

# TMS for OCD and smoking cessation

*What the FDA device records say, and what to ask before booking.*

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A device clearance is tied to a named system, indication and label. A clinic's use of the term TMS does not show that it offers the relevant protocol. Ask for the exact device and current patient information before you book.

## OCD

On 17 August 2018, the FDA permitted marketing of the BrainsWay Deep Transcranial Magnetic Stimulation System for OCD. The announcement describes that specific system. It is not a blanket clearance for every coil, protocol or patient group.

Ask the clinician how the proposed use relates to the current label. Ask what assessment and preparation are needed. Ask how the team coordinates with the clinician who manages your other care. Do not change medicines or other treatment based on a directory entry.

## Smoking cessation

FDA record K200957 gives the original substantial-equivalence letter date as 21 August 2020 for the BrainsWay Deep TMS System. An administrative letter dated 2 June 2021 changes the product code and states that the submission was not reviewed again. Do not treat that later letter as a new treatment indication.

The record describes use as an aid in short-term smoking cessation in adults. Ask the clinic to show you the current label and explain the rest of the smoking cessation plan. The clearance does not promise that a person will stop smoking.

## Funding is a separate question

US clearance does not establish funding or authorization in Canada, the UK or Australia. Even in the US, an insurer can use separate coverage rules. The fetched WPS Medicare LCD L34641 limits coverage to its depression criteria and does not cover all other uses. Ask the insurer about your exact indication and device before paying a deposit.

## Sources

- FDA, *FDA permits marketing of transcranial magnetic stimulation for treatment of obsessive compulsive disorder*, 17 August 2018. <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-transcranial-magnetic-stimulation-treatment-obsessive-compulsive-disorder>. Fetched 2026-10-29.
- FDA, BrainsWay Deep TMS System, K200957. Original clearance 21 August 2020; administrative letter 2 June 2021. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf20/](https://www.accessdata.fda.gov/cdrh_docs/pdf20/)

[K200957.pdf](#). Fetched 2026-10-29.

- CMS/WPS, LCD L34641, *Transcranial Magnetic Stimulation (TMS)*, revision effective 26 March 2026. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34641>. Fetched 2026-10-29.

Confirm suitability, protocol and cost with a qualified clinician.

## Frequently asked questions

**Can this guide decide whether TMS is suitable for me?**

No. Confirm suitability, protocol and cost with a qualified clinician.