2021 REIMBURSEMENT GUIDE

Axonics® System for Sacral Neuromodulation

Overactive Bladder | Urinary Retention | Fecal Incontinence

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Diagnoses

ICD-10-CM diagnosis codes are used by providers to report patient conditions. List all diagnoses on the claim form and code to the highest available level of specificity based on the documentation in the patient's medical record. The following ICD-10-CM codes describe conditions commonly treated with the Axonics System. Other codes may apply based on the patient condition. For a complete list of codes and descriptions, consult the current ICD-10-CM manual.

Table 1: ICD-10-CM Codes

Overactive Bladder or Urinary Retention	ICD-10-CM and Description
N32.81	Overactive bladder
N39.41	Urge incontinence
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
Fecal Incontinence	**ICD-10-CM and Description**
R15.9	Full incontinence of feces
Device Adjustment and Management	**ICD-10-CM and Description**
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord)

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CPT® Procedural Codes

CPT codes have narrative descriptions that are used to report procedures performed by physicians and health care practitioners. CPT codes are used for reporting services delivered in the physician office, hospital outpatient, and ambulatory surgery center settings.

CPT® Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including imaging guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator or receiver, direct to inductive coupling
64585	Revision or removal of peripheral neurostimulator electrode array
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
76000	Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time
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
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 (e.g., 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 (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

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Physician Coding and Payment

Tables 2A-E describe applicable coding guidance for procedures when performed with the Axonics System. Procedures may vary based on the patient condition and documentation. As payer code requirements vary, check billing instructions. Consult the current CPT code manual for additional codes as this list is not all-inclusive.

Tables 2A-E: CPT Codes Physician Services

Table 2A: Basic Trial

CPT® Code	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility[1]	2021 Medicare National Average Payment (In) Facility[2]
Lead Implantation					
64561	5.44	22.83	8.87	$797	$310
Reporting Instructions • CPT 64561 report for temporary or permanent percutaneous placement of the percutaneous electrode array; includes the "percutaneous neuro test stimulation kit"[3] • For bilateral procedures, append the -50 modifier: *-50 Bilateral procedures* • Do not report fluoroscopy separately with CPT 64561. Imaging guidance is included in the descriptor[4]					

Table 2B: Advanced Trial

CPT® Code	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility	2021 Medicare National Average Payment (In) Facility
64581	12.20	N/A	19.30	N/A	$673
Reporting Instructions • CPT code 64581 is reported for lead placement that is tunneled.[5] • Do not report removal of an existing lead when a new lead is replaced					
Imaging Guidance					

[1] Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Final Rule with Comment, Federal Register (85 Fed Reg. No 248) December 28, 2020, 42 CFR Parts 400, 410, 414, 415, 423, 424, and 425 Addendum B

[2] Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Final Rule with Comment, Federal Register (85 Fed Reg. No 248) December 28, 2020, 42 CFR Parts 400, 410, 414, 415, 423, 424, and 425 Addendum B

[3] Coding Brief: Reporting Percutaneous Implantation of Neurostimulator Electrode Arrays Codes (October 2018, Volume 28, Issue 10, pages 8, 12)

[4] CPT Assistant, December 2012 Page 14

[5] CPT Assistant, September 2014 Page 5

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Axonics® System for Sacral Neuromodulation

CPT® Code	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility	2021 Medicare National Average Payment (In) Facility
76000-26	.30	.45	.45	$16	$16
Reporting Instructions • May be reported separately with CPT 64581 • Do not report fluoroscopy separately with CPT 64561. Imaging guidance is included in the descriptor[6]					

