SCS Candidates Quick Guide

- Chronic Back and Leg Pain
- Nonsurgical Back Pain (NSBP)
- Painful Diabetic Neuropathy (PDN)



Intelligent. Responsive. Relief.



Therapy Built on Level 1 Evidence



I0 kHz Therapy™

Traditional SCS

HFX AdaptivA/[™] technology

is built on indication-specific algorithms, enhanced by big data and proven outcomes*



FDA Superiority Labeling for Both Back and Leg Pain¹

Potential Back & Leg Pain Candidates

- Chronic intractable neuropathic pain of the trunk and limbs
- Typically failed less invasive treatments such as physical therapy, injections, and medications
- Failed back surgery (not a requirement)
- Back and/or leg pain
- Radiating nerve pain of the limbs

ICD-10 Diagnosis Codes

| Code Description | ICD-10-CM Code |
|---------------------------------|---------------------------------------------------------------------------------|
| Failed Back Surgery Syndrome | M96.1 |
| Disc Degeneration | M51.35, M51.36 |
| Disc Disorder | M51.06, M51.15, M51.16, M51.17 |
| Disc Displacement | M51.25, M51.26 |
| Dorsalgia | M54.89, M54.9 |
| Lumbago | M54.40, M54.41, M54.42 |
| Radiculopathy | M54.15, M54.16, M54.17 |
| Spinal Stenosis | M48.06X, M48.07 |
| Spondylopathy | M48.35, M48.36, M48.37, M48.8X5, M48.8X6, M48.8X7, M49.85, M49.86, M49.87 |
| Spondylosis | M47.10, M47.16, M47.25, M47.26, M47.27, M47.815, M47.817 |

The First SCS with NSBP Indication²

Potential NSBP Candidates

- Diagnosed with chronic, refractory axial low back pain
- Pain has a predominant neuropathic component
- ✓ No prior back surgery
- Not a candidate for back surgery based on an assessment by a spine surgeon

| Code Description | Description ICD-10-CM Code | |
|--------------------------------------------------------|-----------------------------------------------|--|
| Intervertebral Disc Disorders/ Disc Degeneration | M51.16, M51.36, M51.26, M51.17 | |
| Spondylosis | M47.816, M47.817, M47.814, M54,812, M47.26 | |
| Radiculopathy | M54.16, M54.17, M54.12, M54.14 | |
| Spinal Stenosis | M48.062, M48.061, M48.02 | |

Poor Candidates: Mechanical pain such as joint pain, unrealistic expectations, active opioid addiction or medication abuse

The Most Effective Treatment for Refractory PDN[®]

Potential PDN Candidates

- Diagnosed with diabetes
- Diagnosed with painful diabetic neuropathy for > 1 year or more
- Tried 2+ medications
- ✓ Pain VAS \ge 5
- ✓ HbA1c ≤ 10%
- Deemed medically suitable for minimally invasive procedure

| Code Description | ICD-10-CM Code |
|-------------------------------------------------------------------------------------|----------------|
| Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified | E08.40 |
| Diabetes mellitus due to underlying condition with diabetic polyneuropathy | E08.42 |
| Type 1 diabetes mellitus with diabetic neuropathy, unspecified | E10.40 |
| Type 1 diabetes mellitus with diabetic polyneuropathy | E10.42 |
| Type 2 diabetes mellitus with diabetic neuropathy, unspecified | E11.40 |
| Type 2 diabetes mellitus with diabetic polyneuropathy | E11.42 |
| Other specified diabetes mellitus with diabetic neuropathy, unspecified | E13.40 |
| Other specified diabetes mellitus with diabetic polyneuropathy | E13.42 |

Determinations about the medical needs of a patient and appropriate patient selection are solely the decisions of the physician. These recommendations are not intended to represent a guarantee of coverage or medical necessity. The recommendations are based on the criteria of the primary study of the HFX device for use in patients. Information provided by Nevro is presented for illustrative purposes only and is not intended to and does not constitute coding, reimbursement, legal, business, or other advice. It is the responsibility of the healthcare provider to make determinations regarding the medical necessity of treatment for their patients. Patient experiences with the HFX iQ[™] or Senza Omnia[™] spinal cord stimulation (SCS) system vary by individual, including the amount of pain relief. The occurrence of adverse effects associated with SCS implant surgery or use also varies by patient.

Indications for Use: The HFX iQ, Senza Omnia, and HFX Trial SCS systems aid in the management of chronic intractable pain of the trunk and/or limbs, and, when programmed to 10 kHz, are indicated as aids in the management of chronic intractable pain of the trunk and/or limbs, and, when programmed to 10 kHz, are indicated as aids in the management of chronic intractable pain of the lower limbs associated with diabetic neuropathy and the management of non-surgical refractory back pain. **Contraindications**: These include patients who are poor SCS surgical candidates, are unable to operate the SCS system and fail to receive effective pain relief during trial stimulation. **Warnings**: Interference with other implanted stimulators, may result in sensing problems or inappropriate responses. Sources of electromagnetic interference may result in unexpected changes in stimulation, serious patient injury and system damage. Energy from diathermy can cause tissue damage, resulting in severe injury or death. Senza implantable stimulators are MR conditional and scanning under different conditions may result in severe patient injury or device malfunction. Use of certain medical devices or procedures (electrocautery, radiation therapy, ultrasonic scanning) may result in device damage. Induced electrical currents from radiofrequency (RF) or microwave ablation may cause heating, resulting in tissue damage. **Precautions**: Avoid activities that put stress on the implanted components. Safety has not been established for Transcranial Magnetic Stimulation (TMS) or Electroconvulsive Therapy (ECT) in patients who have an implant site, infection and other surgical risks. Device related adverse events may include loss of pain relief or parestisal, undesirable change in stimulation (uncomfortable, jolting or shocking sensation), tissue reaction or allergy to implanted materials. Refer to www.nevro.com/manuals for product manuals with complete indications, contraindications, warnings, precautions and potential adverse events.



Real-Time App Engagement



Real-time quality of life and device metrics enable more impactful patient interactions¹

Patients report *pain relief in significantly less time* than with traditional programming¹



Pain Relief in Less Time

Additional Benefits



No restrictions on driving

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No restrictions on sleeping



No uncomfortable stimulation

Powering HFX iQ

* HFX AdaptivAI[®] technology includes an advanced algorithm with an ability to interlace bipoles. Senza HFX iQ uses a fixed set of instructions to provide optimized treatment recommendations that utilize direct patient input from assessments on pain and quality of life measures.

1. Data on file. 2. Kapural, L., et al. (2016). Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pair. 24-month results from a multicenter, randomized, controlled pivotal trial. *Neurosurgery*, 79(5), 667–677. 3. Patel, N.P., et al. (2023). Durable responses at 24 months with high-frequency spinal cord stimulation for nonsurgical refractory back pain. *J Neurosurg Spine*:1-11. 4. Petersen, E., et al. (2023). Long-Term Efficacy of High-Frequency (10 kH2) Spinal Cord Stimulation for the Treatment of Painful Diabetic Neuropathy: 24-Month Results of a Randomized Controlled Trial. *Diabetes Research and Clinical Practice*, 110865. HFX, the HFX logo, HFX iQ, HFX AdaptivAI, NEVRO and the

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