).

Coverage Limitations

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.

Limitations

There is insufficient evidence to support the use of TMS for conditions other than MDD.

There is insufficient evidence to support the following, therefore secondary review is recommended:

- TMS for conditions other than major depressive disorder
- TMS for patients younger than 18 years of age
- A repeat course of TMS when there was little or no improvement during the initial course
- More than one repeat course of TMS
- Continuation of the initial or repeat course of TMS longer than identified within the criteria in order to attain additional improvement
- Maintenance TMS, which is continuation of the initial or repeat course of TMS longer than
- identified within the criteria, usually at a reduced frequency, in order to maintain improvement
- Accelerated TMS, which is administration of TMS twice daily instead of once daily, allowing for completion of a course in TMS in half of the usual time Other types of TMS such as:
    - Low field magnetic stimulation
    - Synchronized TMS

Evidence does not currently support use of TMS for major depression with psychotic features (psychotic depression) that is treatment-resistant or treatment-intolerant. Large controlled trials of TMS for psychotic depression have not been done

TMS is generally done as an outpatient procedure, but may occasionally be done in other levels of care. The criteria remains the same

Contraindications:

- No vagus nerve stimulator leads in the carotid sheath
- No other implanted stimulators controlled by or that use electrical or magnetic signals
- No conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of TMS coil placement other than dental fillings
- No acute or chronic psychotic disorder
- No seizure disorder or history of seizure disorder
- No substance abuse at the time of referral or at start of TMS treatments
- No severe dementia
- No known nonadherence with previous treatment for depression

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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