

Getting to Know BrainsWay Deep TMS



Deep TMS at a Glance

Deep Transcranial Magnetic Stimulation (Deep TMS) is an innovative, noninvasive treatment designed to help patients with mental health and addiction conditions such as Major Depressive Disorder (MDD), Anxious Depression, Obsessive-Compulsive Disorder (OCD), and Smoking Addiction. Using advanced H-Coil technology, Deep TMS delivers electromagnetic pulses to stimulate neurons in specific areas of the brain that are associated with mood regulation, impulse behavior, and cognitive function.





PROVEN EFFICACY

Deep TMS is FDA-cleared for treating depression, anxious depression, OCD, and smoking addiction. Clinical studies have shown it can significantly improve symptoms and quality of life, including among patients that have not seen sufficient benefit from traditional treatment options.



PATIENT FRIENDLY

Deep TMS has no systemic side effects commonly associated with medication, and no potential for memory loss, as sometimes seen with ECT. Sessions are short, and most patients experience no significant downtime, making it easy to integrate into daily life.



OUTPATIENT TREATMENT

Patients are awake and alert during the short treatment session, sitting in a comfortable chair under a padded and cooled helmet.



NO SURGERY OR IMPLANTS

The noninvasive nature of Deep TMS means no needles, no anesthesia, and no permanent implants.



SUSTAINED RESULTS

Many patients report lasting symptom relief after completing a full course of treatment, and maintenance sessions can help to sustain results over time.



10 Things to Know Before You Go

1

NONINVASIVE TREATMENT: Deep TMS is a noninvasive procedure, meaning it doesn't require surgery or implantation of any devices.

2

WELL-TOLERATED PROCEDURE: Side effects, such as mild headache and scalp discomfort, are minimal and typically subside after a few sessions.

3

TREATMENT FREQUENCY: Typically, treatments are scheduled 5 days a week for 4-6 weeks, with subsequent maintenance treatments.

4

NO DOWNTIME: After a session, you can immediately resume normal activities.

5

DURATION OF EACH SESSION: Each treatment lasts approximately 20 to 30 minutes.

6

PERSONALIZED CARE: Treatments are customized to each patient, with a pre-treatment "Mapping" session to tailor the therapy.

7

NO NEED FOR SEDATION: There are no needles, no anesthesia, and no recovery period required.

8

CLINICAL EVIDENCE: Deep TMS has been FDA-cleared and is backed by randomized-controlled clinical trials demonstrating its safety and efficacy.

9

COVERED BY INSURANCE: Medicare and private insurers broadly cover Deep TMS for treatment of Major Depressive Disorder and Anxious Depression.

10

NO METAL IMPLANTS: Individuals with ferromagnetic implants in or near the head may not be candidates for Deep TMS due to the strong magnetic fields used. Inform your doctor if you have metal implants near your head.

Consistency is Key for Deep TMS Success

Let us know about any medication changes before you begin treatment

Inform your doctor about any adjustments in your medication regimen, as this can affect your response to treatment. This includes both prescribed and over-the-counter medication.

Report any changes to your daily habits

Changes in your sleeping patterns, energy levels, mood, or behavior may indicate how your body is responding to the treatment. It's important to report these changes to your provider.

Try not to skip treatments

Consistency is key to success. Skipping sessions can delay progress and affect the overall effectiveness of the treatment plan.

Do not use alcohol or caffeine excessively and avoid drug use during treatment

Excessive alcohol and caffeine intake can negatively impact the effectiveness of Deep TMS. Similarly, drug use can interfere with your response to therapy and may cause unwanted side effects.

Frequently Asked Questions

Q: "How does TMS work?"

A: Deep TMS is a neurostimulation technology that uses a magnetic coil to activate neural networks in target areas of the brain implicated in mental health and addiction disorders. Treatment involves sitting comfortably in a chair in your healthcare provider's office and wearing a helmet containing a patented magnetic coil for approximately 20 minutes. BrainsWay treatment does not cause systemic side effects and does not require hospitalization or anesthesia.

