Reimbursement and clinic reference guide

Effective 2024

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[4]

- 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 device is contraindicated for patients with unipolar pacing devices.
- Barostim uses unipolar stimulation.

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

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. Instructions for Use 900133-001 Rev. D available at www.cvrx.com/ifu

Prior authorization

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

CVRx offers a Patient Access Support to help.

CVRx Prior Authorization Program 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 Program 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

Barostim™ titration protocol

BeAT-HF, the clinical trial underlying approval of Barostim therapy, is predicated upon increasing the output of the Barostim device over the course of the first 3-6 months of post-implant office visits to reach therapy stabilization. For most of the patient programming in the trial, therapy was stabilized in 3-5 visits between 2-4 months. The distribution graph below, Fig. 1, reflects the programmed amplitudes in BeAT-HF, and thus the recommended Barostim programming protocol.

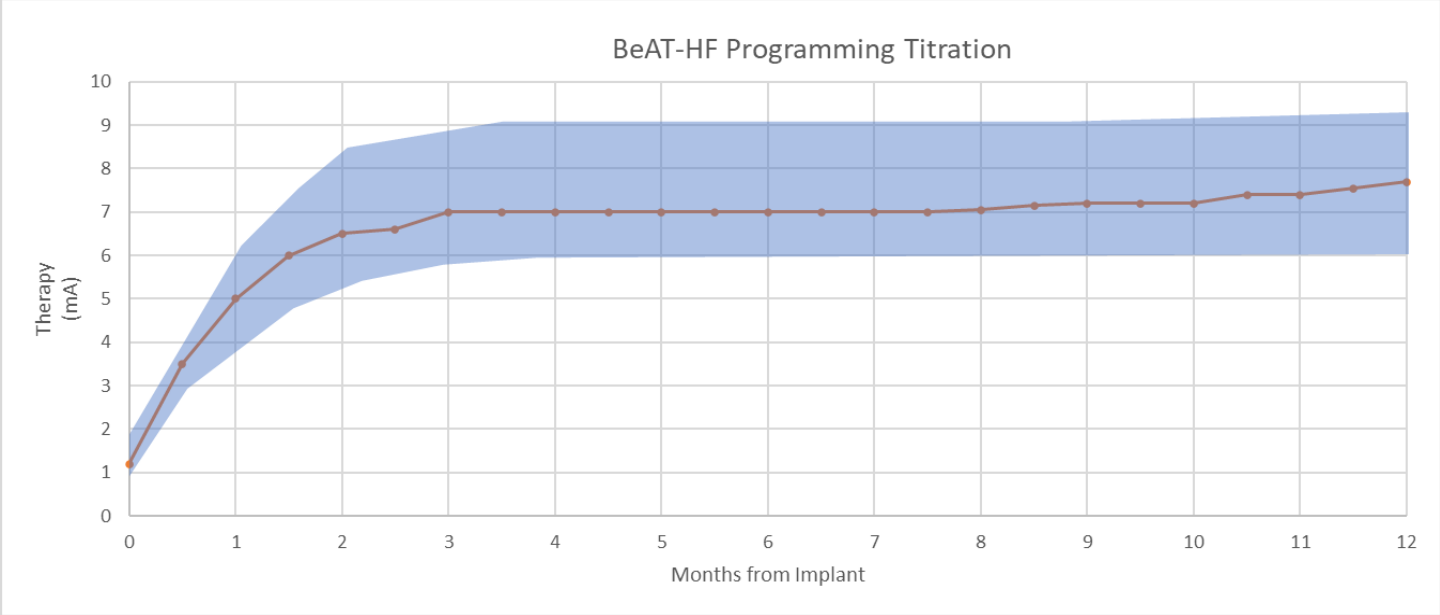


Fig.1 *BeAT-HF clinical trial programmed amplitudes showing Median and inner quartile range (therapy amplitude normalized to 40Hz, 125uS)*

Absent alternative physician orders addressing individual patient needs, CVRx field representatives will assist in programming therapy amplitudes within this protocol, i.e., the shaded blue area of Fig 1. The purpose of this protocol is to program an incrementally higher therapy output at each titration visit to reach stabilization in 2-4 months to emulate the benefits experienced in BeAT-HF.

