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Medtronic shares impact of Medicare coverage updates that now allow nationwide access to spinal cord stimulation therapy for the treatment of painful diabetic peripheral neuropathy

An additional 11 million Medicare beneficiaries will now have access to coverage for spinal cord stimulation therapy for the treatment of painful diabetic peripheral neuropathy

Medtronic, the global leader in healthcare technology, is pleased to share that Medicare has expanded coverage for spinal cord stimulation (SCS) therapy for patients with painful diabetic peripheral neuropathy (DPN).

Two of Medicare's Administrative Contractors (MACs), First Coast Service Options and Novitas Solutions, will retire their local coverage determinations (LCD) for SCS with an anticipated effective date of July 13, 2023, and refer to the CMS National Coverage Determination (NCD) for SCS which places no restrictions on coverage for patients who meet medical necessity criteria. This decision will provide an additional 11 million Medicare beneficiaries in 12 states (Arkansas, Colorado, Delaware, Florida, Louisiana, Maryland, Mississippi, New Mexico, New Jersey, Oklahoma, Pennsylvania, and Texas), along with Washington D.C., with access to SCS coverage for treatment of painful DPN.

"This is impactful news for patients in these states with Medicare or Medicare Advantage insurance coverage," said Dr. Michael Fishman, M.D., M.B.A., Anesthesiologist and Interventional Pain Medicine specialist in Lancaster, Pennsylvania. "Patients with DPN often suffer from debilitating pain for many years, and until recently, many were left with limited options once they exhausted conventional treatments. There is durable clinical evidence supporting the use of SCS therapy for DPN and I'm pleased to see that Medicare will now extend coverage to all beneficiaries nationwide, which represents 35 million people living with this painful condition."

DPN is a debilitating and progressive neurological disorder that affects approximately 30% of people with diabetes, significantly impacting both quality of life and functional ability, including mood, social relationships, and sleep.[1] DPN occurs when high blood sugar (glucose) damages nerves in the body, most often in the legs and feet, which can lead to numbness and burning or stabbing pain. In some patients, the pain can become progressively

worse and excruciating. Patients may be treated with medications, but they are often only partially effective and can result in serious side effects.

Independent studies show patients with DPN achieve significant pain relief when treated with SCS compared to conventional treatments alone.[2,3] In two randomized controlled trials, 70% of patients with DPN receiving SCS treatment experienced pain relief compared to 6% of patients receiving only conventional treatments. Those treated with SCS experienced a 53% average reduction in pain, compared to 0% among patients receiving only conventional treatments. Meta-analyses show a significant improvement in health-related quality of life in patients with DPN treated with SCS compared to those receiving only conventional treatments.[4] A long-term analysis of patients treated in one of the studies using Medtronic SCS technology showed 80% of DPN patients treated with SCS continued to use their devices at five years to treat their pain.[5]

“We’re proud to have played a role in helping communicate the value of this therapy to encourage greater access for patients seeking relief from truly debilitating pain,” said Wendy Chan, vice president, Health Economics, Policy, and Reimbursement for Medtronic’s Neuromodulation, Neurovascular, and Pelvic Health Operating Units, which are part of the Neuroscience Portfolio at Medtronic. “Thanks to the local physicians and specialty societies who also advocated for SCS therapy to treat DPN, 11 million more Medicare beneficiaries will now have access to therapy.”

Medtronic estimates that up to 800,000 US patients suffer from moderate to severe DPN symptoms that are not resolved through conventional medical management approaches, like drugs.[6,7]

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