StimRouter®
neuromodulation system

2022 StimRouter Neuromodulation System Reimbursement Reference Guide
January 2022

StimRouter Neuromodulation System, developed, manufactured and sold by Bioventus LLC, is cleared by the FDA to treat chronic pain of peripheral nerve origin. StimRouter is a minimally invasive device, consisting of an implanted lead, external pulse transmitter (EPT) and conductive electrode, controlled by a small, hand-held patient programmer. StimRouter is programmed at the direction of the physician to meet patient requirements.

Bioventus provides this information for your convenience only. It is the responsibility of the provider to determine coverage and to manage billing codes, including modifiers, and charges for the rendered service. Bioventus provides assistance for FDA cleared indications under 510(k) K142432, K190047 and K200482 only. The information provided is subject to change as government policies get modified.

It is our understanding that many payers currently do not require a documented psychological evaluation as a prerequisite for coverage of a peripheral nerve simulator (PNS) implant for pain. However, there may be exceptions and differences based on individual payer and plan policies. Additionally, not all payers have formal, written coverage policies concerning PNS therapies. Therefore, we recommend that provider's verify payer coverage policy requirements and seek preauthorization on an individual patient basis.

Procedural and Device Codes

Medicare's procedure-to-device edits require that when certain CPT® procedure codes for device implantation are submitted on a hospital outpatient bill, HCPCS II codes for devices must also be billed. Effective January 2015, the edits are broadly defined and may include any HCPCS II device code with any CPT procedure code used in earlier versions of the edits. ICD-10-PCS procedure codes are used instead of CPT codes to report hospital inpatient procedure only. Inpatient admissions are paid by Medicare under Medicare-Severity Diagnostic Related Groups or MS-DRGs. Patients who have similar clinical characteristics and similar treatment costs are assigned to an MS-DRG. One MS-DRG is assigned to each inpatient stay based on their diagnosis, surgical procedures, age, and other information.

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Procedural & Device Codes

Procedure / Component	Procedure Code & Description	CY-22 Medicare Physician Fee Schedule (National) In-Office | Facility	CY-22 Ambulatory Surgery Center (ASC) Base Rate*	Hospital Outpatient APC (Status Indicator)	CY-22 Medicare Hospital Outpatient APC Rate (National)	FY-22 Hospital Inpatient MS-DRG | Rate (National)
Outpatient Lead Implant[1]	**64555:** Percutaneous implantation of neurostimulator electrode array-peripheral nerve	**$2,326 | $333**	**$4,887***	**5462 (J1)** Level 2 Neurostimulator & Related Procedures	**$6,295***	**N/A**
Outpatient Lead Implant	**64575:** Open Implantation of neurostimulator electrode array-peripheral nerve	**N/A | $329**	**$10,236***	**5463 (J1)** Level 3 Neurostimulator & Related Procedures	**$11,483***	**N/A**
Outpatient Lead Revision or Removal	**64585:** Revision or removal of peripheral neurostimulator electrode array	**$254 | $146**	**$1,876**	**5461 (Q2)** Level 1 Neurostimulator & Related Procedures	**$3,346**	**N/A**

APC Status Indicators
- **J1:** OPD services paid through a Comprehensive APC (C-APC).
- **Q2**: T-packaged codes (i.e., packaged only if they are billed on the same date of service with any other codes with a T status indicator)

***ASC payment indicator for code 64555 & 64575: J8 (device-intensive procedure; paid at adjusted rate)**

[1] Ultrasonic guidance, intraoperative (code 76998), is considered an inclusive service to procedure code 64555, Percutaneous implantation of neurostimulator electrode array; peripheral nerve

Procedural and Device Codes Cont.

Every StimRouter patient receives a User Kit that contains the Patient Programmer and External Pulse Transmitter. The implanted lead will only work when using a programmed External Pulse Transmitter. A consumable electrode patch is boxed into a pack of eight (8) and should be replaced every 2 days.

Model No.	Product Name	HCPCS II L-Code & Description	Medicare Outpatient Hospital Payment Status	HCPCS II C-Code & Description[2]	Medicare Outpatient Hospital Payment Status
ST2-1000	**Implantable Lead & Lead Introducer Kit**	**L8680:** Implantable neurostimulator electrode, each	**APC Status Indicator "E"** Noncovered service, not paid under OPPS	**C1778**: Lead, Neurostimulator **C1894:** Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	**APC Status Indicator "N"** Items and services packaged into APC rates
ST2-5000	**User Kit (Patient Programmer & External Pulse Transmitter)***	**L8683:** Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	**APC Status Indicator "A"** Services paid under fee schedule or payment system other than OPPS	**C1787**: Patient programmer, neurostimulator	**APC Status Indicator "N"** Items and services packaged into APC rates
ST2-7000	**Electrode Patches (Disposable)***	**L9900:** Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code	**APC Status Indicator "N"** Items and services packaged into APC rates	**N/A**	**N/A**

Notes:
- HCPCS L-Codes may be used for prior authorization and outpatient facility billing to some non-Medicare payers.
- HCPCS C-Codes are required for hospital outpatient billing to Medicare and some non-Medicare payers.

***Supplies necessary for the effective use of a prosthetic device:** When medically necessary, L-codes for StimRouter "replacement" accessories are billable to Part B MACs (Not DME MACs) by physician offices.

[2] C-codes are a special type of HCPCS II code. They are used only by hospitals when billing Medicare for medical devices utilized in the outpatient setting. Although other payers may accept C-codes, HCPCS II L-codes are generally used for billing non-Medicare payers. For Medicare, billing C-codes are mandatory for medical devices utilized in the outpatient hospital setting.