Programming protocol:

1. **Obtain resting baseline blood pressure (BP) and heart rate (HR)**
2. **Slowly increase amplitude by 0.2 - 0.4mA increments (do not exceed output increases of 5mA per titration visit)**
3. **Record any observed symptoms (e.g., extraneous stimulation, dizziness, tingling, etc.) in the programmer's Therapy Response Log corresponding to the setting producing the symptoms**
4. **At end of session, (i) set therapy to an amplitude at least 1mA below symptoms of extraneous stimulation; (ii) document a 1mA stimulation buffer; and (iii) take BP for final session notes**
5. **Repeat at each titration visit until therapy threshold is consistent**

Access to BP measurements is recommended through use of either an automatic blood pressure cuff or facility staff taking manual BP measurements during the titration session. Accuracy and consistency are improved by properly trained facility staff placing an automatic cuff on the patient's arm and leaving it in the same location for the duration of the titration session or having a facility staff member take manual measurements. To facilitate this, CVRx personnel may carry an automatic blood pressure cuff that, with the assistance of medical personnel to place the cuff, can be used during the titration session.

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.

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

- 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 9)
- 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

- **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 CVRx with any questions:

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

System implant - diagnosis codes

ICD-10-CM	Descriptor	CC	MCC
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	
I50.31	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	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

System implant - physician billing

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

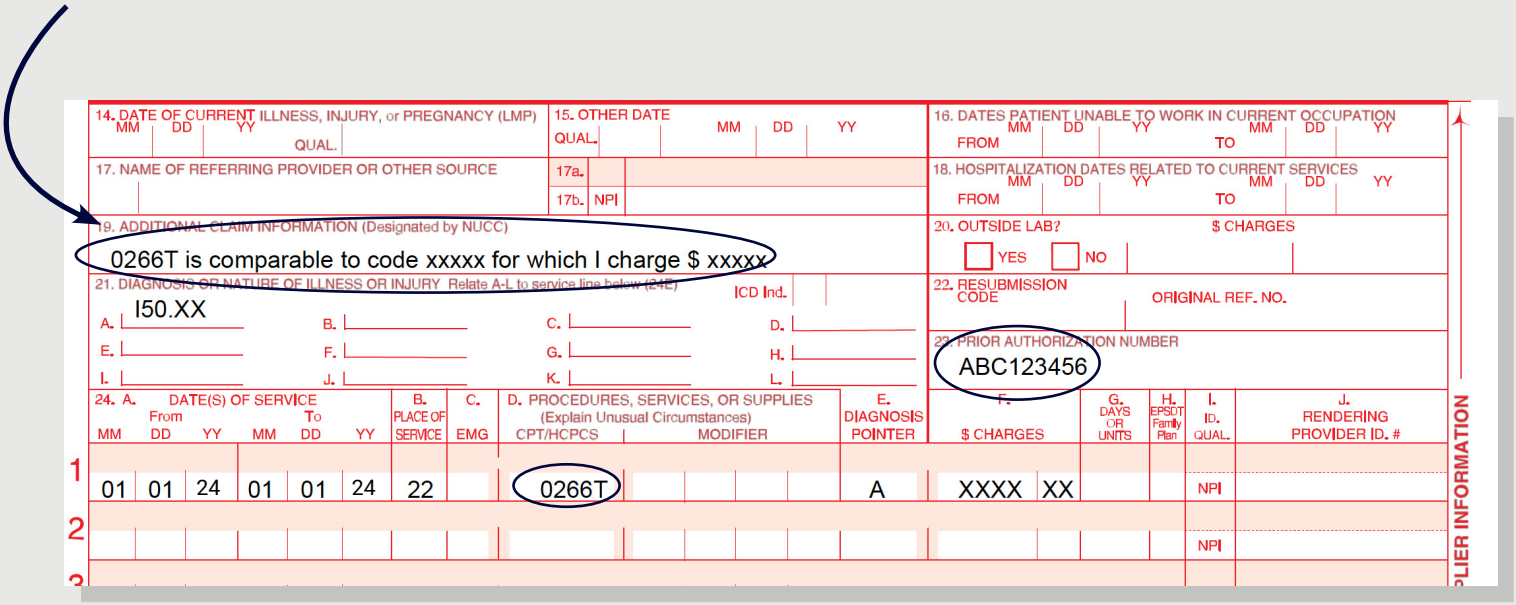
CPT® code	Descriptor
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system

