Deep TMS™ Patient Inquiry Guide

Q&A: How to address questions from potential patients about Deep TMS over the phone or email



GOAL: Set an appointment for a Deep TMS consultation

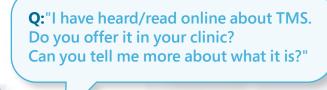
- Educate patients on Deep TMS
- Overcome hesitations they might have about the treatment
- Make sure that they meet the basic criteria for treatment

DO: Always ask for a callback number in case of disconnection.

DO: Always try to keep your answers simple and speak knowledgeably about Deep TMS, reassuring the patient about its efficacy and safety.

DO: For general patient inquiries, mention that the clinic is now offering Deep TMS and ask if the patient is interested to learn more about the treatment option.





A: "Deep transcranial magnetic stimulation (TMS) is a noninvasive in-office brain stimulation procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of mental health and addiction conditions (FDA cleared for Depression including Anxious Depression, OCD, and Smoking Addiction.)" (continued...)

- Noninvasive in-office procedure
- No down-time after treatment
- Short 20-min sessions

- Safe and well-tolerated
- No systemic side effects
- FDA cleared for Depression, OCD, Smoking Addiction

(continued...)

"Treatment consists of approximately 20-minute sessions across a 4-6 week period, in some cases followed by periodic maintenance sessions. During Deep TMS treatment a special helmet containing a magnetic coil is placed over your head, focused on an area of the brain involved in the specific condition. You'll be comfortably sitting in a chair, awake and alert during the treatment and can resume normal activities right afterward. Overall, it is a safe and well-tolerated procedure."

"It can be a great option for people who have not benefited from antidepressant medications or cannot tolerate antidepressant medications due to side-effects."

If they decline a consultation, then you should ALWAYS ask:

"Do you mind me asking what your concerns are, and I'd be happy to clarify?"



Q: "How effective is Deep TMS? / Does it work?"

A: "BrainsWay Deep TMS has been tested in over 60 clinical studies for various clinical indications. Published studies have found that Deep TMS treatment is successful in alleviating symptoms of mental health conditions and offering patients relief. I will be happy to send you our brochure with additional details on success rates, and you can also find more information on BrainsWay's website!"

Q: "How is Deep TMS different from standard TMS / traditional TMS / rTMS / other TMS devices?"

A: "In our clinic we use BrainsWay Deep TMS which is different from standard (or traditional) TMS. BrainsWay's unique coil design enables deeper and broader stimulation than traditional, figure-8 TMS coils, resulting in greater activation of neurons, less likelihood of targeting errors, both of which may increase efficacy."

- Over 60 clinical studies showing significant response and remission rates
- Deeper and broader stimulation than traditional TMS
- Deep TMS has none of the systemic side effects often associated with medication
- Eligibility: no history of or recent episodes of seizures, no metal in or around the head

Q: "How is Deep TMS different from / better than medication?"

A: "Deep TMS is clinically proven to work for patients who have not experienced sufficient benefit from medication and psychotherapy or have had significant side effects that prevented them from remaining on medication. Deep TMS has none of the systemic side effects often associated with medication such as weight gain, sexual dysfunction, nausea, dry mouth, etc. And there are no undesirable effects on cognition or memory loss. The most common side effect can be a mild headache or scalp discomfort that typically goes away after the first few treatments. You can still take medication and pursue therapy while undergoing Deep TMS."

ADDITIONAL INFORMATION

Depression – Real-world data suggests that approximately 3 in 4 patients with depression experience a significant reduction in symptoms, with 1 in 2 reaching remission.

OCD – Approximately 1 in 2 patients with OCD achieve a sustained response. **Smoking Addiction** – Nearly 1 in 3 smokers achieve 4 or more weeks of quitting.

Q: "Am I a good candidate for Deep TMS?"

A: "In order to be a good candidate for Deep TMS, you must have a current diagnosis of depression (or anxious depression, OCD, or smoking addiction), no history of or recent episodes of seizures, no metal in or around the head (dental work is fine), and have been on courses of multiple antidepressant medications without sufficient benefit or with intolerable side effects. We can schedule you for a consultation with our clinical team to discuss the possibility of this being an appropriate treatment for you."

Q: "Is Deep TMS FDA approved?"

A: "BrainsWay Deep TMS has been FDA-cleared to treat depression, anxious depression, OCD, and smoking addiction on the strength of its clinical efficacy and safety."

