Reimbursement and clinic reference guide

Effective as of January 1 2025

Barostim Patient Flow

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

Patient assessment
- Symptomatic despite GDMT
- Recent echo (LVEF ≤ 35%)
- EKG
- Baseline NT-proBNP (< 1600 pg/mL)
  May require medical optimization and re-test
- Consider carotid doppler

Prior authorization
- CVRx Patient Access Support
- 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

Barostim indications[1]

- NYHA III or NYHA II (with recent NYHA III) despite treatment with GDMT* (medications and devices)
- LVEF ≤ 35%
- NT-proBNP < 1600 pg/mL

Barostim delivers Baroreflex Activation Therapy for improvement of patients' heart failure functional status, six-minute hall walk, and quality of life.

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 and Medtronic's EV-ICD contraindicates patients with unipolar pacing devices (e.g.: Barostim, which uses unipolar stimulation)

*Guideline directed medical therapy (GDMT) according to 2022 AHA/ACC/ESC guidelines

Prior authorization

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

CVRx offers Prior Authorization support.

CVRx Prior Authorization support provides case-by-case support for providers who perform Barostim implantation procedures.
It 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 CVRx Prior Authorization support 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: **reimbursement@cvrx.com**
Phone: 763-416-2344
Fax: 855-710-7053

Follow-up

Routine follow-up phase

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

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.

Technical support (24/7)
Phone: 763-416-2343

Contact CVRx with any questions:

Email: **reimbursement@cvrx.com**
Phone: 763-416-2344

System implant - Commonly used diagnosis codes*

ICD-10-CM[2]	Descriptor
I50.2	Systolic (Congestive) Heart Failure
I50.20	Unspecified Systolic (Congestive) Heart Failure
I50.21	Acute Systolic (Congestive) Heart Failure
I50.22	Chronic Systolic (Congestive) Heart Failure
I50.23	Acute on Chronic Systolic (Congestive) Heart Failure
I50.3	Diastolic (Congestive) Heart Failure
I50.30	Unspecified Diastolic (Congestive) Heart Failure
I50.31	Acute Diastolic (Congestive) Heart Failure
I50.32	Chronic Diastolic (Congestive) Heart Failure
I50.33	Acute on Chronic Diastolic (Congestive) Heart Failure
I50.4	Combined Systolic (Congestive) and Diastolic (Congestive) Heart Failure
I50.40	Unspecified Combined Systolic (Congestive) and Diastolic (Congestive) Heart Failure
I50.41	Acute Combined Systolic (Congestive) and Diastolic (Congestive) Heart Failure
I50.42	Chronic Combined Systolic (Congestive) and Diastolic (Congestive) Heart Failure
I50.43	Acute on Chronic Combined Systolic (Congestive) and Diastolic (Congestive) Heart Failure

*Not a complete list

System implant - physician billing

Physician system implant code (this code is used for billing)