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

System implant - outpatient hospital billing

CPT® code	Descriptor	Status indicator	APC
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	Descriptor	APC
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	THROUGH 7
			01012024	01012024

8 PATIENT NAME	a	PATIENT NAME	9 PATIENT ADDRESS	a
b			b	c d e

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30
		01012024																		

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

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

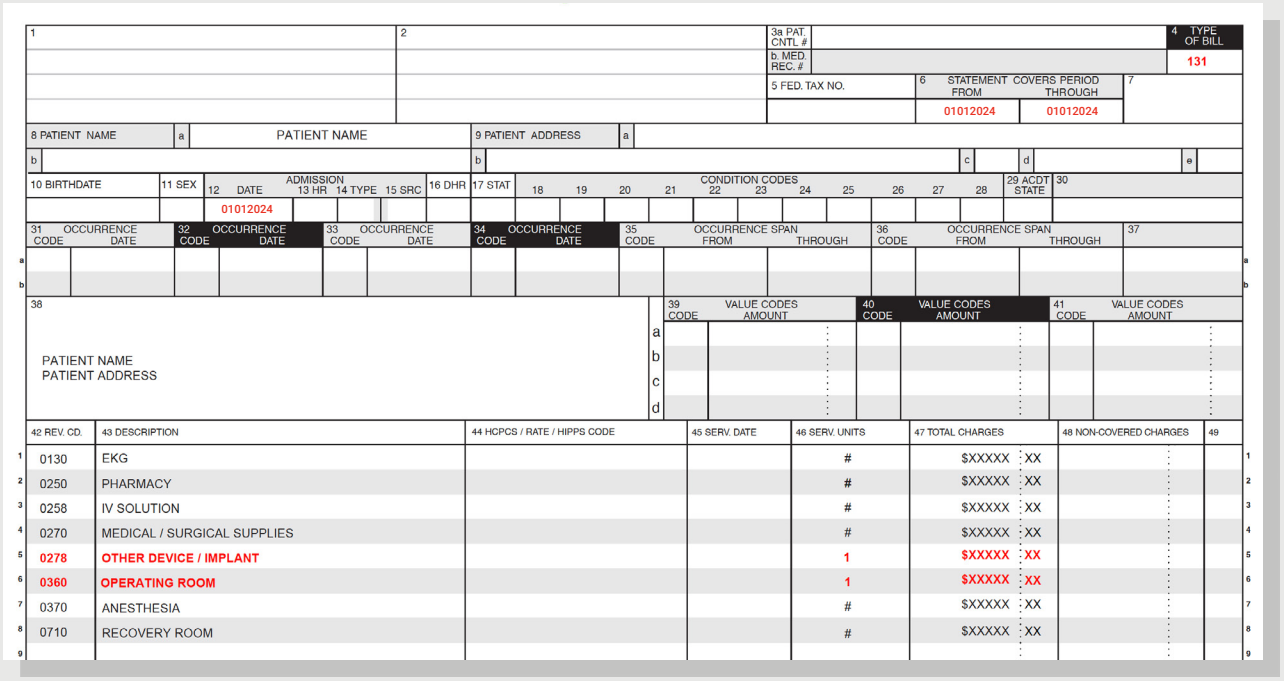
	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0130	EKG			#	$XXXXX XX			1
2	0250	PHARMACY			#	$XXXXX XX			2
3	0258	IV SOLUTION			#	$XXXXX XX			3
4	0270	MEDICAL / SURGICAL SUPPLIES			#	$XXXXX XX			4
5	0278	OTHER DEVICE / IMPLANT	C1825	01012024	1	$XXXXX XX			5
6	0360	OPERATING ROOM	0266T	01012024	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