Table 2C: Full System Procedure

CPT® Code[1]	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility	2021 Medicare National Average Payment (In) Facility
Lead and Generator Implantation					
64581	12.20	N/A	19.30	N/A	$673
Reporting Instructions • CPT code 64581 is reported for lead placement that is tunneled.[7] • Do not report removal of an existing lead when a new lead is replaced					
64590	2.45	8.03	4.71	$280	$164
Imaging Guidance					
76000-26	.30	.45	.45	$15.70	$16
Reporting Instructions • May be reported separately with CPT 64581					
Programming and Analysis					
95971	.78	1.43	1.16	$50	$40
95972	.80	1.65	1.20	$58	$42

Table D: Revision /Removal Procedures

CPT® Code	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility	2021 Medicare National Average Payment (In) Facility
Revision or Removal of Lead /Revision or Removal of Generator					
64585	2.11	7.49	4.20	$261	$147
64595	1.78	7.17	3.72	$250	$130
Reporting Instructions • Report 64595 when the same generator is removed and then re-inserted					

[6] CPT Assistance, September 2014 Page 5
[7] CPT Assistant December 2012 page 14

Table 2E: Programming

CPT® Code	Work RVU	Non-Facility (Office) Medicare Total Relative Values	(In) Facility Medicare Total Relative Values	2021 Medicare National Average Payment Non-Facility	2021 Medicare National Average Payment (In) Facility
Programming and Analysis					
95970	.35	.56	.55	$20	$19
95971	.78	1.43	1.16	$50	$40
95972	.80	1.65	1.20	$58	$42

Reporting Instructions: (95970-95972)

Programming

- Simple programming includes adjustment of one to three parameter(s)
- Complex programming includes adjustment of more than three parameters
- Single parameter that is adjusted two or more times during a programming session counts as one parameter

Operative

- CPT 95970 (analysis without programming) may not be separately reported at the same operative session. This code is inherent to the implantation (codes) 64561, 64581, and 64590.
- For CPT 95971 (simple programming) and 95972 (complex programming), when performed in the operating room, programming the neurostimulator is not inherent to the implantation codes and may be separately reported

Physician Global Surgery Package/Global Period

Surgical procedures are subject to a Global Surgery package also known as a "global period" and includes services normally furnished by the physician who performed the surgery. Services included are pre-operative visits the day before or on the same day as the surgery, postoperative visits, and complications following surgery.

Neurostimulator CPT codes 64561, 64585, 64590 and 64595 have a 10-day global period whereas CPT code 64581 has a 90-day global period.

Modifiers

Modifiers are used to supplement information to provide additional details about a procedure provided by a physician. They help to further describe a procedure code without changing its definition. Modifiers are appended to the relevant procedure code. Check with payer policies for modifier use.

Table 3: Common 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)

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Hospital Outpatient and Ambulatory Surgery Center Coding and Payment

Medicare and some private payers use Ambulatory Patient Classifications (APCs) to prospectively pay outpatient hospital and ambulatory surgery episodes of care. CPT® codes for procedures performed are assigned to APCs. Most commercial insurers pay the hospital negotiated contracted rates (i.e., APC, case rate, or per diem rate). Refer to Tables 2A-E CPT® coding instructions (above).

Tables 4A-D: Hospital Outpatient Coding and Payment

Table 4A: Basic Trial

CPT® Code	APC	APC Descriptor	SI*	2021 Medicare National Average Payment Rate[8]
Lead Implantation				
64561	5462	Level 2 Neurostimulator and Related Procedures	J1	$6,161

Table 4B: Advanced Trial

CPT® Code	APC	APC Descriptor	SI*	2021 Medicare National Average Payment Rate
Lead Implantation				
64581	5462	Level 2 Neurostimulator and Related Procedures	J1	$6,161
Imaging Guidance				
76000	5523	Level 3 Imaging Without Contrast	S	$230
Programming and Analysis				
95971	5742	Level 2 Electronic Analysis of Devices	S	$100
95972	5742	Level 2 Electronic Analysis of Devices	S	$100

