Clinic Reference Guide

BAROSTIM™ PATIENT FLOW

CVRx® | BAROSTIM™

Patient Identification
- ICD consult
- HF hospitalization
- HF diagnostic alert
- EMR screening

Patient Assessment
- Symptomatic despite GDMT
- Recent echo (LVEF ≤ 35%)
- EKG (not CRT candidate)
- Baseline NT-proBNP (< 1600 pg/mL)
  May require medical optimization and re-test
- Consider carotid doppler

Prior Authorization
- CVRx Prior Authorization Service (C-PAS)
- Submit required documentation (NYHA class, EKG, Echocardiogram, NT-proBNP)

Pre-implant Consultation
- Confirm carotid doppler (< 50% stenosis & anatomy)

Implant
- CVRx rep attendance
- Consider device rep attendance for other implanted devices

Wound Check
- Implant + 1 week

Titration Phase
- CVRx rep attendance
- Typically three titration visits (1/month)
- Depending on the patient, the titration phase can extend through 3-6 months

Routine Follow-Up
- Every 6 months

- CARDIOLOGIST
- HF SPECIALIST
- ELECTROPHYSIOLOGIST

- VASCULAR SURGEON
- CT SURGEON
- ELECTROPHYSIOLOGIST

Patient Assessment

PURPOSE	TYPE	TREATMENT OPTIONS FOR PATIENTS WITH NYHA CLASS II OR III, LVEF ≤ 35%[1]		
		QRS < 120 or QRS 120-149 w/o LBBB	QRS ≥ 150 w/o LBBB or 120-149 w/ LBBB	QRS ≥ 150 w/ LBBB
Prevent Sudden Cardiac Death	DEVICE	ICD		
Improve HF Symptoms and Outcomes	DRUG	GUIDELINE DIRECTED MEDICAL THERAPY		
	DEVICE	BAROSTIM[2] **70%**[3]	CRT Class IIa **16%**[3]	CRT Class I **14%**[3]

Patients with an existing CRT system that is not adequately treating their heart failure symptoms are eligible for Barostim

* NYHA Class II with a recent history of NYHA Class III **LBBB** - Left Bundle Branch Block **CRT** - Cardiac Resynchronization Therapy
ICD - Implantable Cardioverter Defibrillator

Barostim Indications[4]

- NYHA III or NYHA II with a recent history of NYHA III
- LVEF ≤ 35%
- Not Indicated for CRT
- NT-proBNP < 1600 pg/mL

No restriction on atrial arrhythmias

Contraindications

- Been assessed to have bilateral carotid bifurcations located above the level of the mandible
- Baroreflex failure or autonomic neuropathy
- Uncontrolled, symptomatic cardiac bradyarrhythmias
- Carotid atherosclerosis that is determined by ultrasound or angiographic evaluation greater than 50%. Ulcerative plaques in the carotid artery as determined by ultrasound or angiographic evaluation
- Known allergy to silicone or titanium
- NOTE: Boston Scientific's S-ICD device is contraindicated for patients with unipolar pacing devices.
- Barostim uses unipolar stimulation.

1. Yancy CM, et al. Circulation. 2013;128: 2013;128:e240–e327;
2. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050. Accessed March 30, 2021;
3 CVRx data on file.
4. Tracy CM, et al. Circulation. 2012;126:1784-1800

Prior Authorization

Barostim requires prior authorization approvals based on the patient medical necessity criteria.

CVRx offers a Prior Authorization Service (C-PAS) to help.

