2026 Reference Guide Percutaneous Electrical Nerve Stimulator (PENS)

The NS100 PNS/PENS is an FDA cleared (Dec 20, 2021), Trigeminocervical (TCN) and Vagus Nerve neurostimulator for the treatment of Painful Diabetic Neuropathy (K212859). This medical device was issued under First Relief which subsequently was rebranded to NS100. It is a programmable, software and voltage-controlled Class 2 medical device that is placed by or under the direction of a medical doctor, or midlevel in certain states. It is a wearable, battery-operated device that is designed to administer periodical low level electrical pulses to the ear over twenty days from the time of activation and implantation of the device.

This programmable, software and voltage-controlled PENS/PNS device requires the precise implantation of 4 titanium electrode arrays each with a 0.0201 cm2 surface area producing a maximum charge density of 65.67 @ 1K microcoulomb/cm2 and Max Average Power Density (W/cm2) of 0.346@ 1K Ohm. As such, these electrode arrays propagate a precisely and well defined, modulating, 1-10Hz differing, interpulse, physiologic rectangular waveform current along the exact implanted branches of Cranial Nerves 5,7,9,10, and the distal C1-2-3 cervical (C1-2-3) spinal root nerves that require pre-implantation identification only by or under the guidance of a physician utilizing real time impedance drop measurement and closed loop feedback.

Neurodynamics exclusively offers the NS100 and associated device training as well as revenue cycle management (RCM) services to its clients. With the offering of these turnkey services, Neurodynamics complies with numerous government agencies, laws and regulations, and payer policies.

OVERVIEW

- NS100 was cleared by the FDA's Division of Neuromodulation and Physical Medicine Devices, Office of Neurological and Physical Medicine Devices, Office of Product Evaluation and Quality Center for Devices and Radiological Health.
- NS100 was FDA cleared based on its substantial technological equivalence to its predicate — the Sprint Peripheral Nerve Stimulator (PNS) System (K202660).
- Four strategically placed Titanium needle electrode arrays are implanted directly into the ear nerves, preprogrammed by the Programmable Technical Unit based on the provider's diagnosis of the patient.
- Temporary device is worn for up to 20 days with possible results lasting up to 6 months or longer.
- Predetermination/billing process is managed by NeuroDynamics to mitigate denials.
- One on one training provided by our team.
- Device is covered by most Commercial payers and Medicare.

This document contains the following sections:

I. FDA Information

The following link provides the FDA December 20, 2021 510(k)
https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212859.pdf

II. Billing Services

We offer comprehensive billing services includes the completion of the following: (1) client set up, (2) predetermination, and (3) post procedure adjudication as described below.

Client Set Up

- Enroll providers into clearinghouse to allow us to submit billed claims
  - Claim is billed under the medical provider or group NPI
  - We are set up for submission of the claims only. All remits remain with provider.
- Establish a secure method for transfer of data (i.e., secure dropbox, secure fax, secure email)
- Set up each provider associated with the facility/practice into NeuroDynamics platform
- Initiate billing kickoff call and provide education on billing sample patient packet.

Predetermination (for each patient referral)

- Review of patient demographics complete including insurance eligibility verification
- Review documentation to verify a clinical note within last three to one year of documented chronic diabetic peripheral neuropathy pain with associated diagnoses code(s)
- Review documentation for prior treatment modalities that failed within the last three months to one year (i.e., pain meds, physical therapy, injections)
- Review documentation to verify a Numerical Rating Scale (NRS) pain score of 5 or greater for NRS pain scale of 0-10 within last three to six months of diabetic peripheral neuropathy
- Review of the Letter of Medical Necessity (LOMN).

Once the patient information is verified as complete, we perform the prior authorization and/or predetermination for applicable patient referrals and as needed, prepares necessary appeals, and/or assist with peer-to-peer payer requests. Upon predetermination approval, we informs provider of patients that are ready to schedule.

Post Procedure Adjudication (for each patient referral)

After the procedure is completed, NeuroDynamics performs the following tasks:

- Review day of procedure notes and signed consent / procedure requisition form
- Bill the claim
- Confirm receipt of the claim by payer and the associated notes (when applicable)
- Receive day of removal notes from provider and place in patient file.

As needed, we prepare necessary appeals, and/or assist with peer-to-peer payer requests. Neurodynamics places phone calls or checks appropriate website/portal to payer in accordance with the state prompt payment laws for payment status. We post the remit and provides a weekly payment posting and reconciliation report to the provider. All remits remain with the provider.