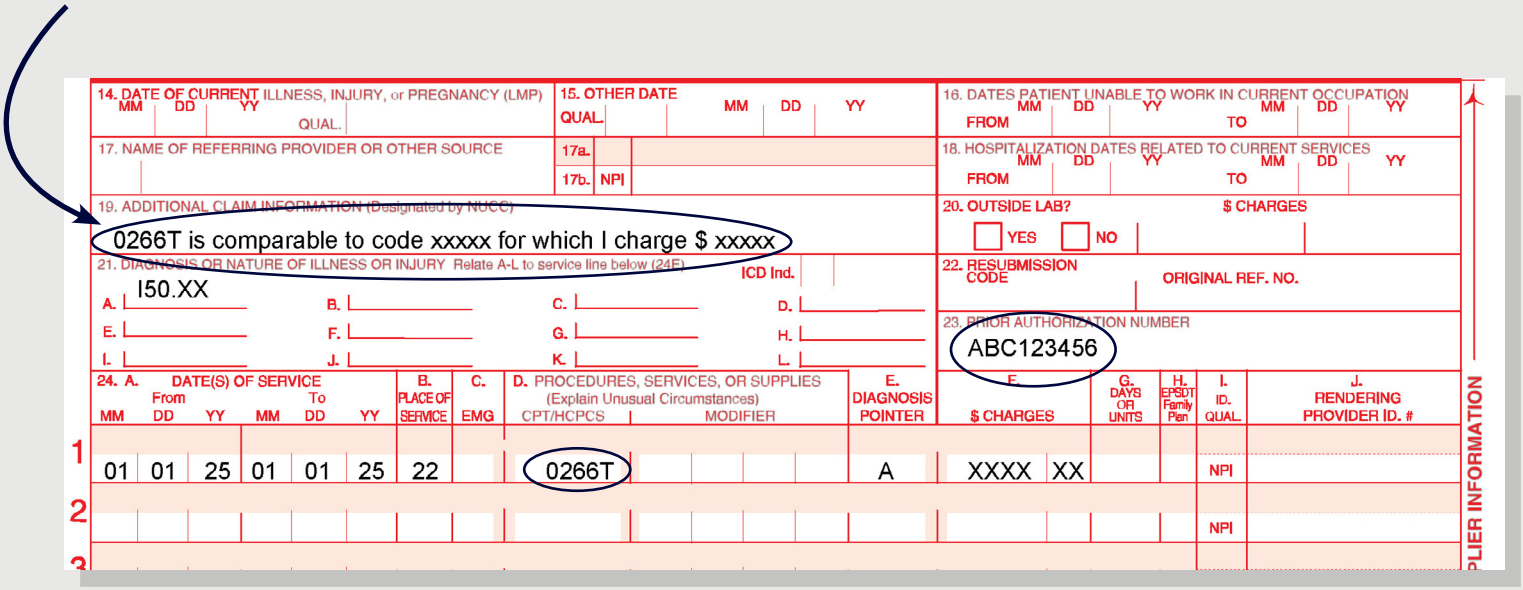
CPT® code[3]	Descriptor
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system

Barostim system implant is reported with a Category III CPT® code. When submitting 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[5]
64568	Open implantation of cranial nerve (eg: vagus nerve) neurostimulator electrode array and pulse generator	9
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	14

System implant physician billing sample



System implant

For an initial "**system implant**" (full device – Generator and Lead at the same time) use the following product numbers:

- **100069-202**, Barostim Neo2 Neurostimulator System IPG Model CSL Comb Kit

This procedure is always billed using **C1825** - Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s).

Any (single part below) **replacements** are billed using **C1767** (Generator) and **C1778** (Lead) – see crosswalk below and more on page 16 under Replacement

100065-202, Barostim NEO2 Model 2104 (**IPG** only)
100063-212, Barostim Neo CSL Kit Model 1036 SH (**lead** only)

Procedure	Descriptor	CPT® code[3]	HCPCS code[4]	Item #
Initial Barostim System Implant (Kit) De novo implant only	Implantation or replacement of carotid sinus baroreflex activation device; total system	**0266T**	**C1825**	100069-202, Barostim Neo2 Neurostimulator System IPG Model CSL **Comb** Kit
Battery replacement only (Barostim)	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only	**0268T**	**C1767**	100065-202, Barostim NEO2 Model 2104 **IPG** (only)
Lead replacement only	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral	**0267T**	**C1778**	100063-212, Barostim Neo CSL Kit Model 1036 SH (**lead** only)

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

System implant - outpatient hospital billing[4]

CPT® code[3]	Descriptor	Status indicator	APC[6]
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	S	1580

S - Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.