CVRx Prior Authorization Service (C-PAS) provides case-by-case support for providers who perform Barostim implantation procedures. C-PAS is a HIPAA compliant entity and offers assistance for the following services:

1. Coding and coverage information
2. Eligibility and benefit verification
3. Prior authorization
4. Pre-determination or certification
5. Pre and post service appeals

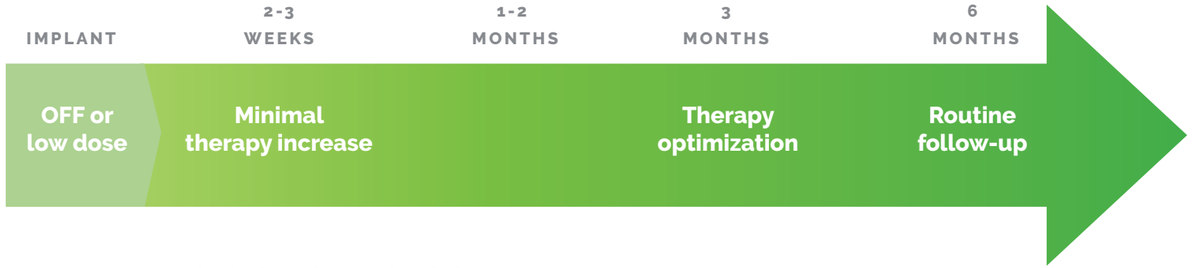
To enroll in the C-PAS service or submit a request online:

www.cvrx.com/healthcare-professionals/reimbursement

Contact the CVRx helpline for copies of the forms or with any questions:

Email: c-pas@cvrx.com
Phone: 763-416-2344
Fax: 855-710-7053

Titration



Recommended Titration Schedule

- Off or low dose of 1mA at Implant
- Minimal therapy increase approximately 2-3 weeks after implant. Titrate no higher than 2mA if the first follow up visit is sooner than week 3.
- Week 3 to month 3 should be a gradual increase in therapy while avoiding undesirable extraneous stim or problematic BP/HR
- The Goal is to reach maximum tolerated therapy between 3 and 6 months.

For initial titration visits

1. Set Frequency to 40 pps.
2. Set Pulse Width to 125 µs.
3. Start with a Pulse Amplitude of 1.0 mA.
4. Increase Pulse Amplitude in 0.2 or 0.4 mA increments until:
   - Symptoms are reported, ex. extraneous stim

   Or
   - Problematic BP/HR. (Check BP at full point intervals (2.0mA, 3.0, 4.0 etc)).
5. Reduce Pulse Amplitude in 0.4 mA steps until symptoms resolve.
6. Always set therapy 0.4 to 1 mA below any extraneous level (i.e. Ext stim at 6mA – set therapy between 5 mA and 5.6 mA).

Follow-Up

Routine Follow-Up Phase

Once a patient has completed their titration phase, they enter in to the routine follow-up phase.

Generally, patients with a chronic Barostim device should be medically treated as if the Barostim was not in place.

TIMING

- Every six months patients should return to their doctor's office for a check of the battery status and lead impedance.
- The Barostim therapy generator is designed to have an average battery life of 5 years with no charging required.

UNSCHEDULED OR URGENT DEVICE CHECKS

- Unlike pacemakers or ICDs, Barostim is not providing beat-to-beat life supporting therapy and a malfunction should not be life threatening.
- However, on rare occasions if the patient is experiencing stimulation in the neck, the therapy can be suspended with a magnet. Therapy will remain off as long as the magnet is in place. Therapy adjustments can then be made when programming is convenient.

CVRx field representatives are available to support device follow-ups and to train staff to perform routine device status checks.

Reimbursement

Reimbursement information provided by CVRx is gathered from 3rd party sources and is presented for illustrative purposes only. This information does not constitute legal or reimbursement advice. CVRx makes no representation or warranty regarding this information or its completeness, accuracy, timeliness or applicability with any particular patient. CVRx specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this document. CVRx encourages providers to submit accurate and appropriate claims for services. Laws, regulations and payer policies concerning reimbursement are complex and change frequently. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions. Accordingly, CVRx recommends that customers consult with their payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters.