III. Coding and Payment Guide for Reimbursement

For the PENS, we use CMS' National Coverage Decision (NCD) 160.7.1 entitled "Assessing Patients Suitability for Electrical Nerve Stimulation Therapy" that was implemented in 2006, and provides, in part:

- Indications and Limitations of Coverage CIM 35-46 - Electrical nerve stimulation is an accepted modality for

assessing a patient's suitability for ongoing treatment with a transcutaneous [penetrating, entering, or passing through intact skin] or an implanted nerve stimulator; and

- Percutaneous Electrical Nerve Stimulation (PENS) - "This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through/under the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, permanent implantation of electrodes is warranted."

The following provides the coding and national payment rates for an office setting and outpatient hospital setting.

III.i. Office Setting – POS 11

The following are the 2026 Medicare coding and national payment rates for PENS procedures performed in the office setting.

Procedure Description	HCPCS/ CPT	Units	2026 Medicare National Average
Percutaneous implantation of neurostimulator electrode array	64555	1	$ 2,223.50
Implantable neurostimulator, pulse generator, any type	L8679	1	$10,832.18

HCPCS/CPT

64555 Percutaneous implantation of neurostimulator electrode array

L8679 Implantable neurostimulator, pulse generator, any type

III.ii. Outpatient Hospital – POS 22

The following are the 2026 Medicare coding and national payment rates for PENS procedures performed in the outpatient hospital setting.

Outpatient Hospital (Traditional Medicare), UB-04

Rev. Code	Revenue Description	HCPCS/ CPT	Units	Medicare National Average
361	Operating Room Services: Minor Surgery	64555	1	$7,040.8
278	Medical/Surgical Supplies and Devices: Other implants	C1767	1	Status Indicator N
270	Medical/Surgical Supplies and Devices: General (Steri-Strips, Alcohol wipes, Tegaderm)	99070	12	Status Indicator N
982	Professional Fee, Outpatient Services	64555	1	$293.93

HCPCS/CPT

64555 Percutaneous implantation of neurostimulator electrode array C1767 Generator, neurostimulator (implantable), non-rechargeable

Outpatient Hospital (All Other Payers except Medicaid), UB-04

Rev. Code	Revenue Description	HCPCS/ CPT	Units	Medicare National Average

361	Operating Room Services: Minor Surgery	64555	1	$7,040.8
278	Medical/Surgical Supplies and Devices: Other implants	L8679	1	Status Indicator N
270	Medical/Surgical Supplies and Devices: General (Steri-Strips, Alcohol wipes, Tegaderm)	99070	12	Status Indicator N

HCPCS/CPT
64555 Percutaneous implantation of neurostimulator electrode array
L8679 Implantable neurostimulator, pulse generator, any type

Outpatient Hospital (All Other Payers except Medicaid), HCFA 1500

Revenue Description	HCPCS/ CPT	Units	Medicare National Average
Professional Fee, Outpatient Services	64555	1	$293.93

III.iii. Ambulatory Surgical Center – POS 24

The following are the 2026 Medicare coding and national payment rates for PENS procedures performed in an Ambulatory Surgical (ASC) setting

ASC-Ambulatory Surgical Center – POS-24 (Traditional Medicare) HCFA

Rev. Code	Revenue Description	HCPCS/ CPT	Units	Medicare National Average
361	Operating Room Services: Minor Surgery	64555	1	**$5781.10.**
278	Medical/Surgical Supplies and Devices: Other implants	L8679	1	Status Indicator N

Codes would be bundled in an ASC, we would bill both L8679 and 64555, and all payment would go under 64555.

ASC-Ambulatory Surgical Center – POS-24 (All Other Payers except Medicaid)

