2024

CODING & REIMBURSEMENT FREQUENTLY ASKED QUESTIONS (FAQ)

Axonics® System for Sacral Neuromodulation Overactive Bladder | Urinary Retention | Fecal Incontinence





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Axonics recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coding, coverage, and payment matters and before using the information in this Guide.

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REIMBURSEMENT RESOURCES

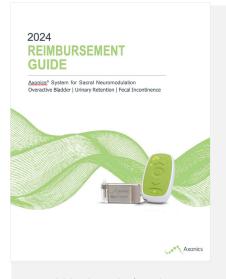
We offer several resources to provide information related to coding, coverage, and payment for sacral neuromodulation and urethral bulking therapies.



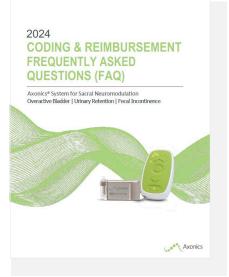
2024 SNM Reimbursement Overview



2024 Bulkamid Reimbursement Overview



2024 SNM Coding & Reimbursement Guide



2024 SNM Frequently Asked Questions (FAQ)

Axonics Reimbursement Support Center

Email: reimbursement@axonics.com Phone: 1 (877) 228-7760 (Messages only) Fax: 1 (949) 333-1573
Please allow 24 hours for a response.

COMMON COVERAGE CRITERIA

Verify the patient meets payer criteria (not an all-inclusive list; consult payer medical policy(ies) as coverage criteria may vary)

Urinary Incontinence

[National Coverage Determination (NCD) for SACRAL Nerve Stimulation For Urinary Incontinence (230.18)]

- Sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention
- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes
 with peripheral nerve involvement) which are associated with secondary manifestations of the above three
 indications are excluded.
- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

Fecal Incontinence

- Patient has experienced chronic fecal incontinence (e.g. average no. times per week for 6 mo. or 12 mo. following childbirth, etc.) unrelated to a neurological condition
- Patient has tried and failed conservative therapy including behavioral therapy and pharmaceutical treatment
- Patient cannot tolerate conservative treatments due to severity impacting ability to work or participate in activities outside the home
- For permanent implantation, documented evidence identifies that the patient experienced relief of incontinence symptoms in the trial period, typically a minimum of 1 week duration and usually at least 50% (may vary by payer)
- A patient diary may be required and included in the medical record

PRIOR AUTHORIZATION GUIDANCE

Medicare Advantage and Non-Medicare Plans

Prior Authorization of services is important to obtain from Medicare Advantage plans, private, and other non-Medicare payers. This will help patients avoid incurring charges for services and items that may not be covered. Traditional Medicare does not prior authorize services.

Steps for obtaining Prior Authorization

Prior authorization may be required for the temporary stimulation test/trial and the permanent implantation if the trial is successful.

- 1. Contact the Insurance Carrier
 - Review carrier requirements for prior authorization
 - Verify benefits and coverage for procedure
 - Identify patient information, diagnoses and corresponding CPT® and HCPCS codes
- 2. Record the name of the individual from the health plan with whom you speak, the reference number for the call, and the date and time of the call or contact
 - Medicare Advantage plans must follow traditional Medicare coverage policies
 - Follow up until a decision has been made
- If the plan does not require prior authorization or it is denied, consider requesting a voluntary predetermination; if the plan agrees, the patient case will be reviewed
 - Documentation should include a letter of medical necessity, patient medical information, product information, peer-reviewed literature, and a bibliography
 - Peer to Peer review may be scheduled between the medical director and the treating physician to review the case

APPEALS

My claim has been denied, how can I obtain payment?

If a claim or service has been denied, it is necessary to file an appeal with the payer. Instructions for submitting an appeal will be located on each payer's website. The reason for the denial may be located in the denial letter and/or explanation of benefits (EOB).

An appeal letter should be written to address the denial reason and included a corrected claim (if needed), product information, patient medical information, relevant supporting clinical evidence in addition to any other supporting documentation.

Submitting relevant medical documentation which supports the medical necessity of the service is a critical component of the appeals process. Examples of medical documentation may include the following:

- Patient medical records
- Treatment plan
- · Physician's order
- Test results
- X-ray or CT Scan reports
- Operative report
- Voiding Diaries
- Product information
- Relevant clinical data
- List of failed treatments
- Discharge notes

FREQUENTLY ASKED QUESTIONS

Check with payers for their specific coding and billing guidance as payer policies vary. You may also contact the Axonics Reimbursement Support Center.

How is a full system implant reported?

Report both a lead and a generator code (64561 or 64581 with 64590).

What is the difference in 64561 and 64581?

- 64561 describes the implantation of the lead via a percutaneous approach for a temporary or permanent lead implantation. *CPT Assistant October 2021 Volume 31 Issue 10 page 7.*
- 64581 describes the implantation of the lead via an open approach.
- 64561 or 64581 selection is based on the approach rather than the type of lead (temporary or permanent).

When lead and sacral nerve neurostimulator implant procedures are performed together during the same operative session in the hospital outpatient setting, will the hospital be reimbursed separately for each procedure?

No. Medicare will reimburse the hospital a single payment based on the primary "J1" (status indicator) service for the claim. For a full system implant, payment is based on the neurostimulator implant (64590) with adjunctive services packaged (e.g., lead implant, fluoroscopy, etc.).