HCPCS code[4]	Descriptor	APC[6]
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	2030

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

Outpatient UB-04 sample

1	2	3a PAT. CNTL #	4 TYPE OF BILL
		b. MED. REC. #	131
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM: 01012025 THROUGH: 01012025

8 PATIENT NAME	9 PATIENT ADDRESS
PATIENT NAME	

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18–28 CONDITION CODES	29 ACDT STATE	30
		01012025								

31 OCCURRENCE CODE / DATE	32 OCCURRENCE CODE / DATE	33 OCCURRENCE CODE / DATE	34 OCCURRENCE CODE / DATE	35 OCCURRENCE SPAN CODE / FROM / THROUGH	36 OCCURRENCE SPAN CODE / FROM / THROUGH	37
a						a
b						b

38	39 VALUE CODES CODE / AMOUNT	40 VALUE CODES CODE / AMOUNT	41 VALUE CODES CODE / AMOUNT
PATIENT NAME PATIENT ADDRESS	a		
	b		
	c		
	d		

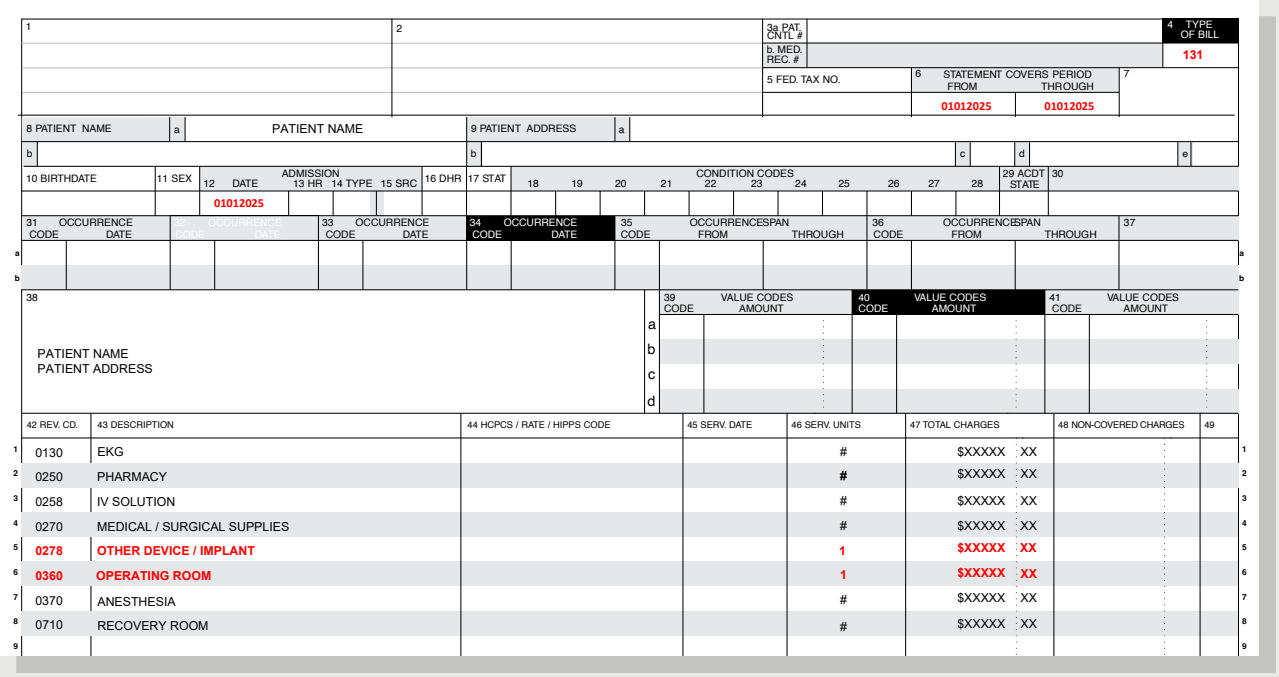
	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0130	EKG			#	$XXXXX XX		1
2	0250	PHARMACY			#	$XXXXX XX		2
3	0258	IV SOLUTION			#	$XXXXX XX		3
4	0270	MEDICAL / SURGICAL SUPPLIES			#	$XXXXX XX		4
5	**0278**	**OTHER DEVICE / IMPLANT**	**C1825**	**01012025**	**1**	**$XXXXX XX**		5
6	**0360**	**OPERATING ROOM**	**0266T**	**01012025**	**1**	**$XXXXX XX**		6
7	0370	ANESTHESIA			#	$XXXXX XX		7
8	0710	RECOVERY ROOM			#	$XXXXX XX		8
9								9
10								10