Checklist for Physician Billing Submissions

- Barostim FDA approval letter
- Barostim pivotal trial publication
- In the claim form Item 19, or on the electronic form 837P-Loop, REF02, REF01=P4, enter a crosswalk CPT code I and verbiage around the expected reimbursement for that code in the dollar amount. (See example on Page 4)
- Paper claim CMS 1500 or electronic equivalent. **Please ensure the Prior Authorization number is included in every claim submitted to commercial insurance providers.**
- Detailed medical notes (operative report) which capture both the procedural information that documents the time and complexity of the work associated with the service and the patient's medical condition

Checklist for Facility Billing Submissions

- Barostim FDA approval letter
- Barostim pivotal trial publication
- **Please ensure the Prior Authorization number is included in every claim submitted to commercial insurance providers.**
- Please ensure Barostim specific procedure codes are used for both outpatient (CPT 0266T and C1825) or inpatient coding (0JH60MZ and 03HK3MZ)
- UB-04 (outpatient or inpatient) or electronic equivalent

Contact the CVRx with any questions:

Email: c-pas@cvrx.com
Phone: 763-416-2344

System Implant - Diagnosis Codes

ICD-10-CM	Descriptor	CC	MCC
I50.1	Left ventricular failure, unspecified	X	
I50.20	Unspecified systolic (congestive) heart failure	X	
I50.21	Acute systolic (congestive) heart failure		X
I50.22	Chronic systolic (congestive) heart failure	X	
I50.23	Acute on chronic systolic (congestive) heart failure	X	
I50.3	Diastolic (congestive) heart failure	X	
I50.30	Unspecified diastolic (congestive) heart failure	X	
I50.31	Acute diastolic (congestive) heart failure		X
I50.32	Chronic diastolic (congestive) heart failure	X	
I50.33	Acute on chronic diastolic (congestive) heart failure		X
I50.4	Combined systolic (congestive) and diastolic (congestive) heart failure	X	
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	X	
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure		X
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	X	
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure		X
I50.8	Other heart failure		
I50.81	Right heart failure		
I50.810	Right heart failure, unspecified		
I50.811	Acute right heart failure		
I50.812	Chronic right heart failure		
I50.813	Acute on chronic right heart failure		
I50.814	Right heart failure due to left heart failure		
I50.82	Biventricular heart failure		
I50.83	High output heart failure		
I50.84	End stage heart failure		
I50.89	Other heart failure		
150.9	Heart failure, unspecified		

System Implant - Physician Billing

Physician System Implant Code (this code is used for billing)

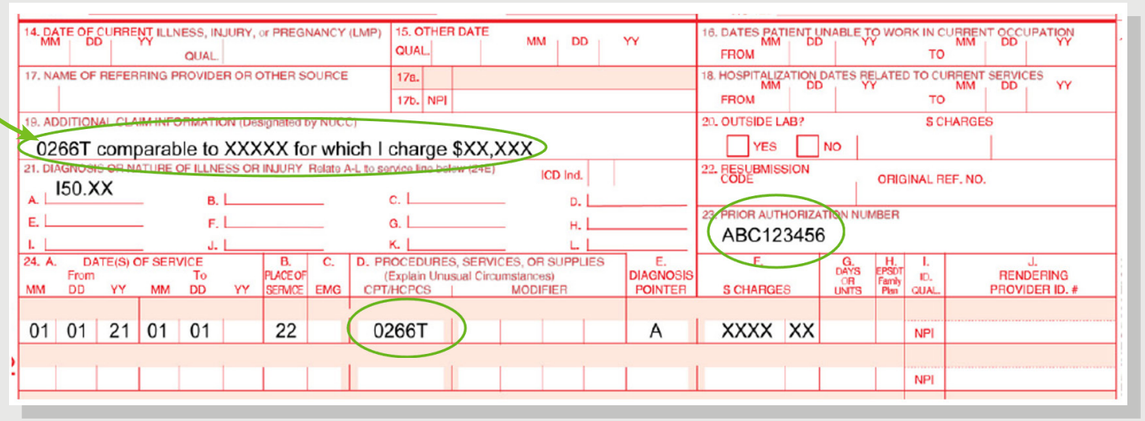
CPT® Code	Descriptor
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system

Barostim system implant is reported with Category III CPT codes. When submitting information system codes, providers may choose to reference a comparative Category I CPT procedure code with similar or equivalent resources (i.e. RVUs) to the Barostim implant in the claims form box 19.

