CMS Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (TMS) for the Treatment of Depression L34998

Transcranial magnetic stimulation (TMS) is a non-invasive, non-systemic treatment that uses Magnetic Resonance Imaging (MRI)-strength, pulsed, magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil is placed on the scalp that induces a focal current in the brain and temporary modulation of cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Depending on stimulation parameters, repetitive TMS to specific cortical regions can either decrease or increase the excitability of the targeted structures.

When used as an antidepressant therapy, TMS produces a clinical benefit without the systemic side effects typical with oral medications, has no adverse effects on cognition, and unlike electro-convulsant therapy does not induce amnesia or seizures. TMS offers a well-tolerated, non-pharmacologic alternative that does not require attendant anesthesia services and can be administered in an outpatient setting for patients with DSM-IV defined Major Depressive Disorder who have failed to benefit from initial treatment of their depression. When effective, TMS may prevent the need to utilize more complex pharmaceutical augmentation strategies (e.g., atypical antipsychotic medication), electroconvulsive therapy (ECT), and inpatient hospitalization at later stages of the illness.

Admission Criteria	Continued Stay Criteria	Discharge Criteria
The following criterion must be met: Left prefrontal TMS is considered reasonable and necessary for patients diagnosed with severe Major Depression (single or recurrent episode) as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), who also have at least one of the following: 1. Resistance to treatment with psychopharmacologic agents as evidenced by a lack of clinically significant response to four trials of such agents, in the current depressive episode, from at least two different agent classes. At least one of the treatment trials must have been administered at an adequate course of mono- or poly–drug therapy; or	**Any of the following criteria must be met:** 1. TMS is reasonable and necessary for up to 30 visits over a 7-week period followed by 6 taper treatments. 2. Repeat acute treatment for relapse of depressive symptoms is considered medically necessary if the patient responded to prior treatments, specifically > 50% improvement in a standard rating scale for depressive symptoms (e.g, (GDS), PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score). If patient meets the relapse criteria, up to 30 visits for the acute	**Any of the following may be met:** 1. The use of TMS as a maintenance therapy is not supported by controlled clinical trial at this time and is therefore, considered not reasonable and necessary.

2. Inability to tolerate psychopharmacologic agents as evidenced by trials of four such agents with distinct side effects; or 3. History of good response to TMS in a previous episode; or 4. If patient is currently receiving electro-convulsive therapy, TMS may be considered reasonable and necessary as a less invasive treatment option **Cautionary Uses:** 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 seizure (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence). • The presence of vagus nerve stimulator leads in the carotid sheath. • The presence of an implanted medical device located within 30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, or vagus nerve stimulators. **Exclusions:** TMS is considered not reasonable and necessary when used as a treatment modality for patients with any of the following: 1. Presence of psychotic symptoms in current depressive episode.	phase treatment followed by an additional 6 visits for tapering is considered reasonable and necessary.	

2. Dementia or other degenerative neurologic conditions such as Parkinson's Disease or Multiple Sclerosis. 3. Chronic or acute psychotic disorder such as Schizophrenia, Schizophreniform Disorder, or Schizoaffective Disorder. 4. Active current substance use. 5. TMS should not be used in patients who have conductive, ferromagnetic or other magneticsensitive 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.		