Q: "How do I know if Deep TMS is right for me?"

A: If you are struggling with depression, OCD, or smoking addiction, and other treatments haven't been effective or presented you with significant side effects, Deep TMS may be a good option. The best way to determine if Deep TMS is right for you is by consulting with your doctor, who can evaluate your medical history and discuss the potential benefits and risks based on your individual needs.

Q: "What is the success rate of Deep TMS?"

A: Deep TMS has shown positive results in clinical trials, with many patients reporting significant improvements in mood, anxiety, and overall well-being. The success rate can vary, but many patients experience meaningful symptom relief, with some achieving long-term benefits. Greater than 4 out of 5 patients with depression and greater than 1 out of 2 patients with OCD will achieve a response.¹ Success is generally higher when patients complete the full course of treatment and follow through with maintenance sessions if needed.

Q: "How long will it take to see results?"

A: Many patients begin to notice improvements after 2-4 weeks of treatment, although some may experience benefits earlier. For optimal results, it is important to complete the full recommended course of treatment (as prescribed by your provider). Maintenance sessions may be recommended for continued symptom relief.

Q: "How long do the effects of Deep TMS last?"

A: The duration of the effects of Deep TMS varies from person to person. Many patients report lasting symptom relief for a year or more after completing the initial course of treatment.² Maintenance sessions may be recommended to prolong the effects, especially for those with chronic conditions like depression or OCD.

Q: "Are there any safety concerns related to Deep TMS?"

A: Deep TMS is a noninvasive treatment that has been tested in clinical trials. It is generally well-tolerated, with very few risks. However, as with any medical treatment, it's important to consult your doctor to ensure it is the right choice based on your medical history. Individuals with metal implants in or near the head may not be candidates for Deep TMS due to the strong magnetic fields used.

¹ Tendler A, et al. Deep TMS H1 Coil treatment for depression: Results from a large post marketing data analysis. *Psychiatry Research*. Vol 324, June 2023, 115179

Roth Y, et al. Real-world efficacy of deep TMS for obsessive-compulsive disorder: Post-marketing data collected from twenty-two clinical sites. *J Psychiatr Res*. 2020 Nov 4;S0022-3956(20)31065-7

² Senova S, et al. Durability of antidepressant response to repetitive transcranial magnetic stimulation: Systematic review and meta-analysis. *Brain Stimulation* 12 (2019) 119-128

Q: "Does BrainsWay Deep TMS have any side effects?"

A: While side effects are typically mild, some patients may experience discomfort such as scalp tingling, headache, or facial twitching. These side effects are usually temporary and resolve within a short time. If you experience persistent side effects, it's important to notify your treatment provider. Your provider can adjust your treatment if necessary to ensure your comfort and enhance results.

Q: "Does Deep TMS treatment entail any discomfort?"

A: Some patients report feeling some mild discomfort during the treatment, such as a tapping or tapping-like sensation on the scalp. The sensation is usually brief, and any discomfort generally subsides after several sessions. If discomfort continues or becomes bothersome, your provider can adjust device settings to minimize these sensations.

Q: "Is Deep TMS safe for pregnant women or people with certain health conditions?"

A: Deep TMS treatment for pregnant women or people with implanted medical devices, such as pacemakers or neurostimulators, is not specifically contraindicated by the FDA. That said, it is crucial to inform your healthcare provider about any medical conditions before beginning treatment.

Q: "Are there any risks to having Deep TMS if I have a history of seizures?"

A: If you have a history of seizures or a condition that may predispose you to seizures, speak to your doctor about the appropriateness of Deep TMS treatment. It's crucial to discuss your medical history, including any seizure disorders, with your doctor to determine if Deep TMS is safe for you.

Q: "Will I need to stop my medication or therapy?"