Example Comparative Codes (these codes are examples, they are not billed)

Comparative Code	Descriptor	Work RVU
35301	Thromboendarterectomy,	21.16
33249	Insertion or replacement of permanent implantable defibrillator system	14.92
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	9.00

System implant physician billing sample



System Implant - Outpatient Hospital Billing

CPT® Code	Descriptor	Status Indicator	APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	J1	5465

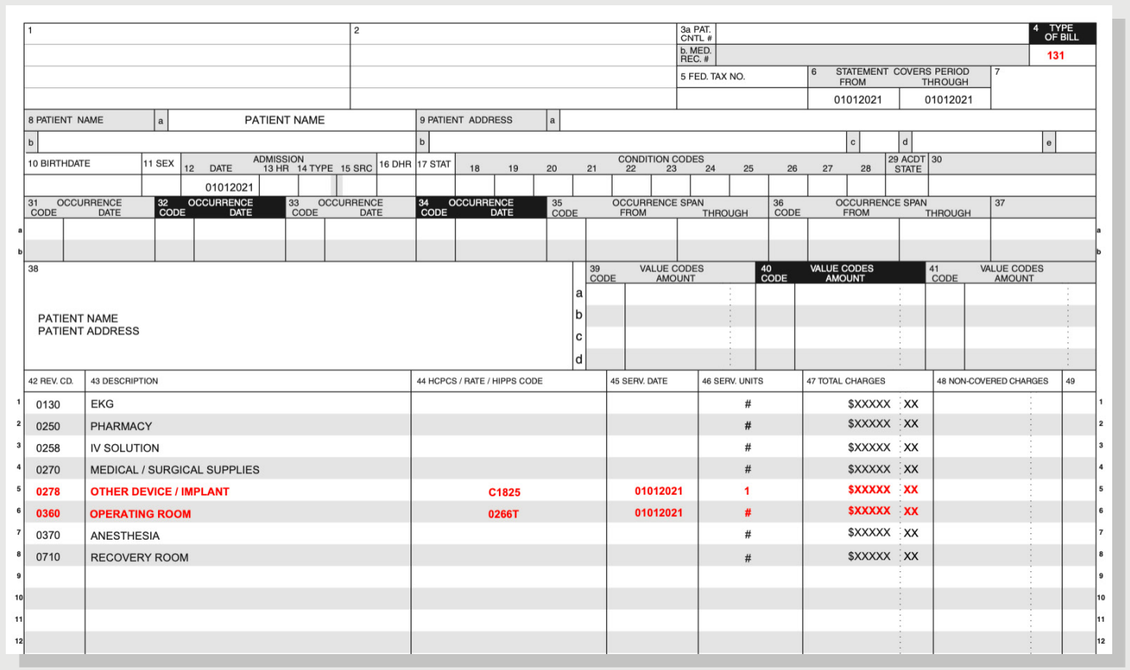
J1 - Hospital Part B services paid through a Comprehensive APC (C-APC). Comprehensive APCs (C-APCs) were established for certain payment groups (e.g., device intensive) whereby Medicare only reimburses a single C-APC on a date of service.

HCPCS Code	Descriptor	APC
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	2030

Medicare outpatient and ambulatory surgery center implant cases involving the use of Barostim system are eligible for Transitional Pass-Through Payment.

Contact CVRx Reimbursement team for initial chargemaster set up at 763-416-2344 or reimbursement@cvrx.com.