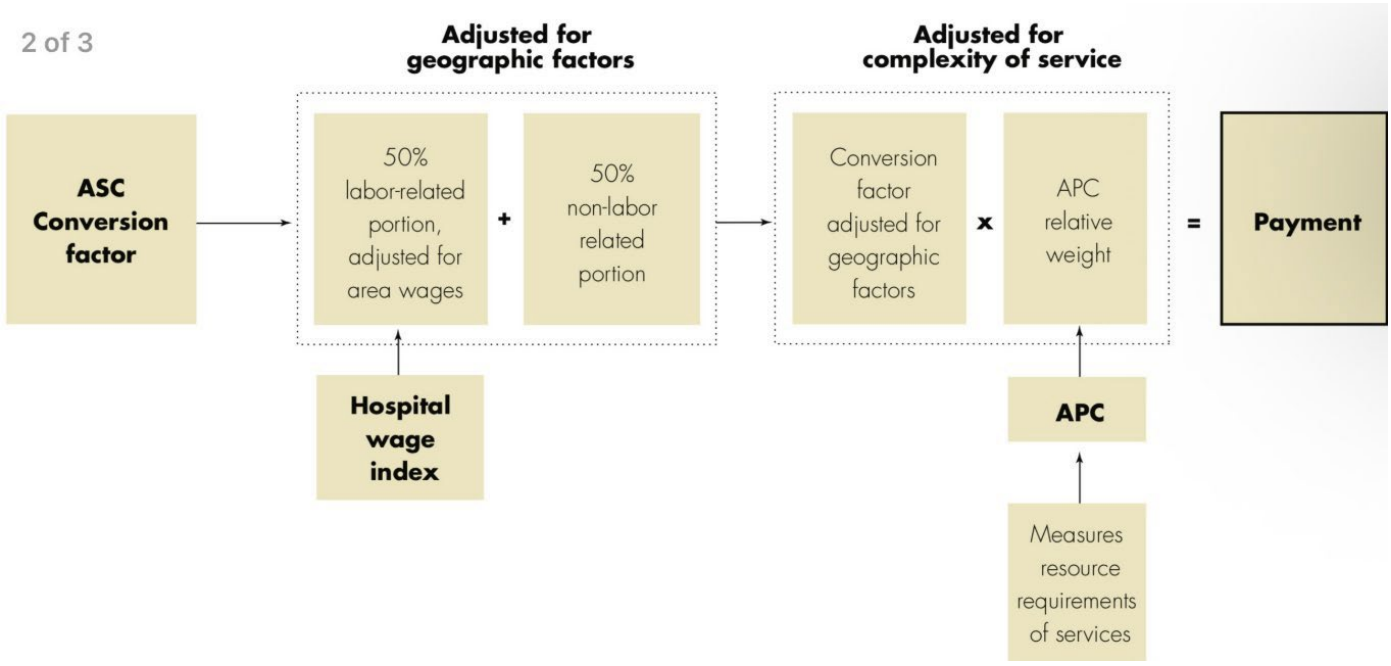
Rev. Code	Revenue Description	HCPCS/ CPT	Units	Medicare National Average
361	Operating Room Services: Minor Surgery	64555	1	**$5781.10.**
278	Medical/Surgical Supplies and Devices: Other implants	L8679	1	Status Indicator N

Commercial billing is pursuant to the provider contracting amount but does follow the CMS rules

HCPCS/CPT
POS is **24**

64555 Percutaneous implantation of neurostimulator electrode array
L8679 Implantable neurostimulator, pulse generator, any type

ASC conversion factor formula:



MAC-ASC FEE SCHEDULES

MAC Sites to obtain specific ASC reimbursement per zip code

NGS-ASC Fee Schedule-

https://www.ngsmedicare.com/fee-schedule-lookup?lob=96664&state=97133&rgion=93623

WPS-ASC Fee Schedule-Spreadsheet

https://www.wpsgha.com/guides-resources/view/1244

Palmetto-ASC Fee Schedule-Interactive Site

https://www4.palmettogba.com/asc_partb_fee_schedule/home?region=jm

Novitas-ASC Fee Schedule-Spreadsheet

https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00300026

Noridian-ASC Fee Schedule-Spreadsheet

https://med.noridianmedicare.com/web/jeb/fees-news/fee-schedules/asc-fees/asc-payment-rates-for-2026

First Coast-ASC Fee Schedule-Interactive Site

https://medicare.fcso.com/SharedTools/faces/FeeSchedule_en.jspx?lob=Part%20B&state=FL

IV. Durable Medical Equipment

Based on the guidelines identified in the document from the Medicare Claims Processing Manual (https://www.cms.gov/media/136746), the Neurostimulator is disposable and is a single use device. Therefore, it does not meet the qualifications for durable medical equipment.

Durable Medical Equipment (DME) is generally defined as medical equipment and supplies that are not disposable, but are medically necessary and are appropriate for home use. A provider does not have to be a "Medicare DME Provider" to perform and bill the procedure for a neurostimulator. This is exemplified by the following two Sections in the **Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Table of Contents (Rev. 4202, 01-18-19).**

V. ICD-10 Diagnoses Codes

Below are a few of the most common ICD10 diagnosis codes for chronic pain from diabetic peripheral neuropathy. Ultimately the assignment of the proper diagnosis code is the responsibility of the ordering provider.

□

Diagnosis	Diagnosis Description
E10.41	TYPE 1 diabetes mellitus with diabetic mononeuropathy
E10.42	TYPE diabetes mellitus with diabetic polyneuropathy
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	TYPE 2 diabetes mellitus with diabetic polyneuropathy

VI. Contraindications

The following are the contraindications: Hemophilia, Pregnancy, implantable devices that emit an electrical impulse / current into the body - (i.e., pacemaker, defibrillator), and indwelling/implantable stimulator devices (i.e., Deep Brain Stimulator, Spinal Cord Stimulator).

