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Medicare Expands Coverage For Spinal Cord Stimulation To Treat Diabetic Peripheral Neuropathy

Nevro Executives Say Their Device Offers An Option For Patients With Pain

by [Brian Bossetta](#)

Medicare's recent expansion of coverage for spinal cord stimulation therapy to treat diabetic peripheral neuropathy could mean relief for some 11 million Americans. Executives from Redwood City, CA device maker Nevro talked to *Medtech Insight* about the expansion and what it means for patients who use their technology.

Millions of Americans with diabetes struggle with diabetic peripheral neuropathy, an often painful complication of the disease that usually starts in the feet and legs before moving up to the hands and arms.

Common symptoms, which usually worsen at night, can include numbness, reduced ability to feel pain or temperature changes, tingling and burning, sharp pain and cramps, muscle weakness, severe foot damage, and extreme sensitivity to touch.

While the condition mostly affects those with type 2 diabetes, it can develop in type 1 diabetics as well.

Spinal cord stimulation (SCS) therapy — which delivers mild electrical impulses to the spinal cord to interrupt pain signals to the brain — is a treatment option that just became available to millions of more Americans with the condition.

The Centers for Medicare and Medicaid Services (CMS) recently expanded SCS coverage into 12

states — Arkansas, Colorado, Delaware, Florida, Louisiana, Maryland, Mississippi, New Mexico, New Jersey, Oklahoma, Pennsylvania, and Texas as well as Washington, DC — making the treatment now covered across the entire US and accessible to 11 million more Americans with government plans.

The P is for Pain

But while diabetic peripheral neuropathy, or DPN, represents the entirety of the disease process, David Caraway, chief medical officer at medical device company Nevro, prefers the anacronym PDN, or painful diabetic neuropathy, because treating the pain is his primary focus.

“Some patients describe the burning sensation and pain in their feet like walking on broken glass.” — Carla Monacelli

As Caraway explained to *Medtech Insight*, diabetics that experience PDN represent a subgroup of overall diabetics. Of the 37 million Americans with diabetes, half of those, around 18 million, develop diabetic neuropathy; but only half of those, around 9 million, develop pain.

But more specifically, half of those, 4.5 million, do not respond well to traditional treatments such as medication and need an alternative.

For this group, Caraway believes SCS with Nevro’s Senza HFX — an implantable pacemaker-like device — can be the solution.

What makes Senza’s line of high-frequency 10kHz systems unique, Caraway said, is that the frequency stimulates 10,000 times per second, which is much higher than the nerves can track and at amplitudes where the nerves do not feel any stimulation. In contrast, the stimulation rate for traditional spinal cord stimulation is much slower, so patients still feel the vibrations and tingling sensations, Caraway added.

“Our system is not meant to mask the pain but to modulate or change the pain impulses on the way to the brain,” he said.

Backed by Data

Though first approved by the FDA in 2015 to treat chronic low-back and leg pain, the Senza HFX became the first SCS device approved to treat PDN in July 2021. That expanded indication, Caraway said, was backed by two years of data from [SENZA PDN](#), a 430-patient randomized trial

comparing HFX therapy plus medical management to medical management alone. (Also see "[Nevro's HFX Offers Durable Benefit In People Suffering Diabetic Pain](#)" - Medtech Insight, 7 Jun, 2022.)

Senza's efficacy, according to Caraway, is further supported by another [randomized trial](#) of 216 patients split equally into the Senza SCS study arm and a cohort receiving conventional treatment.

The study, which was published in *Diabetes Care*, showed "marked improvement" in many different domains, Caraway said, including pain reduction as well as sleep quality.

One of the more surprising benefits from the study, he added, was improvement in sensory deficits for the majority of patients. "That's important because we're talking about a disease process that should be progressively deteriorating, which is normally what you see in these patients," Caraway said, "but we saw improvement."

This is significant, Caraway explained, because restoring sensation can prevent injuries to the feet, such as burns from hot sidewalks that many patients with PDN cannot feel. "So, if we can give them back sensation that's really protective and can lead to less trauma and perhaps less amputations," he said.

Because Senza's 10kHz is free of paresthesia — the burning and tingling associated with PDN — it also increases quality of life by reducing dependence on drugs, according to Carla Monacelli, Nevro vice president of government affairs and market access.

"Our device can make you more independent," Monacelli told *Medtech Insight*, "you can drive with it."

But the other bonus, in Monacelli's view, is that it can limit or do away with the need for painkillers. "It's helped many patients have a reduction in meds, if not going off them completely," Monacelli said.

Caraway noted that many patients find the medications they are prescribed for PDN intolerable, even when they work as indicated. Caraway said up to 65% of patients discontinue medications even when they get results because the side effects are just not worth it. "They feel off, they gain weight, they just can't tolerate the side effects," he said. "So that leaves this large pool of patients with no options and they're miserable."

And with Medicare's coverage of SCS now in all 50 states, the therapy is being embraced by more doctors as an alternative to treatments such as painkillers, injections and surgery.

“We're excited because we think we've got an answer for these millions of patients.” — David Caraway

Doctors are especially passionate about the treatment for PDN, according to Monacelli, because patients were left without options once traditional approaches failed.

“Some patients describe the burning sensation and pain in their feet like walking on broken glass,” she said. “But we're getting great results.”

Learning from the Patient

Nevro's newest model, the Senza HFX iQ, Monacelli said, further separates the company's SCS technology from the competition.

This model uses a sophisticated AI algorithm based on data from 80,000 patients over the last 10 years, including 20 million datapoints related to patients' quality-of-life and function, programming changes, and demographics.

In other words, it learns over time.

“It gets smarter as it's in you,” Monacelli said. “Nobody else has this algorithm. It takes the guesswork out.”

Caraway expects the AI platform to lead to faster, better patient outcomes.

In a real-world study of HFX iQ, according to data provided by Nevro, 87% of patients reported moderate to significant improvement in symptoms, 92% preferred using a digital patient interface to adjust their therapy over more frequent programming calls, and 82% were satisfied or very satisfied with using the patient interface to make therapy adjustments.

The newer model is also helping the company gain ground on some of its larger competitors, such as Abbott, Boston Scientific, and Medtronic. In March, Nevro CEO Keith Grossman cited the Senza HFX iQ launch as an important growth driver for the company. (Also see "[Nevro Attacks Pain And Competition With Individualized AI-Enabled Spinal Cord Stimulator](#)" - Medtech Insight, 6 Apr, 2023.)

But for Caraway, the bottom line is that with the expansion of government coverage more patients dealing with PDN are going to have access to the care they need. And many, he noted,

are not only Medicare recipients but Medicaid as well.

“It’s a remarkably effective therapy,” Caraway said. “And we throw into that the improvements in sleep, mood, and function. Nothing like that has been seen in this space. So that’s why we’re excited because we think we’ve got an answer for these millions of patients.”