Outpatient UB-04 sample



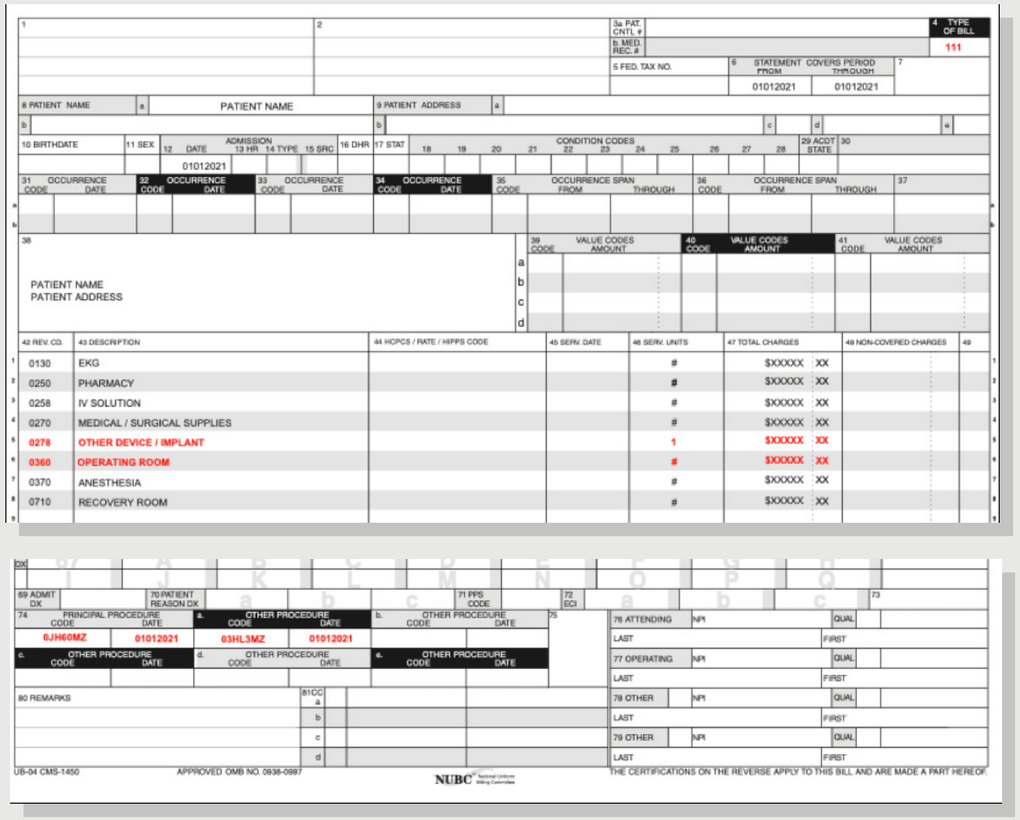
System Implant - Inpatient Hospital Billing

ICD-10-PCS Procedure Code	Descriptor	Typical MS-DRG Assignment
0JH60MZ **AND** 03HK3MZ **OR** 03HL3MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach Insertion of stimulator lead into right internal carotid artery, percutaneous approach Insertion of stimulator lead into left internal carotid artery, percutaneous approach	252. with MCC 253. with CC 254. without CC/MCC

Medicare hospital inpatient system implant cases involving the use of Barostim system are eligible for New Technology Add-On Payment.

Contact CVRx Reimbursement team for initial chargemaster set up at 763-416-2344 or reimbursement@cvrx.com.

Inpatient UB-04 sample



Follow-Up - Physician Billing

Possible **primary diagnosis** codes for interrogation and programming. Possible **secondary diagnosis** codes for interrogation and programming are Heart Failure diagnosis codes (see page 3)

Code	Descriptor
Z45.09	Encounter for adjustment and management of other cardiac device
Z45.89	Encounter for adjustment and management of other implanted devices

Follow up visits or services may be billed independently from the Barostim device interrogation (with or without programming) and evaluation visits.

Part 1 Physician Billing: Follow up visit CPT Codes

Category III CPT codes are not assigned global periods, so any subsequent visits or services may be billed independently from the initial procedure. The following E/M CPT codes may be used to report follow-up visits. If device interrogation/programming is also performed, the -25 modifier may be added to the E/M code to indicate that it is a separate service.

CPT® Code[3]	Descriptor
99211	Office or other outpatient visit for the evaluation and management of an established patient, Typically, 5 minutes are spent performing or supervising these services.
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Typically, 10 minutes are spent face-to-face with the patient and/or family.
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Typically, 15 minutes are spent face-to-face with the patient and/or family
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Typically, 25 minutes are spent face-to-face with the patient and/or family.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Typically, 40 minutes are spent face-to-face with the patient and/or family.