Table 4C: Full System

CPT® Code	APC	APC Descriptor	SI*	2021 Medicare National Average Payment Rate
Lead Implantation				
64581	5462	Level 2 Neurostimulator and Related Procedures	J1	$6,161
Generators Implantation or Replacement				
64590	5464	Level 4 Neurostimulator and Related Procedures	J1	$20,480
Imaging Guidance				
76000	5523	Level 3 Imaging Without Contrast	S	$230
Programming and Analysis				
95971	5742	Level 2 Electronic Analysis of Devices	S	$100
95972	5742	Level 2 Electronic Analysis of Devices	S	$100

Table 4D: Revision/Removal Procedures

CPT® Code	APC	APC Descriptor	SI*	2021 Medicare National Average Payment Rate
Revision or Removal of Lead or Generator				
64585	5461	Level 1 Neurostimulator and Related Procedures	J1	$3,275
64595	5461	Level 1 Neurostimulator and Related Procedures	J1	$3,275

[8] Medicare Program; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final Rule with Comment, Federal Register (85 Fed Reg. No. 249) December 29, 2020, 42 CFR Parts 410, 411 412,414,416, 419, 482, 485 and 512; Addenda A, B and D1

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*OPPS Status Indicators

- Status Indicator: J1 Hospital Part B Services Paid Through a Comprehensive APC (C-APC)
  NOTE: Assignment of a CPT procedure code to a C-APCs is considered a primary procedure. All other services and procedures reported on the claim would be considered adjunctive to the primary procedure. CMS will make a single APC payment for the entire hospital outpatient encounter. There is no additional payment for the adjunctive services or procedures. When procedures performed in an episode of care map to multiple C-APCs, the entire episode will map to the highest paying C-APC.
- Status Indicator: S Significant Procedure Not Subject to Multiple Procedure Discounting

Tables 5A-D: Ambulatory Surgery Center Coding and Payment

Table 5A: Basic Trial

CPT® Code	Payment Indicator*	2021 Medicare National Average Payment Rate [9]
Lead Implantation		
64561	J8	$4,574
95971	NA	NA
95972	NA	NA

Table 5B: Advanced Trial

CPT® Code	Payment Indicator*	2021 Medicare National Average Payment Rate
Lead Implantation		
64581	J8	$4,842
Imaging Guidance		
76000	Z3	NA
Programming		
95971	NA	NA
95972	NA	NA

Table 5C: Full System Implant

CPT® Code	Payment Indicator*	2021 Medicare National Average Payment Rate
Lead Implantation		
64581	J8	$4,842
Generator Implantation or Replacement		
64590	J8	$18,030
Imaging Guidance		
76000	Z3	$27
Programming		
95971	NA	NA
95972	NA	NA

[9] Medicare Program; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final Rule with Comment, Federal Register (85 Fed Reg. No. 249) December 29, 2020, 42 CFR Parts 410, 411 412,414,416, 419, 482, 485 and 512; Addenda AA, BB and DD1

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Table 5D: Revision/Removal Procedures

CPT® Code	Payment Indicator*	2021 Medicare National Average Payment Rate
Revision or Removal of Lead or Generator		
64585	A2	$1,831
64595	A2	$1,831

*ASC Payment Indicators

- J8 Device-intensive procedure; paid at adjusted rate
- A2 Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.
- Z3 Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS non-facility PE RVUs

HCPCS Level II Codes

HCPCS Level II Codes are alphanumeric codes that describe products, supplies, and services not included as part of the CPT® Code system. HCPCS contains a category of "C" codes that are billed on Medicare claims for the Hospital Outpatient Prospective Payment System (HOPPS) for specific device-dependent procedures. Hospital chargemasters are list these codes for identification/costs.

Private payers may use C codes or Durable Medical Equipment Prosthetic and Orthotic (DMEPOS) HCPCS codes to identify devices.