VII. Neurostimulators are Proven and Effective

Over the past four decades, multiple forms of implantable neurostimulators have been utilized in the market:

1. The first peripheral neurostimulator for intractable pain developed in 1976
2. Spinal cord neurostimulator that was FDA cleared on September 4, 1979
3. Cranial nerve stimulator of any type that has been cleared on June 28, 1984.

Supporting the statement of Proven and Effective are three clinical trials (two of which are completed and one is initiated) using the NS100 providing outcomes of over 68.5% decrease in pain. Additionally, off-label benefits of lowering blood sugar and lowering and/or elimination of pain and diabetes medications were also observed.

1. **A double-blind, Randomized, Placebo-Controlled Trial** (submitted with the FDA 510(k))
    a. Enrolled 89 subjects with peripheral neuropathy caused by type 2 diabetes mellitus.
    b. Patients were randomly assigned to receive either standard fixed (group A), a variable-sweep frequency (group B) or a sham placebo (group C) cranial and distal spinal root NS100 device for 12 weeks on a week-on week-off basis. (6 weeks total intermittent stimulation treatment).
    c. 68.25% of the subjects (that is, those 43 receiving stimulation of the total 63), or 100% of the subjects (2 outliers excluded) receiving stimulation treatment (fixed and sweep) reached one of the highest p-values of statistical significance ($p<<.001$) — for decrease in VAS (pain), as well as simultaneous improvement in VPT (nerve sensory function), ONLS (patient function) and ISI/HAS (anxiety and sleep) scores. Thus, these effects are reproducible, and directly from the neurostimulation treatment.
    a. Double-blind, Randomized, Placebo-Controlled Trial published 03/05/2019 by S. Madhuchander, ,S. Gurunath. Comparing Percutaneous Comparing Percutaneous Electrical Neuro-Stimulation with Placebo in the Management of Diabetic Peripheral Neuropathic Pain.
2. **Observational Trial published in Frontiers in Neuroscience August 2025. Trigeminocervical and Vagus Nerve Stimulation is a Treatment for Diabetic Peripheral Neuropathic Pain and Glucose Control in Patients with Moderate to Severe Diabetes.**
    a. Statistical analysis of 83 Native American patients for an average of 227 days
    b. Within 90 days Primary NRS Pain and EAG Glucose Endpoints:
        i. Showed a drastic pain reduction: 7.92 --> 1.04 and a normalization of mean glucose from 209--> 121. Both endpoints maintained for 7.85 months.
        ii. From a subset of 45 patients, 36 patients (80%) reported stopping ALL pain and diabetes medications.
    c. Staats, P. S., Staats, A., Mikhaiel, B., Chen, J., Azabou, E., & Rangon, C.-M. (2025). Combined Minimally Invasive Vagal Cranial Nerve and Trigeminocervical Complex Peripheral Nerve Stimulation Produces Prolonged Improvement of Severe Painful Peripheral Neuropathy and Hyperglycemia in Type 2 Diabetes. *Frontiers in Neuroscience*, vol. 19, 2025, article 1644961, doi:10.3389/fnins.2025.1644961. **https://doi.org/10.3389/fnins.2025.1644961**
3. **Multi-center, prospective, open-label, observational study. Neurostimulation for Moderate to Severe Painful Diabetic Neuropathy**. A 2-year study, with a minimum of 2,000 moderate to severe DPN subjects with Visual Analog Score (VAS) >5 for 200 days.

a. Early returns **<u>data on only the first 28 patients already showed at an average of 67.2 days</u>** supports the RCT and Native American trial results.
    i. Shows a drastic pain reduction: 7.9 7.92 --> 0.18 (97.80% improvement)
    ii. A trend towards normalization of mean glucose from 8.0 --> 6.2
    iii. 68% improvement in pain medications and 16% improvement in diabetes medications.

Additionally, as of March 2020, there are 2,706 cursory searches in neurostimulation in one database, PubMed. Of these searches, 343 are randomized controlled studies. Thus, there is robust Level 1 Evidence for this device and summarily refutes the overpayment reason for "experimental or investigational." Furthermore, a few of these randomized controlled studies for diagnoses of chronic pain are a few of these abstracts. A few of these abstracts are provided in the attachment. In addition, two white papers are also provided: (1) Effectiveness of Neurostimulation Technologies for the Management of Chronic Pain: A Systematic Review with 175 references and (2) Current Innovations in Peripheral Nerve Stimulation with 39 references.

VIII. Summary

NS100 is programmable and surgically implanted directly on the cranial and distal cervical spinal root nerve endings by objectively measuring closed loop neural impedance drop to propagate adjustable current controlled stimulatory fields at the precisely localized titanium electrode arrays/neural interface (at variable cycle per second hertz and pulse widths of electrical power). This physiologic basis for PENS/PNS is well defined within the growing published literature, including direct Level 1 double-blind, randomized, placebo-controlled longitudinal trials.