Follow-Up - Physician Coding and Billing (Continued)

Part 2 Physician Billing: Follow up visit device interrogation with programming

Whenever programming is performed, it is essential that physicians individually document the specific parameters changed for coding purposes. Barostim device interrogation is reported with Category III CPT codes. When submitting claim information, providers may choose to reference a comparative Category I CPT procedure code with similar or equivalent resources (i.e. RVUs) to the Barostim implant in the claims form box 19.

This code is used for billing:

CPT 0273T - Interrogation device evaluation with programming

Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report; with programming

Example Comparative Codes (these codes are examples, they are not billed):

Comparative Codes	Descriptor	Code	RVU
Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional…	…multiple lead transvenous implantable defibrillator system	93284	3.07
	…multiple lead pacemaker system	93281	2.44
	…single lead transvenous implantable defibrillator system	93282	2.32

This code is used for billing:

CPT 0272T – Interrogation Device Evaluation

Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)

Example Comparative Codes (these codes are examples, they are not billed):

Comparative Codes	Descriptor	Code	RVU
Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter…	…single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements	93289	2.09
	…implantable subcutaneous lead defibrillator system	93261	2.02
	…single, dual, or multiple lead pacemaker system, or leadless pacemaker system	93288	1.60

Follow up and device titration physician billing sample

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.
15. OTHER DATE QUAL. MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): 027XT comparable to XXXXX for which I charge $XX,XXX
20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.: A. Z45.XX B. I50.XX C. D. E. F. G. H. I. J. K. L.
22. RESUBMISSION CODE ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	01	01	21	01	01	21	22		027XT *		A	XXX	XX		NPI	
2	01	01	21	01	01	21	22		9921X	25	A	XXX	XX		NPI	
3															NPI	
4															NPI	
5															NPI	
6															NPI	

* Use 0272T for Device Interrogation only
Use 0273T for Device Interrogation and Programming

PHYSICIAN OR SUPPLIER INFORMATION

Additional Reimbursement Information

1500 Form Locator

Item Number	Title	Notes
Item 19	Additional Claim Information	Enter crosswalk CPT code I and verbiage around the expected reimbursement for that code in dollar amount
Item 21 (1-4)	Diagnosis or Nature of Illness or Injury	Enter the ICD-10 CM diagnosis codes to identify the patient's diagnosis and/or condition
Item 23	Prior Authorization Number	Enter payer's prior authorization number (if obtained prior to the procedure)
Item 24D	Procedures, Services or Supplies	Enter CPT codes for each procedure or service rendered, with one CPT code in each line. Include modifiers if needed, eg. -80, if assistant surgeon
Item 24E	Diagnosis Pointer	Point the services in 24 D to the diagnosis codes listed in 21 1-4

Generator Replacement - Physician Billing

Physician Generator Replacement Code (this code is used for billing)

CPT® Code[3]	Descriptor
Battery Replacement	
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)

Barostim generator replacement is reported with Category III CPT codes. When submitting claim information, providers may choose to reference a comparative Category I CPT procedure code with similar or equivalent resources (i.e. RVUs) to the Barostim implant in the claims form box 19.

Example Comparative Codes (these codes are examples, they are not billed)

Comparative Code		Work RVU
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	**15.49**

Generator Replacement - Outpatient Hospital Billing

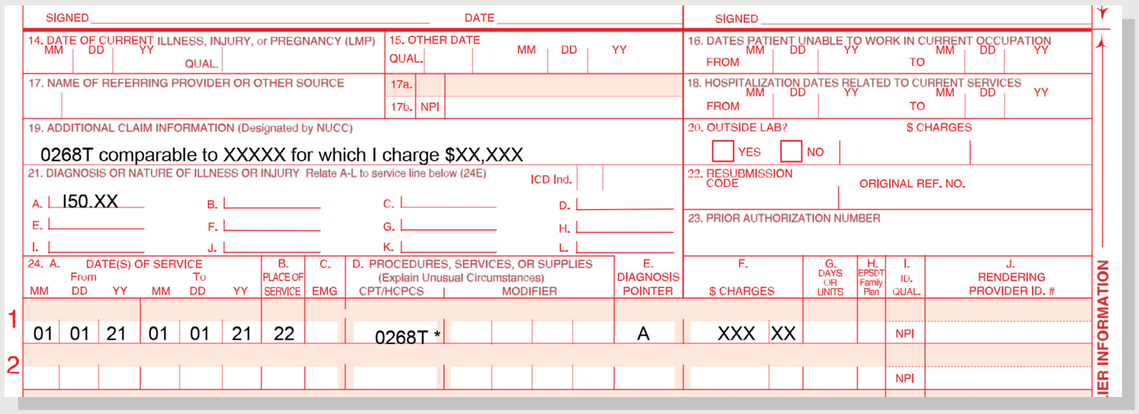
CPT® Code[3]	Descriptor	Status Indicator	APC
Battery Replacement			
0268T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5465