Q: "Is it safe? What are the side effects? Can it damage my brain?"

A: "BrainsWay's clinical trials have demonstrated Deep TMS to be **safe and well-tolerated** for patients. The most common TMS side effects are temporary, **mild headaches or discomfort at the treatment site**, typically occurring within the **first week** of treatment."

- FDA-cleared to treat depression, anxious depression, OCD, and smoking addiction
- Safe and well-tolerated
- Most common side effect: mild headaches or discomfort at the treatment site
- Over 100K patients have been treated with Deep TMS
- It is NOT like ECT. It is noninvasive, no general anesthesia, no induced seizures. You are awake and alert.

ADDITIONAL INFORMATION

Always mention that patients should consult their doctor to see whether Deep TMS is right for them based on their own personal medical history. It can be noted that BrainsWay's Deep TMS side effects do not include many of those which are associated with antidepressant medications, and also, unlike ECT, patients experience no potential temporary loss of memory function.

Q: "How many patients have you treated with Deep TMS?"

A: [Cite clinic-specific data] – "We've treated approximately [X] patients with Deep TMS and have seen very strong results." Across the US, over 100K patients have been treated with Deep TMS, and it has been validated extensively in placebo-controlled research."

Q: "Is it similar to ECT or "shock therapy"?"

A: "ECT uses electricity to specifically induce a seizure. ECT requires the patient be anesthetized and may entail significant side effects, such as short-term memory loss. BrainsWay Deep TMS does not induce a seizure, does not involve anesthesia, has no effects on memory, and is generally well-tolerated."

Q: "Is it covered by insurance?"

A: Deep TMS insurance coverage depends on the treatment type, geographical location, and insurance plan. Most insurances cover depression treatment. Coverage for OCD is more limited but expanding. Our staff will **verify your insurance eligibility** during the consultation and may **assist in seeking to obtain prior authorization** from your insurance before treatment.

If covered, the only out-of-pocket cost would likely be a co-pay or co-insurance until the deductible has been met. We are happy to **schedule you for a consultation** with one of our staff members to determine if Deep TMS is right for you and verify your insurance coverage."

- Most insurers cover Depression
- Limited (but expanding) OCD coverage
- · We will always verify your insurance eligibility first

ADDITIONAL INFORMATION

Depression/Anxious Depression: Most commercial insurances and Medicare are now covering Deep TMS for depression and anxious depression.

OCD: Several insurers are now covering Deep TMS treatment for OCD, including Highmark BCBS, Centene, HCSC BCBS, Tricare, and Palmetto Medicare. If your insurance plan does not yet cover OCD treatment, we can submit a claim based on medical necessity and pursue any necessary appeals to try to obtain coverage for your case. If unsuccessful, treatment would still be available on a cash-pay basis for [\$X].

Smoking Addiction: Deep TMS treatment for Smoking Addiction is not yet covered by insurance. Our clinic's fee for the course of treatment is [\$X].

Notes	

Q: "What happens during the Deep TMS procedure?"

A: "During the procedure, a helmet holding the H-Coil is placed on your head, sending magnetic pulses to targeted areas of the brain. It is a completely noninvasive procedure where you will be able to catch up on your reading or social media during sessions. You will experience a light tapping sensation on your scalp during the treatment. Each session takes about 20 minutes, after which you will be able to drive yourself home and resume your daily routine."

Q: "How often do I have to come? How long is the procedure?"

A: "BrainsWay's Deep TMS treatment is normally spread out over a few weeks. During this time, patients come in for sessions 5 times per week, and each of these sessions last about 20 minutes. Depending on the condition being treated, there may be additional maintenance sessions after the initial course of treatment."

- Noninvasive in-office 20 minutes procedure
- Special helmet placed over your head
- You feel a clicking sound and feel a tapping sensation in the area of stimulation

For Depression/Anxious Depression:

- Daily sessions for 4 weeks, followed by periodic maintenance sessions.
- Sessions last approximately 20 minutes (3-min intermittent theta burst session is also available).
- Typically, **36 total sessions** would be completed.

For OCD:

- Daily sessions over a 6-week period.
- Treatment sessions involve a brief personalized exposure to activate the relevant areas of the brain, followed by an 18-minute TMS treatment.
- A full course usually requires a total of 29 sessions.

