

## Coverage Guidance for TMS for Smoking Cessation

### COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

**Introduction:** 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, patterned 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. TMS parameters include cranial location, stimulation frequency, pattern, duration, intensity and the state of the brain under the coil.

**History/Regulatory:** In October 2008, conventional rTMS with a figure-8 coil was FDA cleared for the treatment of adults with major depressive disorder (MDD) who had one failed medication trial. In January 2013 rTMS with the H1 coil was cleared for adults with MDD who failed any number of treatments. In August of 2018 rTMS with the H7 coil was cleared as an adjunctive treatment for adults with Obsessive Compulsive Disorder (OCD). In August of 2020, rTMS with the Brainsway Deep Transcranial Magnetic Stimulation System using the H4 coil was FDA cleared for short-term smoking cessation in adults

**Smoking Cessation:** According to the CDC and the surgeon general, smoking is the leading cause of mortality and morbidity in the United States<sup>1</sup>. The life expectancy of smokers is at least ten years shorter than nonsmokers, and quitting smoking before the age of forty reduces the risk of dying from smoking related diseases by 90%. Substance use disorders are chronic recurring illnesses. FDA regulated treatment options for tobacco use disorder include nicotine replacement, bupropion or varenicline. Evidence for efficacy of the H4 coil comes from a pilot study of 115 smokers and a subsequent multicenter study of 262 smokers<sup>2,3</sup>. The H4 coil symmetrically stimulates the bilateral prefrontal cortex, bilateral insular cortex and anterior cingulate cortex<sup>4</sup>. Treatments are scheduled five days a week for three weeks followed by once weekly for three weeks. Daily TMS for smoking cessation is administered to motivated patients using a craving induction protocol after a minimum of two hours of abstinence. In the multicenter study, the four-week continuous quit rate for active completers was 28% compared to 11% for the sham group. Patients assigned to active treatment are slower to initiate smoking their first cigarette of the day<sup>5</sup>, in addition to the immediate reduction in craving from the treatment and reduction in total number of cigarettes.

Smokers under forty and those with more than twelve years of education had higher quit rates, suggesting that combination treatment strategies or longer treatment courses may be necessary in more refractory populations<sup>6</sup>.

### INDICATIONS FOR COVERAGE

TMS for smoking will be covered if it is prescribed by a licensed prescriber who is trained in the use of TMS, if the patient meets the below criteria:

**Initial Treatment:** TMS for smoking cessation is considered medically necessary for use in an adult who meets #1 and #2 of the following criteria:

1. Has a confirmed diagnosis of Tobacco Use Disorder (TUD) as per DSM-5 criteria<sup>7</sup>

AND

2. One or more of the following:

- Resistance to treatment as evidenced by persistent TUD symptoms after two of the following, each for a minimum of four weeks:
  - one nicotine replacement treatment
  - one prescription medication indicated for TUD (e.g. bupropion, varenicline)
  - a course of evidence-based therapy for TUD
- Inability to tolerate or contraindication to psychopharmacologic agent for TUDs
- History of COPD, coronary or peripheral artery disease, lung cancer or other comorbid medical condition secondary to TUD

Retreatment: TMS for smoking cessation is considered medically necessary for use in an adult who meets the following criteria:

1. Has a confirmed diagnosis of Tobacco Use Disorder (TUD) as per DSM-5 criteria<sup>7</sup>

AND

2. History of clinically meaningful response to TMS for TUD in the past as defined by at least four weeks of abstinence.

The order for treatment or retreatment must be written by a prescriber who has examined the patient, reviewed the record, and is prescribing an evidence-based TMS protocol. This prescriber shall oversee the treatment, but they do not have to personally administer the sessions nor be in the area. The prescriber must be reachable and interruptible in case of questions or problems during 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 disorders or medical conditions may increase the risk of seizure. There is always an extremely small chance for TMS to cause a seizure during the TMS session in non-epileptics<sup>8</sup>.

The seizure risk with TMS is somewhat higher in patients with known seizure risk factors, however it remains a very low risk. TMS may be indicated in patients with known seizure risk factors if the potential benefit outweighs the risk<sup>9</sup>.

Repetitive TMS is contraindicated in the presence of an implanted magnetic-sensitive medical device located less than or equal to 10 cm from the TMS coil<sup>10,11</sup>.

#### UTILIZATION GUIDELINES

The treatment must be provided by a device cleared by the FDA for the purpose of TMS for smoking cessation, using an evidence-based protocol. It is expected that the services will be performed as indicated by current medical literature and standards of practice.

TMS for adolescents with Tobacco Use Disorder may be appropriate if there is a higher level of treatment resistance. These cases should be reviewed individually for medical necessity and considered a compassionate use.

TMS for smoking cessation is reasonable and necessary for at least 18 visits. The authorization therefore includes 18 treatments to reflect usual practice.

## CODING

CPT Code	CODE DESCRIPTION
90867 x 1	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; INITIAL, INCLUDING CORTICAL MAPPING, MOTOR THRESHOLD DETERMINATION, DELIVERY AND MANAGEMENT
90868 (all other days)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT DELIVERY AND MANAGEMENT, PER SESSION
90869 (once a week)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT MOTOR THRESHOLD REDETERMINATION WITH DELIVERY AND MANAGEMENT

## REFERENCES

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