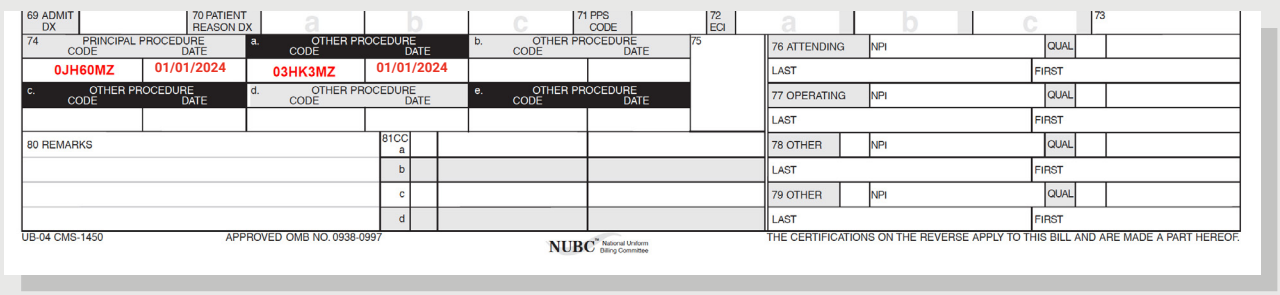
ICD-10-PCS procedure code	Descriptor	Typical MS-DRG assignment	
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach	252	with MCC
AND			
03HK3MZ	Insertion of stimulator lead into right internal carotid artery, percutaneous approach	253	with CC
OR			
03HL3MZ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

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
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	a. OTHER PROCEDURE CODE	a. OTHER PROCEDURE DATE	b. OTHER PROCEDURE CODE	b. OTHER PROCEDURE DATE
0JH60MZ	01/01/2024	03HK3MZ	01/01/2024		

c. OTHER PROCEDURE CODE	c. OTHER PROCEDURE DATE	d. OTHER PROCEDURE CODE	d. OTHER PROCEDURE DATE	e. OTHER PROCEDURE CODE	e. OTHER PROCEDURE DATE

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 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	3.14 T 1.25 W
	…multiple lead pacemaker system	93281	2.50 T .85 W
	…single lead transvenous implantable defibrillator system	93282	2.37 T .85 W

This code is used for billing:

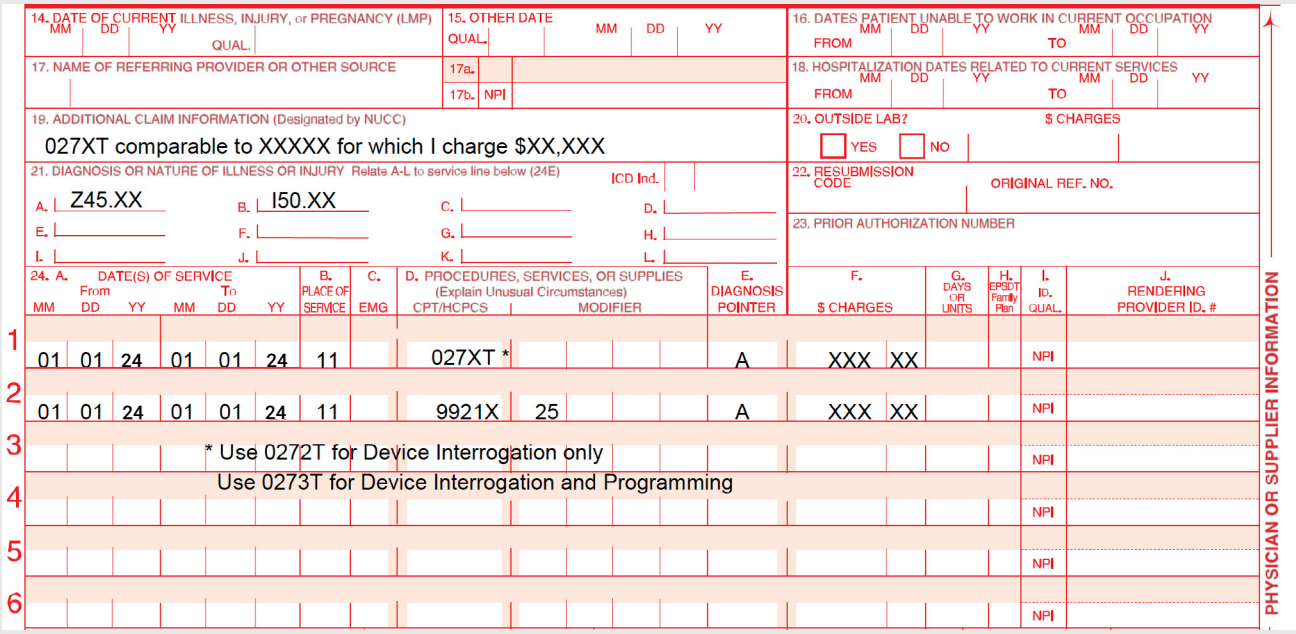
CPT 0272T – Interrogation device evaluation

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):

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	2.15 T .75 W
	…implantable subcutaneous lead defibrillator system	93261	2.08 T .74 W
	…single, dual, or multiple lead pacemaker system, or leadless pacemaker system	93288	1.68 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 TO MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
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	24	01	01	24	11		027XT *		A	XXX	XX		NPI	
2	01	01	24	01	01	24	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

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)

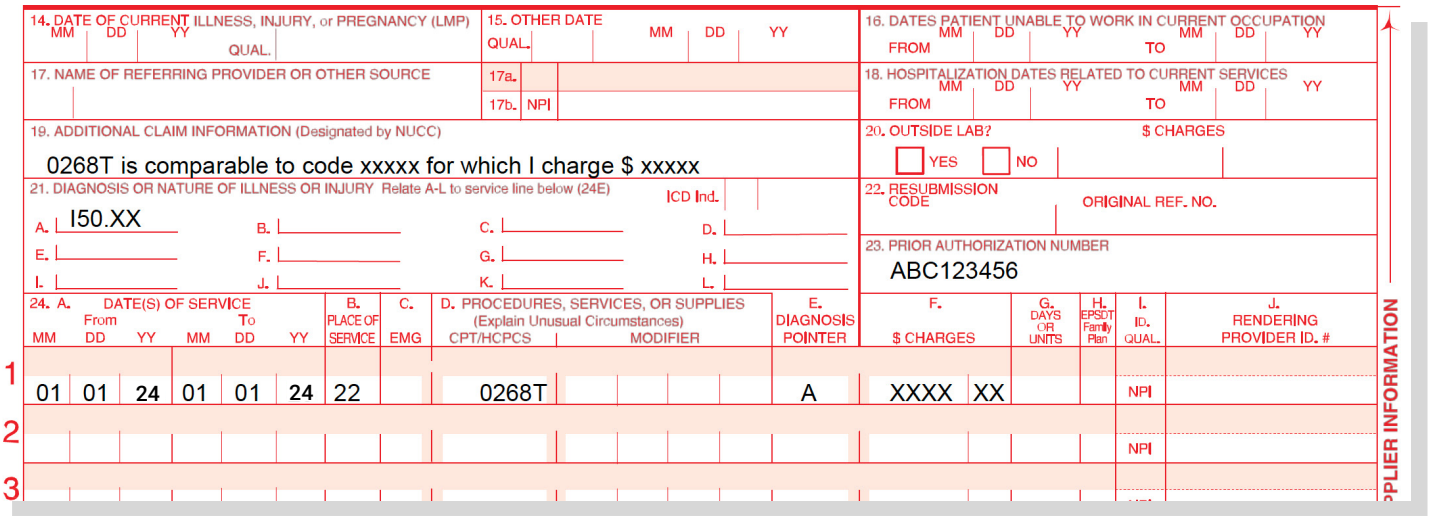
CPT® code[3]	Descriptor
Battery replacement	
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)