System implant - inpatient hospital billing[6]

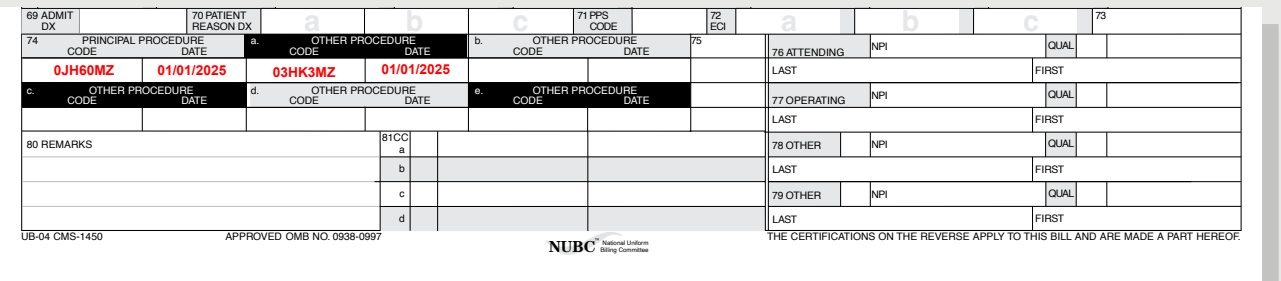
ICD-10-PCS procedure code[2]	Descriptor	Typical MS-DRG assignment[7]
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach	276
AND		
03HK3MZ	Insertion of stimulator lead into right internal carotid artery, percutaneous approach	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
OR		
03HL3MZ	Insertion of stimulator lead into left internal carotid artery, percutaneous approach	

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

Inpatient UB-04 sample



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0130	EKG			#	$XXXXX XX		
0250	PHARMACY			#	$XXXXX XX		
0258	IV SOLUTION			#	$XXXXX XX		
0270	MEDICAL / SURGICAL SUPPLIES			#	$XXXXX XX		
0278	OTHER DEVICE / IMPLANT			1	$XXXXX XX		
0360	OPERATING ROOM			1	$XXXXX XX		
0370	ANESTHESIA			#	$XXXXX XX		
0710	RECOVERY ROOM			#	$XXXXX XX		



74 PRINCIPAL PROCEDURE CODE	74 PRINCIPAL PROCEDURE DATE	74a OTHER PROCEDURE CODE	74a OTHER PROCEDURE DATE	74b OTHER PROCEDURE CODE	74b OTHER PROCEDURE DATE
0JH60MZ	01/01/2025	03HK3MZ	01/01/2025		

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

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 6)

Code[2]	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]	
99211	Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional.
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.

Follow-up - physician coding and billing (continued)

Part 2 Physician billing: follow-up visit device interrogation with programming[3]

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):

CPT® Code[3]	Descriptor	RVU[5]
93284	…multiple lead transvenous implantable defibrillator system	3.12 T 1.25W
93281	…multiple lead pacemaker system	2.47 T .85 W
93282	…single lead transvenous implantable defibrillator system	2.35 T .85 W

This code is used for billing:

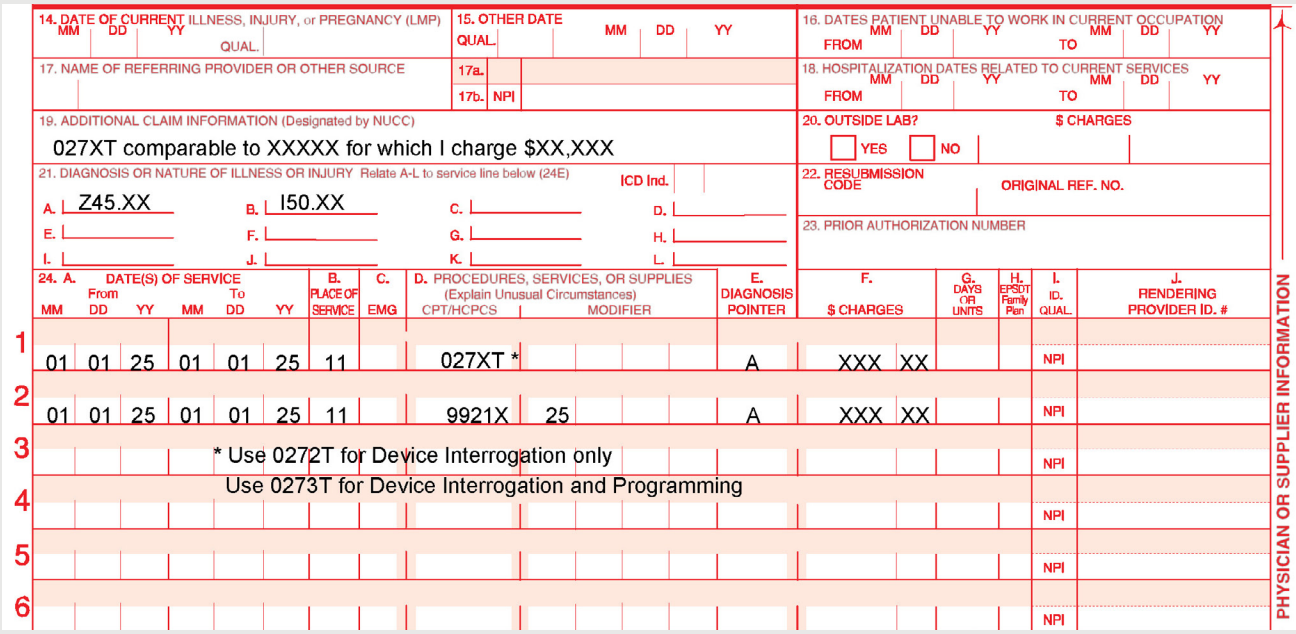
CPT® 0272T – Interrogation device evaluation

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):

CPT® Code[3]	Descriptor	RVU[5]
93289	…single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements	2.12 T .75 W
93261	…implantable subcutaneous lead defibrillator system	2.08 T .74 W
93288	…single, dual, or multiple lead pacemaker system, or leadless pacemaker system	1.66 T .43 W

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	25	01	01	25	11		027XT *		A	XXX XX			NPI	
2	01	01	25	01	01	25	11		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

Generator replacement - physician billing

Physician generator replacement code (this code is used for billing)

