

SAINT Neuromodulation Therapy (Magnus Medical)

Request: Maintain 2025 APC assignments for SAINT Neuromodulation Therapy Services (CPT codes 0890T, 0891T, 0892T)

- SAINT System (Stanford Accelerated Intelligent Neuromodulation Therapy) is a breakthrough medical device cleared by FDA for the treatment of major depressive disorder in adults who fail to achieve improvement from medication
- Personalized, Image-Guided, Accelerated Transcranial Magnetic Stimulation (TMS)

Presenters: Brandon Bentzley, MD PhD

- Board-Certified Psychiatrist
- Magnus Medical, Co-Founder and Chief Scientific Officer

Eric Greig, Cooley LLP, Partner

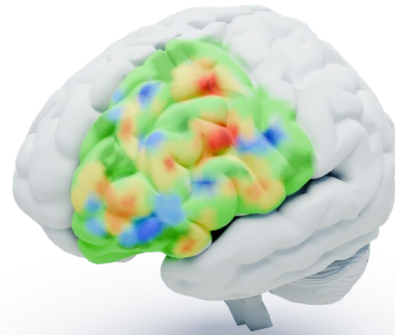
SAINT is the only TMS therapy combining fMRI targeting and a 5-day TMS treatment Protocol



STEP 1

Functional & Structural MRI

Approximately 45-minute scan to map the brain using our proprietary sequences



STEP 2

Individual Target Identification

Proprietary algorithm identifies optimal brain location to target with precise, individualized stimulation



STEP 3

5-day Accelerated TMS Therapy Protocol

Unique theta burst stimulation delivered in 10 precisely-timed sessions, each day for 5 days, with real-time neuronavigation.

Best in class efficacy repeated across clinical trials (total n>400)



Williams 2018, *Brain*

Open Label
5/6, 80% remitted by MADRS



Cole 2020, *AJP*

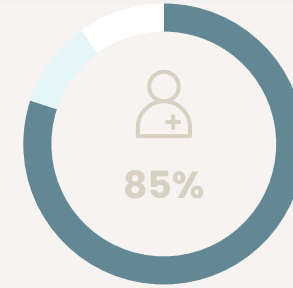
Open Label
19/21, 90% remitted by MADRS



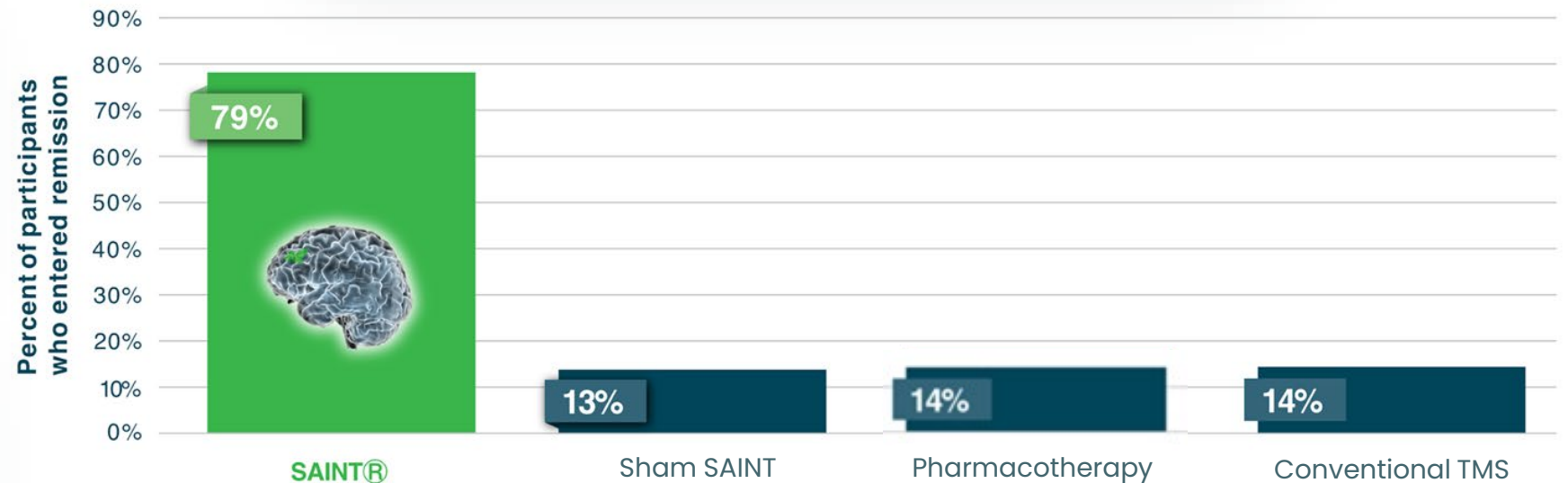
Cole 2022, *AJP*

RCT
11/14, 79% remitted – Active
2/15, 13% remitted – Sham

In clinical trials, SAINT relieved symptoms for **85% of clinical trial participants**, with no serious adverse events, in just 5 days.