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	6.05

Generator replacement physician billing sample



Generator replacement - outpatient hospital billing

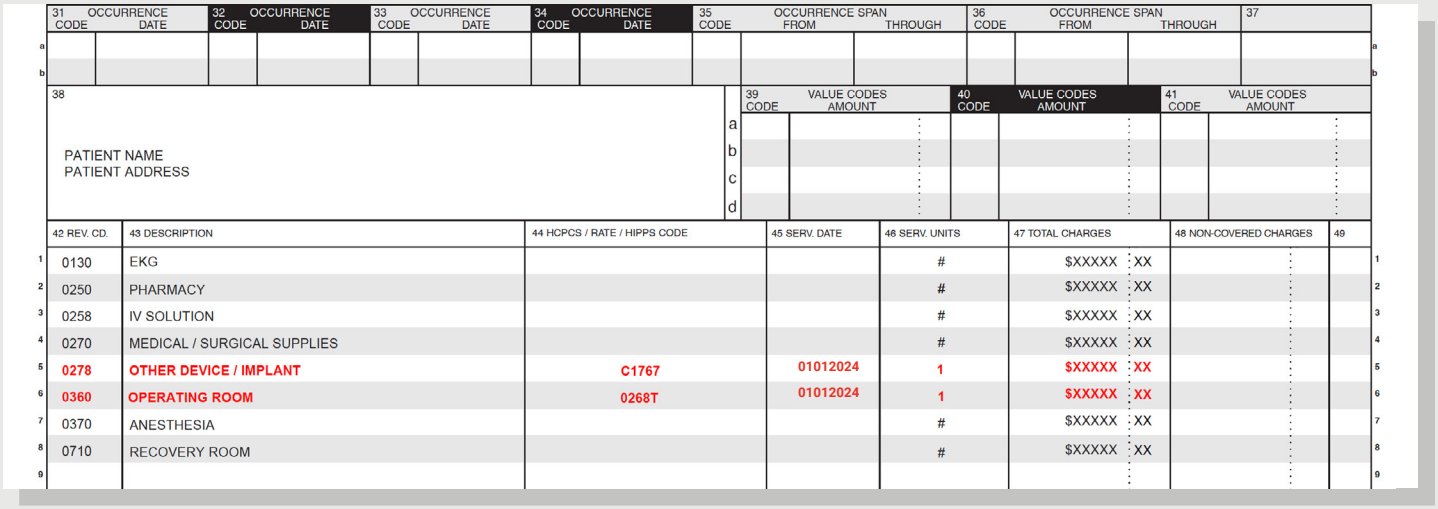
CPT® code[3]	Descriptor	Status indicator	APC
Battery replacement			
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5465

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[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 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 CODE	VALUE CODES AMOUNT	40 CODE	VALUE CODES AMOUNT	41 CODE	VALUE CODES 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	01012024	1	$XXXXX XX			5
6	0360	OPERATING ROOM	0268T	01012024	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 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	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 2024

CVRx contacts

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Fax: 855-710-7053
Email: reimbursement@cvrx.com

Prior authorization
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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 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 National Uniform Claim Committee, 1500 Health Insurance Claim Form Reference Instruction Manual. Version 9.1 5/14. 1

Facility Billing

1 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.
2 ICD-10-PCS and ICD-10-CM 2024. American Medical Association, Chicago, IL.
3 2024 IPPS Final Rule 1785-F
4 2024 OPPS and ASC Final Rule CMS-1786-FC.
5 2024 HCPCS Level II Expert. AAPC, Salt Lake City, UT.
6 https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0

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.

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