

## Transcranial magnetic stimulators attract attention



[Elizabeth Cairns](#)



### **As Brainsway pioneers a new option in obsessive compulsive disorder, Vantage looks at how these devices have moved into new indications over the past decade.**

Five years after US clearance for depression, Brainsway's deep transcranial magnetic stimulation system has become the first ever noninvasive medical device approved for treating obsessive compulsive disorder.

Implanted neurostimulators have been used to treat this condition, and a whole suite of other CNS disorders, for years, and patients will surely be grateful no longer to be required to go under the knife. The clinical trial data look fairly convincing, but the product is only approved as second fiddle to drug therapy, and with patients generally requiring 20 to 30 20-minute sessions under the device some could still find it burdensome.

Brainsway's system looks a little like the old-style hairdryers that used to be common in salons: the patient sits in a chair and a helmet enclosing a magnetic coil is lowered over their head. According to Frost & Sullivan analysts, the coil is specifically tailored to OCD, and targets the anterior cingulate cortex rather than the left dorsolateral prefrontal cortex, as in depression.

#### **BOCS clever**

The *de novo* clearance of Brainsway's device in its new indication was based on data from a [sham-controlled trial in 100 OCD patients](#). After six weeks there was a statistically significant improvement in treated patients' average score on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS), the gold standard measure of OCD symptoms severity, versus sham ( $p=0.0127$ ). The improvement was maintained a month later.

Moreover 38.1% of treated patients had a reduction of over 30% in their Y-BOCS score versus 11.1% of patients in the sham group. This difference was also statistically significant at  $p=0.0033$ . Headaches were prevalent in both groups, with 37.5% and 35.3% of Brainsway and sham patients experiencing them respectively.

Though the therapy is non-invasive in that it does not require an incision in the skin or placement of an implant, undergoing the treatment is not exactly a breeze. Pivotal trial patients had to spend 20 minutes under the helmet every day for five weeks, followed by four treatments in the sixth week, making 29 treatment sessions in all.

In practice, patients are expected to undergo 10 weeks of treatment. They will need to have fairly debilitating

drug-resistant OCD to sign up for this level of commitment.

## \$500

According to Frost & Sullivan, treatment for depression with Brainsway's device costs around \$5,000-10,000. But in the US 95% of the cost being picked up by insurance companies, so patients must pay up to \$500 out of pocket for a course of treatment.

Transcranial stimulation has picked up in popularity since the first device, Neuronetics' Neurostar, was approved for drug-resistant depression a decade ago. Now the various devices in this category are approved for disorders including headache and migraine and, more recently, to lessen the symptoms of opioid withdrawal, as painkiller addiction in the US claims ever more lives.

### Selected FDA-approved transcranial magnetic stimulation devices

Company	Device	Indication	Decision date	510(k) number*	FDA device classification 4
Brainsway	Brainsway Deep TMS system	Obsessive compulsive disorder	Aug 2018	-	Transcranial magnetic stimulator
Dyansys	Drug Relief	Opioid withdrawal	May 2018	K173861	Percutaneous nerve stimulator for opioid withdrawal
Innovative Health Solutions	NSS-2	Opioid withdrawal	Nov 2017	DEN170018	Percutaneous nerve stimulator for opioid withdrawal
Nexstim	Nexstim Navigated Brain Therapy system 2	Major depressive disorder	Nov 2017	K171902	Transcranial magnetic stimulator
Electrocore	Gammacore	Headache	Apr 2017	DEN150048	Non-invasive vagus nerve stimulator - headache
Magventure	Magvita	Major depressive disorder	Jul 2015	K150641	Transcranial magnetic stimulator
Magstim	Rapid therapy system	Major depressive disorder	May 2015	K143531	Transcranial magnetic stimulator
Cefaly Technology	Cefaly	Migraine	Mar 2014	DEN120019	Stimulator, nerve, electrical, transcutaneous, for migraine
Eneura	Neuralieive Cerena	Migraine	Dec 2013	DEN130022	Transcranial magnetic stimulator for the treatment of migraine headache
Brainsway	Brainsway Deep TMS system	Major depressive disorder	Jan 2013	K122288	Transcranial magnetic stimulator
Neuronetics	Neurostar	Major depressive disorder	Oct 2008	DEN070003	Transcranial magnetic stimulator

\*DEN code denotes a de novo 510(k) clearance; K code denotes a standard 510(k). Source: EvaluateMedTech.

In this respect the technique is following neurostimulators, which have moved from deep brain stimulation for CNS disorders to a wider range of uses concerning the peripheral nerves ([Neurostimulation approvals show therapy's potential](#), October 10, 2017).

In terms of regulatory approvals, though, transcranial magnetic stimulation in the US has some way to go before it matches the European market. Brainsway's device alone is CE marked for conditions including Alzheimer's disease, autism, bipolar disorder, chronic pain, depression, Parkinson's disease and schizophrenia.

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