A: You do not need to stop your medications or psychotherapy before beginning Deep TMS therapy. In fact, Deep TMS can be used alongside other treatments, including antidepressants and psychotherapy, to enhance the therapeutic effect. However, always consult with your doctor before making any changes to your treatment plan.

Q: "Can Deep TMS be used to treat conditions other than depression?"

A: Yes, in addition to Major Depressive Disorder (MDD), Deep TMS is FDA-cleared for the treatment of Obsessive-Compulsive Disorder (OCD) and Smoking Addiction. Research is also ongoing into its potential for treating other neurological and psychiatric conditions.

Q: "Can Deep TMS help with anxiety or other mood disorders?"

A: Deep TMS is FDA-cleared for treating depression, OCD, and smoking addiction. It is also FDA-cleared to treat anxiety co-occurring with depression. If you are dealing with anxiety, it's worth discussing this option with your healthcare provider to determine if it could be beneficial for your specific situation.

Q: "Will I need to continue seeing my therapist while undergoing Deep TMS?"

A: Yes, you can continue seeing your therapist during Deep TMS therapy. In fact, many patients find that combining Deep TMS with ongoing psychotherapy can enhance the benefits of both treatments. It's important to communicate with your therapist and treatment team to coordinate care and ensure you're receiving the best possible outcomes.

Q: "What if I miss a treatment session?"

A: Missing a treatment session may impact the effectiveness of your treatment plan. If you need to miss a session, it's important to notify your provider as soon as possible. They can help you reschedule and discuss how to stay on track with your treatment plan to get the best results. Consistency is key for the best treatment response.

Q: "Is Deep TMS covered by insurance?"

A: Many insurance plans cover Deep TMS for FDA-cleared indications such as Major Depressive Disorder (MDD) and Obsessive-Compulsive Disorder (OCD). Coverage may vary depending on your individual insurance provider, so it's a good idea to contact your insurance company beforehand to verify benefits and discuss any potential out-of-pocket costs.

Q: "How do I prepare for my Deep TMS treatment?"

A: There is no special preparation required before your treatment. It's important to arrive well-rested and avoid caffeine or alcohol just before your session. Your doctor or clinician will walk you through the process, so you'll know exactly what to expect. If you have any questions before your appointment, don't hesitate to ask your treatment provider.

Q: "What is the "Mapping" session?"

A: The motor threshold mapping is a preliminary step in Deep TMS therapy where your provider locates the optimal area of your brain to target during treatment and optimal stimulation intensity. Using a magnetic coil, your doctor will stimulate your brain and observe your response to determine the best location and intensity for treatment.

Q: "How long does the Mapping session take?"

A: The initial session usually takes about 30 minutes to an hour, consisting of a mapping process and initial treatment. The motor threshold mapping is an essential part of personalizing your treatment plan.

Q: "Can I drive myself to my Deep TMS appointments?"

A: Yes, you can drive yourself to and from your Deep TMS sessions. The treatment itself is noninvasive and does not require sedation, so you should be able to drive or resume normal activities immediately afterward.

Learn More About Whether this Clinically Proven, Noninvasive Treatment is Right for You

You can:

- ✓ **SPEAK** with your healthcare provider
- ✓ **SCAN** the QR code for more information
- ✓ **VISIT** www.brainsway.com
- ✓ **CALL** us at 844-386-7001
- ✓ **EMAIL** us at DeepTMS@brainsway.com



Indication—BrainsWay Deep TMS™ is indicated by the FDA for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder, who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode. FDA 510(k) No. K122288 (Model 102), FDA 510(k) No. K173540 (Model 104), FDA 510(k) No. K210201, No. K203735 (Models 102 & 104).

Safety Information—Patients should consult with their doctor before undergoing BrainsWay Deep TMS. The most common side effects include headaches and application site pain or discomfort. There is also a very rare risk of seizure associated with the treatment. Patients with metal in or around the head as in metal plates, implants, and stents should not undergo Deep TMS treatment.