For Smoking Addiction:

- A full course typically requires 3 weeks of daily treatments, followed by one treatment per week for three additional weeks.
- Treatment session consists of a brief exposure designed to activate the relevant brain circuitry, an 18-minute TMS treatment, and brief counseling.
- Total of 18 sessions.

Q: "Is there any discomfort during the procedure? Any down time after the procedure?"

A: "Typically, patients hear a **clicking sound** and feel a **tapping sensation** in the area of stimulation during BrainsWay Deep TMS treatment. To diminish the sound, the patient is provided with **earplugs**. Some patients experience **temporary mild pain or discomfort** in the area of the treatment site. This typically occurs only during the first several sessions of treatment and can be mitigated by over-the-counter pain medication.

There is no "recovery time", so patients can drive home afterwards and return to their usual activities."

Overcoming Barriers Questions Guide

"It sounds	
scary to me"	

"Deep TMS is a very safe procedure. The side-effects are mild, with the most common being headaches and some scalp discomfort during the first few visits. It has none of the systemic side-effects of medication."

"Can I come off my medications if my treatment is successful?"

"A lot of people have come off their medications completely or had their dosages significantly reduced after Deep TMS. It will be a collaborative decision between you and your treating provider."

"Sounds very experimental and unproven"

"TMS treatments, including Deep TMS, have been used in many influential academic hospitals and private clinics across the US and showed significant benefit in treating patients with certain mental conditions. Over 100K patients have been treated with Deep TMS, and in our clinic we've treated approximately [X] patients with Deep TMS and have seen very strong results! TMS and Deep TMS are both FDA-cleared for multiple indications based on a substantial body of clinical evidence and have been in use commercially since 2009."

"How long will the improvement last? Is it a total cure?"

- a. **DEPRESSION/ANXIOUS DEPRESSION**: "The data suggests improvement to be sustained around 1 year on average, but it varies from person to person. It also depends on whether the person is receiving regular maintenance sessions."
- b. OCD: "The data suggests that the average durability is nearly 2 years, with 87% of patients having at least 1 year of durability. But it may vary from person to person as well is depending on whether the person is receiving regular maintenance sessions."
- c. **SMOKING ADDICTION:** "In the clinical study for Deep TMS treatment of smoking addiction, 2 out of 3 patients who quit remained quitters for at least 3 months, but it hasn't yet been studied beyond that timeframe."

Overcoming Barriers Questions Guide (continued)

"It sounds very expensive"

- a. **DEPRESSION/ANXIOUS DEPRESSION:** "Most insurances and Medicare are now covering Deep TMS for depression and anxious depression. Our staff will first verify your coverage benefits and work to help you obtain prior authorization from your insurance plan."
- b. OCD: "Deep TMS treatment for OCD is currently covered by a few insurance companies right now, but if your insurance plan does not yet cover OCD treatment, we will do our best to help you obtain coverage. In the case that insurance does not cover, there would be an out-of-pocket option. I understand that it can be frustrating, but think about your treatment as a long-term investment into your mental health."
- c. **SMOKING ADDICTION:** "Currently, treatment is not covered by insurance, but we are working with insurance companies to change that. In the meantime, out-of-pocket treatment is available. It helps to think about the cost of treatment compared to the cost of buying cigarettes over the course of the year."

"Too much of a time-commitment"

"I understand, it is a big time-commitment, but do you mind if I ask—how long have you been suffering from depression/OCD/smoking addiction? (Listen) Wouldn't you rather spend a few months trying a treatment that does work for patients who haven't improved from medication or therapy, as opposed to doing more of the same?"

"Too busy/won't work with my schedule"

"I completely understand you're very busy, but we make situations like yours work all the time. Most likely, during your busy day you have a lunch break, or time before or after work. Think about it like your mini mental health workout during that time, like going to the gym. Our treatments are very short and have no down time, allowing you to resume your daily activities and get back to work right away! I recommend you come talk to our clinical staff and then we'll see what we can do to make sure you can get the treatment you need on a schedule that accommodates you."

"It's too far of a drive"

"I understand, it is a big commitment, but do you mind if I ask—how long have you been suffering from depression/OCD/smoking addiction? (Listen) I see. So, with that in mind, would you mind making the trip every day for a couple months if it meant that your depression/OCD/smoking addiction became significantly more manageable?"

Q: "How do I get started?"

A: "First, we will **schedule you for a consultation** with one of our providers so you can discuss the treatment in detail and determine if it is a good option for you. Our staff will also verify your insurance benefits to determine if you are eligible for insurance coverage."





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