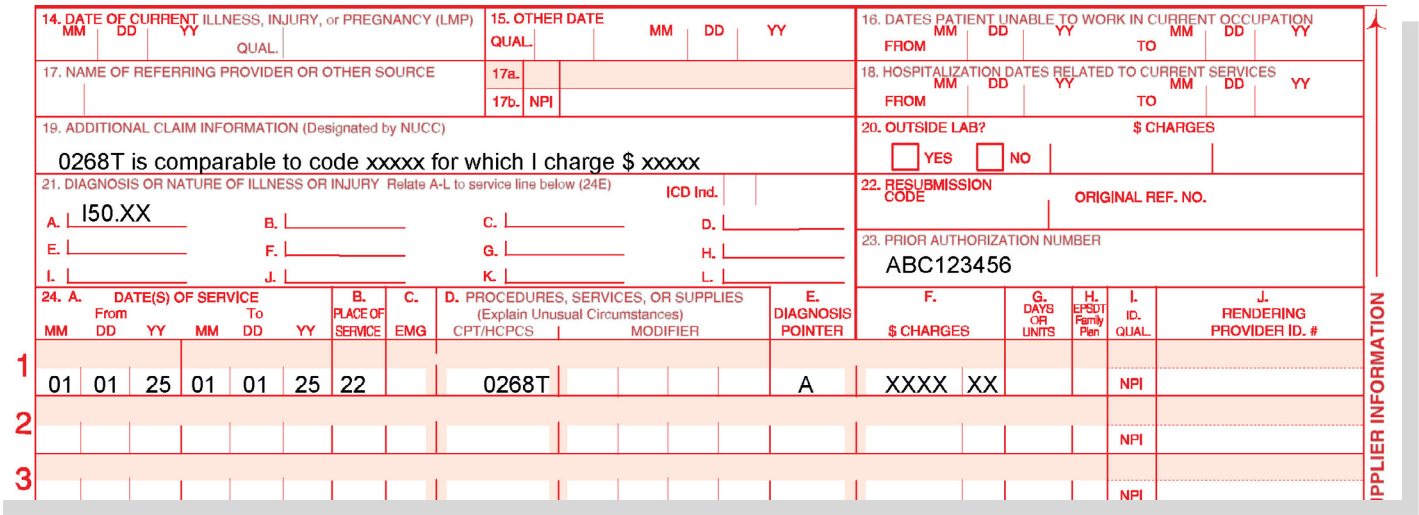
CPT® code[3]	Descriptor
Battery replacement	
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)

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[5]
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	6.05

Generator replacement physician billing sample



Generator replacement - outpatient hospital billing

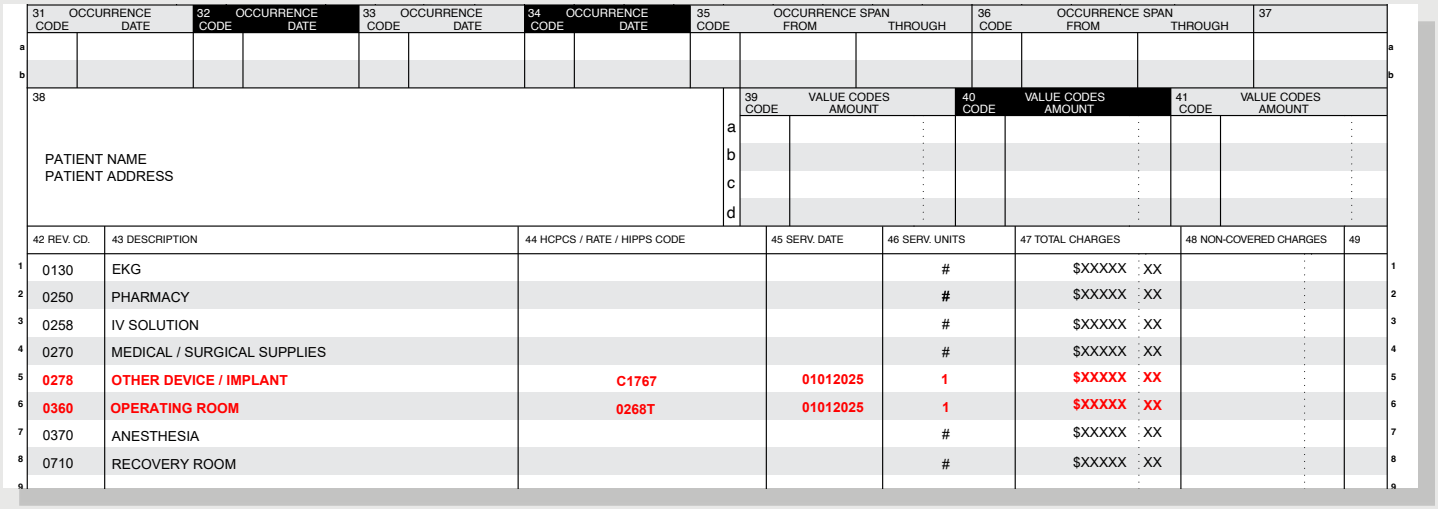
CPT® code[3]	Descriptor	Status indicator	APC[6]
Battery replacement			
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5465