Table 6: Medicare Device C Codes for Hospital Outpatient Reporting

C1897	Lead, neurostimulator test kit (implantable)
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1787	Patient Programmer, neurostimulator
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser
C1883	Adaptor/extension, pacing lead or neurostimulator or lead (implantable)

Table 7. DMEPOS Codes

A4290	Sacral nerve stimulation test lead, each
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Check with private payers if the "L" or "C" HCPCS codes are applicable.

Hospital Inpatient Procedure Coding and Reimbursement

Medicare and many private payers use MS-DRGs to reimburse hospitals for inpatient admissions. Inpatient services are "grouped" to one MS-DRG based on the ICD-10-CM and ICD-10-PCS codes dependent on documentation in the patient's medical record. Each MS-DRG has a prospectively established payment rate, which includes all rendered services during the inpatient encounter. Most private or commercial insurers pay hospitals a negotiated, contracted rate (i.e., DRG, case rate, or per diem rate). Tables 8 and 9 list common ICD-10-PCS codes and MS-DRGs that may be appropriate to describe procedures and inpatient encounters that include use of the Axonics System. This list is not an all-inclusive list. For a complete list of codes, consult the current ICD-10-PCS code manual.

Table 8: ICD-10-PCS Codes

ICD-10-PCS	Descriptor
Lead Implantation	
01HY0MZ	Insertion of neurostimulator lead into peripheral nerve, open approach
01HY3MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous approach
Generator Implantation	
0JH70CZ	Insertion of single array stimulator generator rechargeable into back subcutaneous tissue and fascia, open approach
Lead Removal	
01PY0MZ	Removal of neurostimulator lead from peripheral nerve, open approach
01PY3MZ	Removal of neurostimulator lead from peripheral nerve, percutaneous approach
Generator Removal	
0JPT0MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JPT3MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, percutaneous approach
Lead Revision	
01WY0MZ	Revision of neurostimulator leas in peripheral nerve, open approach
01WY3MZ	Revision of neurostimulator lead in peripheral nerve, percutaneous approach
Generator Revision	
0JWT0MZ	Revision of stimulator generator in trunk subcutaneous tissue and fascia, open approach
0JWT3MZ	Revision of stimulator generator in trunk subcutaneous tissue and fascia, percutaneous approach

Table 9: Hospital Inpatient MS-DRGs

MS-DRG	Descriptor	FY 2021 Medicare National Average [10]
Urinary – Generator and Lead or Lead only		
673	Other Kidney and Urinary Tract Procedures with MCC	$22,259
674	Other Kidney and Urinary Tract Procedures with CC	$15,300
675	Other Kidney and Urinary Tract Procedures without MCC/CC	$11,261
Extensive OR Procedures		
981	Extensive OR Procedure Unrelated to Principal Diagnosis W MCC	$29,616
982	Extensive OR Procedure Unrelated to Principal Diagnosis W CC	$16,335
983	Extensive OR Procedure Unrelated to Principal Diagnosis W/O CC/MC	$10,636
Nervous System Procedures		
40	Peripheral/Cranial Nerve and Other Nervous System Procedures W MCC	$25,438

[10] Medicare Program; Hospital inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospitals Prospective Payment System and Policy changes and Fiscal Year 2021 Rates; final Rule, September 18, 2020, 42 CFR Parts 405, 412, 413, 417, 476, 480, 484, and 495; CN Table 1A-1E, Table 5

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MS-DRG	Descriptor	FY 2021 Medicare National Average [10]
41	Peripheral/Cranial Nerve and Other Nervous System Procedures W MCC or Peripheral Neurostimulators	$15,110
42	Peripheral/Cranial Nerve and Other Nervous System Procedures W/O CC/MCC	$12,115

MCC- Major Complication and Comorbidities
CC- Complications and/or Comorbidities

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.