HCPCS Level II Device Codes

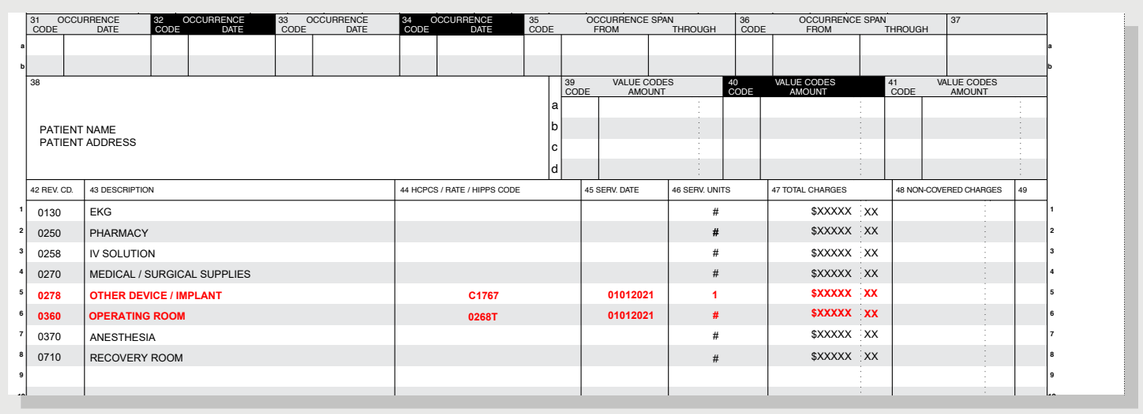
The following HCPCS Level II codes should be used for cost reporting purposes when reporting Barostim generator replacement. In general, C-codes are used for billing Medicare and L-codes are used for billing private payers, although some private payers may also accept C-codes.

HCPCS[5] Code	Descriptor
Battery and lead Replacement	
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8680	Implantable neurostimulator electrode, each

Generator replacement physician billing sample



Generator replacement outpatient UB-04 sample



Ambulatory Surgery Center

Procedures involving the Barostim System may be also performed in the Ambulatory Surgery Centers (ASC). The following CPT codes may be used as a guide for Ambulatory Surgery Center (ASC) reporting.

Medicare outpatient ambulatory surgery center implant cases involving the use of Barostim system are eligible for Transitional Pass-Through Payment.

CPT® Code[3]	Descriptor	ASC Payment Indicator
Insertion/Replacement		
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	J8
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
Revision/Removal		
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	G2

J8 – Device intensive procedure, paid at adjusted rate
G2 – Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight

Reimbursement Appendix

CPT® Code[3]	Descriptor	Status Indicator	APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	J1	5465
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461
0268T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5465
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	Q2	5432
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)	S	5721
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report; with programming	S	5721

Hospital Outpatient Status Indicator:
J1- Hospital Part B services paid through a Comprehensive APC (C-APC). Comprehensive APCs (C-APCs) were established for certain payment groups (e.g., device intensive) whereby Medicare only reimburses a single C-APC on a date of service.
Q2- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator "T".
S- Procedure or Service, Not Discounted When Multiple; *Medicare rate for 2021

CVRx Contacts

Contact

Technical Support (24/7)
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www.cvrx.com/reimbursement