Best in class clinical effectiveness



Hospital Resource Investment: SAINT Treatment Day

- **SAINT Software and Equipment Cost**
 - The per-service cost for the hospital to use the specialized SAINT equipment, software, and ongoing support during stimulation treatment sessions and between treatment days, involves an episode-of-care fee of \$18,400, divided over a five-day episode of care: **\$3,680 per day**
- **Cost of Supplies, Clinical Labor, and Overhead Per Day of Treatment**
 - Supplies: Per-day cost of single-use supplies such as bite block, earplugs, surgical tape, and other items
 - Clinical Labor: 290 minutes of a trained TMS technologist
 - Overhead: 10+ hours to repeatedly deliver precisely-timed stimulation on an hourly basis; dedicated space and resources to remain on-site for regular monitoring.
 - Cost for these additional resources are estimated at **~\$1,900 per day**, using a cross-walk to conventional TMS (CPT codes 90869 and 90868), times 10 to reflect 10 units of stimulation per day
- **Hospitals' Estimated Total Per-Service Costs = ~\$5,500 per day**
 - No material difference in hospitals' costs among treatment days

2026 Proposed APC Assignment Concerns



- CMS assigned SAINT treatment delivery procedures (0890T, 0891T, 0892T) to New Technology APC 1525 to align payment with hospital costs and facilitate access
- In the proposed CY 2026 OPPS rule, CMS would assign codes 0890T and 0891T to New Technology APCs 1521 and 1522, respectively
 - Reassignment would reduce hospital reimbursement by 40–50%
 - The cost of delivering these procedures is at least two times the proposed payment rates

CPT ® Code ¹	Description	Provider 1	2025 NT APC and Payment Rate	Proposed 2026 APC and Payment Rate
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day		1525 (\$3,750)	1521 (\$1,950) <u>-48% reduction</u>
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management; subsequent treatment day		1525 (\$3,750)	1522 (\$2,250) <u>-40% reduction</u>
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management; subsequent motor threshold redetermination with delivery and management, per treatment day		1525 (\$3,750)	1525 (\$3750)

Data Analysis Shows High Variability in Reported Costs from a Single Hospital is Driving Average Cost Reduction and Proposed Payment Cuts

- Only two (2) hospitals nationwide began offering outpatient SAINT treatment in 2024, after codes became effective July 1, with 12-15 Medicare patients treated in total
- Novel technology and innovative protocol created high variability in reported costs. “Provider 2” has acknowledged that an error in revenue code assignment and charges caused under-reporting of costs
 - Provider 2’s reported costs of <\$500 for 0890T and 0891T are ~10% of the actual cost and Provider 1’s reported costs for SAINT
- Claims from ~7 patients from “Provider 2” dramatically reduced average reported costs for two of the three SAINT treatment delivery codes (0890T and 0891)

Hospital	HCPCS	Average Charges	Revenue Code	CCR	Average Costs	Units
Provider 1	0890T	\$7,735	0900	0.5799	\$4,485	(1)*
Provider 1	0891T	\$7,735	0900	0.5799	\$4,485	17
Provider 1	0892T	\$7,735	0900	0.5799	\$4,485	(1)*
Provider 2	0890T	\$4,600	0361	0.1042	\$479	(1)*
Provider 2	0891T	\$4,600	0361	0.1042	\$479	33

Analysis provided by Braid-Forbes Health Research

*Indicates a value of 10 or less

Summary

- Request: Recommend that CMS **maintain** APC assignments for SAINT services (codes 0890T, 0891T, 0892T) to ensure continued outpatient access to this highly effective, accelerated therapy for severe depression
 - Reimbursement reductions of 40–50% will create barrier to continued access
 - Very low volume of services in 2024, and high variability in reported costs, do not support dramatic change in payment policy
 - Creating significant differences in payment amounts among SAINT services will create inappropriate market distortion

Thank you!