When lead and sacral nerve neurostimulator implant procedures (64561 with 64590 are performed together during the same operative session in the ASC setting, will the hospital be reimbursed separately for each procedure?

Yes. The ASC Medicare payment methodology allows for separate payment of both the lead and implant procedures. A multiple reduction does not apply to these codes for ASC reporting.

Can the separate lead device code, HCPCS code A4290 Sacral nerve stimulation test lead, be reported in addition to CPT® 64561 (lead implantation)?

No, CPT® Code 64561 includes "percutaneous neuro test stimulation kit" per NCCI guidelines.

When removing a lead and implanting a new lead, what code is reported?

Report either CPT® Code 64561 or 64581 based on the surgical approach (percutaneous or open). Do not separately report the removal of the existing lead.

How is a generator removal reported when it is not replaced?

CPT® Code 64595 is reported when an existing generator is removed without replacement.

When is a patient eligible for a new device or device exchange?

- Payer policies vary, but in general, most Medicare and non-Medicare payers stipulate that either the generator
 or leads can be replaced based on a documented device "end of useful life" or malfunction, or patient medical
 necessity. Reasons related to "patient convenience" or "wanting a new device" or a rechargeable device do not
 meet the criteria for a medically necessary device replacement.
- Rationale for a device replacement and exchange must be documented in the medical record. For Medicare Advantage and commercial payers, pursue prior authorization.

Is programming of the Sacral Neurostimulator system included in the "physician global period"?

No, electronic analysis of implanted neurostimulator pulse generator systems with and without programming are not subject to the global period.

What HCPCS code is assigned to reporting a rechargeable neurostimulator?

HCPCS C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system is reported for Medicare and some non-Medicare payers.

What HCPCS code is assigned to reporting a non-rechargeable neurostimulator?

HCPCS C1767 describes the non-rechargeable neurostimulator.

What is the difference between "simple" and "complex" programming"?

Adjustment of three or fewer parameters is "simple" programming. "Complex" programming involves adjustment of three or more parameters. Adjustment of one parameter several times counts as one adjustment.

Can programming codes (95971 or 95972) be reported when the physician programs a neurostimulator in the operating room?

Yes, when performed in the operating room, programming the neurostimulator is separately reported.

Note, test stimulation that is performed during the implantation procedure may not be separately reported with programming codes.

Per CPT, who can perform the programming codes?

The programming codes are reported when performed by a physician or qualified healthcare provider (QHP).

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Health care providers should consult with their payers, reimbursement specialists, and/or legal counsel regarding these matters.

PLACE OF SERVICE

Payment is different depending on the site of service which is reported with the appropriate Place of Service (POS) code on the claim form. Physician office settings are defined as locations where healthcare professionals "routinely provide health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis. Specifically excluded are hospitals, skied nursing facilities, military treatment facilities and intermediate care facilities.

Category	Туре	Place of Service (POS) Code
Non-Facility	Physician Office	11
Facility	Off Campus -Outpatient Hospital	19
Facility	On Campus - Outpatient Hospital	22
Facility	Ambulatory Surgery Center (ASC)	24

CODING

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Category	Туре				
Electrode an	Electrode and Pulse Generator Implant				
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed				
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling				
Revision or Removal					
64585	Revision or removal of peripheral neurostimulator electrode array				
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver				
Programming					
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming				

Programming	
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

COMMON CPT® MODIFIERS

Modifiers indicate that a service or procedure performed has been altered by some specific circumstance, but not changed in its definition or code. They are used to add information or change the description of service to improve accuracy or specificity. Modifiers can be alphabetic, numeric or a combination of both, but will always be two digits.*

CPT® Modifiers			
-26	Professional Component		
-50	Bilateral Procedures		
-51	Multiple Procedures		
-53	Discontinued Procedure		
-58	Staged or Related Procedure or Service by the Same Physician or Other Qualified Health Care Professional During the Postoperative Period		
-59	Distinct Procedural Service		
-73	Discontinued Outpatient Procedure Prior to Anesthesia Administration (Facility Reporting Only)		
-74	Discontinued Outpatient Procedure After Anesthesia Administration (Facility Reporting Only)		

CODING RESOURCES & REFERENCES

The following resources may assist you in accurately reporting sacral neuromodulation procedures.

Axonics Resources:

Reimbursement materials may be found at: https://www.axonics.com/hcp/resources/reimbursement

For additional information please contact Axonics Reimbursement Support Center at **1-877-228-7760**

Or email us at: reimbursement@axonics.com

Other Resources:

American Medical Association: www.ama-assn.org
2024 Current ProceduralTerminology (CPT®), Professional Edition, ©2021 American Medical Association

Available online at: www.ama-assn.org

CPT® Network: An online, subscription-based service for coding

information: www.ama-assn.org

CPT® Assistant: A monthly coding publication of the American

Medical Association

2024 NCCI Program Manual:

NCCI Policy Manual for Medicare | CMS

Medicare Program website: www.cms.gov

Provides a wide range of information and resources

Axonics Reimbursement Support Center

Email: reimbursement@axonics.com

Phone: 1 (877) 228-7760 (Messages only)

Fax: 1 (949) 333-1573

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