Analysis and Programming Codes

According to CPT coding guidelines, simple intraoperative or subsequent programming of the neurostimulator pulse generator/transmitter (95971) includes changes to three or fewer of the following parameters: pulse amplitude, pulse duration, pulse frequency, eight or more electrode contacts, cycling, stimulation train duration, train spacing, number of programs, number of channels, alternating electrode polarities, dose time (stimulation parameters changing in time periods of minutes including dose lockout times), more than one clinical feature (eg, rigidity, dyskinesia, tremor). Complex intraoperative or subsequent programming (95972-95979) includes changes to more than three of the above.

In the office, analysis and programming may be furnished by a physician, practitioner with an "incident to" benefit, or auxiliary personnel under the direct supervision of the physician, with or without support from a manufacturer's representative. The patient or payer should not be billed for services rendered by a Bioventus representative. Contact your local contractor or payer for interpretation of applicable policies.

Procedure	CPT Code & Description	CY-22 Medicare Physician Fee Schedule (National) In-Office | Facility	Hospital Outpatient APC (Status Indicator)	CY-22 Hospital Outpatient APC Rate (National)
Simple or Complex Analysis without Programming	**95970**: Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming	**$19 | $19**	**5734 (Q1)** Level 4 Minor Procedures	**$115**
Simple Intraoperative or Subsequent Programming & Analysis	**95971**: Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	**$50 | $40**	5742 (S) Level 2 Electronic Analysis of Devices	**$103**

Complex Intraoperative or Subsequent Programming & Analysis	**95972**: Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	**$57 | $41**	5742 (S) Level 2 Electronic Analysis of Devices	**$103**
APC Status Indicators • **Q1:** STVX-Packaged Codes (Packaged if billed on the same date of service as "S," "T," "V," or "X.") • **S:** Significant Procedure, Not Discounted When Multiple				

References

- 2021 CPT® Professional Edition. American Medical Association. CPT® is a registered trademark of the American Medical Association. All Rights Reserved.
- CMS National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7). Benefit Category: Prosthetic Devices. Effective August 7, 1995.
- FY2022 IPPS Final Rule Home Page. U.S. Center for Medicare and Medicaid Services: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page
- CY2022 ASC Final Rule Home Page. U.S. Center for Medicare and Medicaid Services: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment
- CY2022 MPFS Final Rule Home Page. U.S. Center for Medicare and Medicaid Services: https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched
- CY2022 OPPS Final Rule Home Page. U.S. Center for Medicare and Medicaid Services: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps
- HCPCS Level II, 2019 Expert. Ingenix, St. Anthony Publishing/Medicode. Salt Lake City, 2019.

Frequently Asked Questions

Q1: *Do most commercial payers have coverage policies concerning implanted Peripheral Nerve Stimulation (PNS) therapy?*

A1: It is important to recognize that not all payers currently have coverage policies concerning implanted PNS therapy. In these cases, coverage is determined based on medical necessity for individual patients. For payers that do have coverage policies for implanted PNS therapy, their criteria for PNS coverage is often located within the scope of larger policies with titles such as "Electrical Stimulation for Pain" or "Stimulation Therapy and Devices" and others. Such polices may address several different device modalities and therapies. Therefore when researching payer coverage policies for implanted PNS therapy, it is important to not confuse this therapy with other, disparate therapies for treating pain (E.g., SCS, PENS, PSFS). Regardless, seeking payer pre-authorization is an important first step to verifying coverage for all patients.

Q2: *I am trying to locate our payers' coverage policies for implanted Peripheral Nerve Stimulation (PNS) therapy and come across policies for peripheral "subcutaneous field stimulation" (PSFS). Is this the same therapy?*

A2: The StimRouter Neuromodulation System does not provide peripheral "subcutaneous field stimulation" (PSFS) also called peripheral nerve field stimulation (PNFS) or target field stimulation. With PNFS the implanter places a lead in the subcutaneous tissue to directly stimulate the cutaneous afferents (rather than a discernable nerve) involved in the pain process. By creating an electrical field around a "painful area" of neurons, the nociceptive pathways themselves are impacted.[i] On the other hand with PNS (E.g., the StimRouter Neuromodulation System), the implanter places a lead adjacent to a specific nerve that has been established as the origin of pain, using a percutaneous delivery approach. This neuropathic pain condition often has a history of trauma/injury to the nerve itself and should not be confused with implantation to painful area, i.e. field stimulation.

Q3: *Is implanted Peripheral Nerve Stimulation (PNS) therapy coverage available for Medicare patients?*

A3: According to CMS' National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) -- Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators. Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators.

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[i] Source: Deer et al. Perspective: *Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation Birds of a Different Feather*. Pain Medicine 2015; 16: 411–412.

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The StimRouter Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.

Do not use the StimRouter Neuromodulation System in users who have an implanted demand cardiac pacemaker, implanted cardioverter defibrillator (ICD), or other implanted active device, or who have bleeding disorders that cannot be stopped in advance of the StimRouter implantation procedure. Do not use the system where a metallic implant or a cancerous lesion is present in the immediate implant area. Effects of stimulation during pregnancy are not known. StimRouter is capable of producing skin irritation and muscle ache in the area of stimulation.

Full prescribing information can be found in the Clinician Guide or https://stimrouter.com/safety-information.

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Disclaimer: *This information is current as of January, 2022 and is intended for informational purposes only. It is the provider's responsibility to determine if the services provided are accurately described. It is not intended to increase or maximize reimbursement by any payer. By providing this information, Bioventus does not and cannot guarantee that payment or coverage will be received. The content provided by the Centers for Medicare & Medicaid Services is updated frequently. It is the responsibility of the health services provider to confirm the appropriate coding required by their local Medicare contractors and commercial payers.*