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## Medicare To Start Covering Magnetic Pulse...



by Deeda Payton

An innovative treatment uses magnetic pulses to treat depression. Starting next week, Transcranial Magnetic Stimulation (TMS) will be covered by Medicare in Texas. An Austin psychiatrist says it can leave patients symptom-free after just six weeks.

Julie Tomlinson waits for the coil to lock into place -- next come the magnetic pulses. While the machine is loud, she says there's something calming about the tapping. "It just really clarifies things," said Tomlinson.

Tomlinson's psychiatrist, Dr. Marilyn Vache, says each pulse targets the part of the brain affected by depression which has been well mapped out to be the left pre-frontal cortex. "You apply that magnetic field over that area and when it hits the wet tissue of the brain, it turns into a tiny current and that stimulates that area," said Vache.

Vache says it carries a 56 percent success rate, "I see it's a big benefit for people who have failed medication during this episode of depression." However, it doesn't work instantly. "It does take several treatments, typically about 30 treatments to get full effect," said Vache.

Tomlinson, who has dealt with major depression for most of her life, says she noticed a difference after four weeks. "It gave me the ability to pull myself up and do the things I needed to do to feel even better."

"We could see she was becoming more active, that she was more engaged, that she enjoyed things more," said Vache.

It's a huge relief for Tomlinson who has tried just about every other therapy and anti-depressant out there. "I would highly recommend it especially for someone who has not had success with medication," said Tomlinson.

Vache says less than 30 percent of patients have had to come back for additional treatments. "It's amazing, it's pretty amazing," said Tomlinson.

Medicare will begin covering TMS in Texas on Dec. 5. And Vache hopes one day this treatment will replace prescription medications as a first line of response. She says the military is already researching the technology for their patients with PTSD and traumatic brain injury. NeuroStar TMS Therapy indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode.

The safety and efficacy of NeuroStar TMS Therapy in Major Depressive Disorder (MDD) was studied in a randomized controlled trial of patients who had failed to receive benefit from one to four prior antidepressant medications. A retrospective subgroup analysis of the overall study population demonstrated that the device was safe and effective for patients who had failed to benefit from one prior antidepressant medication of adequate dose and duration in the current episode. In this study population, patients had received a median of 4 total prior antidepressant medication attempts in the current episode, one of which achieved treatment adequacy at or above the minimal effective dose and duration.

In a controlled trial, patients treated with active NeuroStar TMS Therapy received greater than 3 times the improvement in depressive symptoms compared to placebo at four weeks (MADRS, -7.1 vs -2.1, P=0.0006).<sup>1</sup> An open-label, uncontrolled clinical study showed approximately half of the patients treated with NeuroStar TMS Therapy experienced significant improvement in their depression symptoms. About a third of the patients treated with NeuroStar TMS Therapy experienced complete symptom relief at the end of 6 weeks.<sup>1</sup>

NeuroStar TMS Therapy should not be used (is contraindicated) in patients with implanted metallic devices or nonremovable metallic objects in or around the head. NeuroStar TMS Therapy is not associated with systemic side effects reported for antidepressant medications. The most frequently reported side effect with NeuroStar TMS Therapy is scalp pain or discomfort at the treatment location. There is a rare risk of seizure with NeuroStar TMS Therapy; in post-market experience, the risk is approximately 0.1% (1 in 1000 patients). Patients undergoing treatment for Major Depressive Disorder, including NeuroStar TMS Therapy should be monitored closely for worsening symptoms and signs of suicidal behavior and/or unusual behavior. The safety of NeuroStar TMS Therapy in the presence of concomitant antidepressant medication was evaluated in a 6-month follow-up open-label clinical trial in patients who had previously responded to acute NeuroStar TMS Therapy. The safety outcomes did not differ from those observed during acute TMS monotherapy.<sup>2</sup>

The safety and effectiveness of NeuroStar TMS Therapy has not been established in the following patient populations or clinical conditions through a controlled clinical trial: Patients who have failed to receive benefit from 2 or more antidepressant medications given at or above minimal effective dose and duration in the current episode or who have had no prior antidepressant medication failure; Patients who cannot tolerate withdrawal of antidepressant medications; Patients who have a suicide plan or have recently attempted suicide; Depression secondary to a general medical condition or substance-induced; seasonal affective disorder; Patients younger than 22 years of age or older than 70 years of age; Patients with history of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder; Patients with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features; Patients with neurological conditions that include history of seizures, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS; Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents; Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators: Patients with major depressive disorder who have failed to receive clinical benefit from ECT or VNS; Patients who are pregnant or nursing. NeuroStar TMS Therapy has not been demonstrated to be equivalent in efficacy to ECT for the treatment of major depressive disorder. Efficacy was not studied in patients using concomitant antidepressant medications or receiving psychotherapy during TMS Therapy treatments. Safety and efficacy have not been established for NeuroStar TMS Therapy beyond a 4-6 week acute course, use of treatment parameters outside the labeled protocol or for maintenance therapy.

NeuroStar TMS Therapy is available by prescription only. Patients should talk to their doctor when considering NeuroStar TMS Therapy as a treatment option. For questions regarding this article, please contact Customer Service at 1-877-600-7555. Full safety and prescribing information is available at www.NeuroStar.com.

- 1. Demitrack MA, Thase ME. Clinical significance of transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant depression: synthesis of recent data. Psychopharm Bull. 2009, 42(2): 5-38
- Janicak P, et al. Transcranial Magnetic Stimulation (TMS) in the Treatment of Major Depression: A Comprehensive Summary of Safety Experience from Acute Exposure, Extended Exposure and During Reintroduction Treatment. Journal of Clinical Psychiatry, February 2008