1. **How is a complete system implant reported?**
    a. Report a lead and a generator code.
2. **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?**
    a. No. Medicare will reimburse the hospital a single payment based on the highest Comprehensive APC. For a full system implant, the payment would be for the neurostimulator implant only (64590).
    b. There would be no additional payment to the hospital for the procedure to implant the lead.
3. **Can the separate lead device code, HCPCS code A4290 Sacral nerve stimulation test lead, be reported in addition to CPT 64561 (lead implantation)?**
    a. No, CPT® Code 64561 includes "percutaneous neuro test stimulation kit" per NCCI guidelines**.**
4. **How is the removal of an existing lead with an implant for a new lead reported?**
    a. Report either CPT Code 64561 or 64581.
    b. Do not separately report the removal of the existing lead.
5. **How is a generator removal reported when it is not replaced?**
    a. CPT Code 64595 is reported when an existing generator is removed without replacement.
6. **When is a patient eligible for a new device or device exchange?**
    a. 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.
    b. Rationale for a device replacement and exchange should be documented in the medical record and for Medicare Advantage and commercial payers, should be confirmed in the prior authorization process.
7. **Are CPT 64561, 64581 and 64590 subject to a multiple reduction when performed in the ASC?**
    a. No. A multiple reduction does not apply to these codes for ASC reporting.
8. **Is programming of the Sacral Neurostimulator system included in the "global period"?**
    a. No, electronic analysis of implanted neurostimulator pulse generator systems with and without programming are not subject to the global period.

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9. **Does HCPCS C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system apply to the Axonics System?**
    a. Yes. HCPCS C1820 describes a rechargeable neurostimulator and includes the rechargeable battery and charging system and may be reported for Medicare and some non-Medicare payers.
10. **Is a "C" code(s) reported for the lead, generator, sheath, and extension when submitting a bill to the ASC?**
    a. No. Medicare has designated "C" codes as packaged into the primary procedure. They are not separately reportable or payable to the ASC.
11. **What is the difference between "simple" and "complex" programming"?**
    a. Adjustment of three or fewer parameters is "simple" programming. "Complex" programming involves adjustment of three or more parameters.
12. **Can programming codes (95971 or 95972) be reported when the physician programs a neurostimulator in the operating room?**
    a. Yes, when performed in the operating room, programming the neurostimulator is separately reported.
    b. Note, test stimulation that is performed during the implantation procedure may not be separately reported with programming codes 95970, 95971 or 95972.

Prior Authorization: Medicare Advantage and Non-Medicare Plans

Prior Authorization of benefits 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
    a. Review carrier requirements for prior authorization
    b. Verify benefits and coverage for procedure
    c. 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
    a. Medicare Advantage plans must follow traditional Medicare coverage policies
    b. Follow up until a decision has been made
3. Verify the patient meets payer criteria (not an all-inclusive list; consult payer medical policy(ies) as coverage criteria may vary)

    Urinary Incontinence
    a. Patient has been symptomatic for 6 months not related to a neurologic condition (e.g. non-obstructive urinary retention, urgency- frequency syndrome, urinary urge incontinence)
    b. Patient has tried and failed conservative therapy including behavioral therapy and pharmaceutical treatment

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c. For permanent implantation, evidence that the patient experienced relief of incontinence symptoms in the trial period, usually at least 50%

Fecal Incontinence

a. 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
b. Patient has tried and failed conservative therapy including behavioral therapy and pharmaceutical treatment
c. Patient cannot tolerate conservative treatments due to severity impacting ability to work or participate in activities outside the home
d. For permanent implantation, evidence that the patient experienced relief of incontinence symptoms in the trial period, usually at least 50%
e. A patient diary may be required and included in the medical record

4. If the plan does not require prior authorization or it is denied, consider requesting a voluntary pre-determination; if the plan agrees, the patient case will be reviewed
    a. Documentation should include a letter of medical necessity, patient medical information, product information, peer-reviewed literature, and a bibliography
    b. Peer to Peer review may be scheduled between the medical director and the treating physician to review the case

Sources

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2021 ICD-10-PCS Professional The complete official code set, Optum 360 2020
2021 DRG Expert Volume 1 Optum 360, LLC