Local Team

Sales

Clinical support

Training

References:
Physician Billing
1 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050
2 ICD-10-CM 2022. American Medical Association, Chicago, IL 2019.
3 Current Procedural Terminology 2022, American Medical Association. Chicago, IL 2022. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/ DFARS apply.
4 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050 National Uniform Claim Committee, 1500 Health Insurance Claim Form Reference Instruction Manual. Version 9.1 5/14. 1 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050

Facility Billing
1 Current Procedural Terminology 2022, American Medical Association. Chicago, IL 2022. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
2 ICD-10-PCS and ICD-10-CM 2022. American Medical Association, Chicago, IL 2019.
3 2020 IPPS Final Rule. CMS-1716-F.
4 2022 OPPS and ASC Final Rule. CMS-1753-FC.
5 2022 HCPCS Level II Expert. AAPC, Salt Lake City, UT 2019.
6 https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0

Barostim™ Brief Summary for Physicians
The Barostim System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

Patients are contraindicated if they have been assessed to have bilateral carotid bifurcations located above the level of the mandible, baroreflex failure or autonomic neuropathy, uncontrolled symptomatic cardiac bradyarrhythmias, carotid atherosclerosis that is determined by ultrasound or angiographic evaluation greater than 50%, ulcerative plaques in the carotid artery as determined by ultrasound or angiographic evaluation, known allergy to silicone or titanium.
Warnings include: only trained physicians may use this system, prescribing physicians should be experienced in the diagnosis and treatment of heart failure and should be familiar with the use of this system, monitor blood pressure and heart rate during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively, post-implantation, program the system to avoid the following: heart rate falls below 50 beats per minute (BPM), or systolic pressure falls below 90 mmHg, or diastolic blood pressure falls below 50 mmHg, or problematic adjacent tissue stimulation is noted, or undesirable interaction indicated by monitoring of any other implanted electrical device (see "Device Interaction Testing" in Section 10), or any other potentially hazardous patient responses are observed. Do not use Magnetic Resonance Imaging (MRI) on patients implanted with the system. Improper system implantation could result in serious injury or death. Do not use diathermy therapy including shortwave, microwave, or therapeutic ultrasound diathermy on patients implanted with the system. Patients should be counseled to stay at least 15 cm (6 inches) away from devices with strong electrical or magnetic fields such as strong magnets, loudspeaker magnets, Electronic Article Surveillance (EAS) system tag deactivators, arc welders, induction furnaces, and other similar electrical or electromechanical devices. This would include not placing items such as earphones in close proximity to the implanted pulse generator. The IPG may affect the operation of other implanted devices such as cardiac defibrillators, pacemakers, or neurological stimulation systems. For patients who currently have an implanted electrical medical device, physicians must verify compatibility with the implanted device during implantation of the system. Contralateral implant of the Barostim NEO IPG may help to reduce potential interactions. Interactions are more likely in devices that contain a sensing function, such as an implantable cardiac defibrillator or pacemaker. If an interaction is observed, the Barostim NEO IPG should be programmed to reduced therapy output settings in order to eliminate the interaction. If necessary, change settings in the other implant only if the changes are not expected to negatively impact its ability to perform its prescribed therapy. During the implant procedure, if device interactions cannot be eliminated the Barostim NEO System should not be implanted.
Precautions include: the system should be implanted and programmed carefully to avoid stimulation of tissues near the electrode or in the area of the IPG pocket. Such extraneous stimulation could involve the following: the regional nerves, causing laryngeal irritation, difficulty swallowing, or dyspnea, the cervical musculature, causing intermittent contraction, skeletal muscles, causing intermittent contraction around the IPG pocket. Proper sterile technique during implantation should be practiced and aggressive pre-operative antibiotics are recommended. Infections related to any implanted device are difficult to treat and may necessitate device explantation.

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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

See System Reference Guide 900120-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events. For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/. CVRx, Barostim, Neo, Barostim Neo, BAT, BATwire, Barostim Neo2, Neo2, and Outsmart the heart are all trademarks of CVRx, Inc. All other trademarks are property of their respective owners.

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