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 code[4]	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 outpatient UB-04 sample



31 OCCURRENCE CODE	DATE	32 OCCURRENCE CODE	DATE	33 OCCURRENCE CODE	DATE	34 OCCURRENCE CODE	DATE	35 OCCURRENCE SPAN CODE	FROM	THROUGH	36 OCCURRENCE SPAN CODE	FROM	THROUGH	37
a														a
b														b

38	39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	AMOUNT
PATIENT NAME PATIENT ADDRESS	a					
	b					
	c					
	d					

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0130	EKG			#	$XXXXX XX			1
2	0250	PHARMACY			#	$XXXXX XX			2
3	0258	IV SOLUTION			#	$XXXXX XX			3
4	0270	MEDICAL / SURGICAL SUPPLIES			#	$XXXXX XX			4
5	**0278**	**OTHER DEVICE / IMPLANT**	**C1767**	**01012025**	**1**	**$XXXXX XX**			5
6	**0360**	**OPERATING ROOM**	**0268T**	**01012025**	**1**	**$XXXXX XX**			6
7	0370	ANESTHESIA			#	$XXXXX XX			7
8	0710	RECOVERY ROOM			#	$XXXXX XX			8
9									9

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.

CPT® code[3]	Descriptor	ASC[6] 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[4]

CPT® code[3]	Descriptor	Status indicator	APC[6]
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	S	1580
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; pulse generator only (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- Paid under OPPS; Addendum B displays APC assignments when services are separately payable.
S- Procedure or Service, Not Discounted When Multiple; *Medicare rate for 2025

CVRx contacts

Contact

Technical support (24/7)
Phone: 763-416-2343

Reimbursement
Phone: 763-416-2344
Fax: 855-710-7053
Email: reimbursement@cvrx.com

Prior authorization
Email: **c-pas@cvrx.com**
www.cvrx.com/reimbursement

Local Team

Sales

Clinical support

Training

Reimbursement

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References:

1. Instructions for Use 900133-001 Rev. E available at **www.cvrx.com/ifu**
2. ICD-10-PCS and ICD-10-CM 2024. American Medical Association, Chicago, IL.
3. Current Procedural Terminology 2024, American Medical Association. Chicago, IL. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright American Medical Association. All Rights Reserved. Applicable FARS/ DFARS apply.
4. Source: Optum360 EncoderProForPayers.com
5. 2025 Physician Final Rule CMS -1807.
6. 2025 OPPS and ASC Final Rule CMS 1809-FC.
7. 2025 IPPS Final Rule CMS-1808-F.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. See Instructions for Use 900133-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events.

Barostim is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of ≤ 35%, and a NT-proBNP <1600 pg/ml. Barostim delivers Baroreflex Activation Therapy for improvement of patients' heart failure functional status, six-minute hall walk, and quality of life.

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. 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.

It is anticipated that subjects will be exposed to operative and post-operative risks similar to related surgical procedures involving the neck and/or a pacemaker implant. These risks and potential risks of chronic device based baroreflex activation may include, but are not limited to: stroke, transient ischemic attack (TIA), systemic embolization, surgical or anesthetic complications, infection, wound complications, arterial damage, pain, nerve damage/stimulation, hypotension, hypertensive crisis, respiratory, exacerbation of heart failure, cardiac arrhythmias, tissue erosion/IPG migration, injury to baroreceptors, fibrosis, allergic reaction, general injury to user or patient, need for reoperation, secondary operative procedure, and death. Patients implanted with the system may receive Magnetic Resonance Imaging (MRI) only when all MR Conditional safety parameters are met as listed in the instructions for use.

For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/
For a list of all applicable patents, see www.cvrx.com/patent-marking.

CVRx, Inc.
9201 West Broadway Ave., Suite 650
Minneapolis, MN 55445
Phone: (763) 416-2840
Fax: (763) 416-2841
www.cvrx.com

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