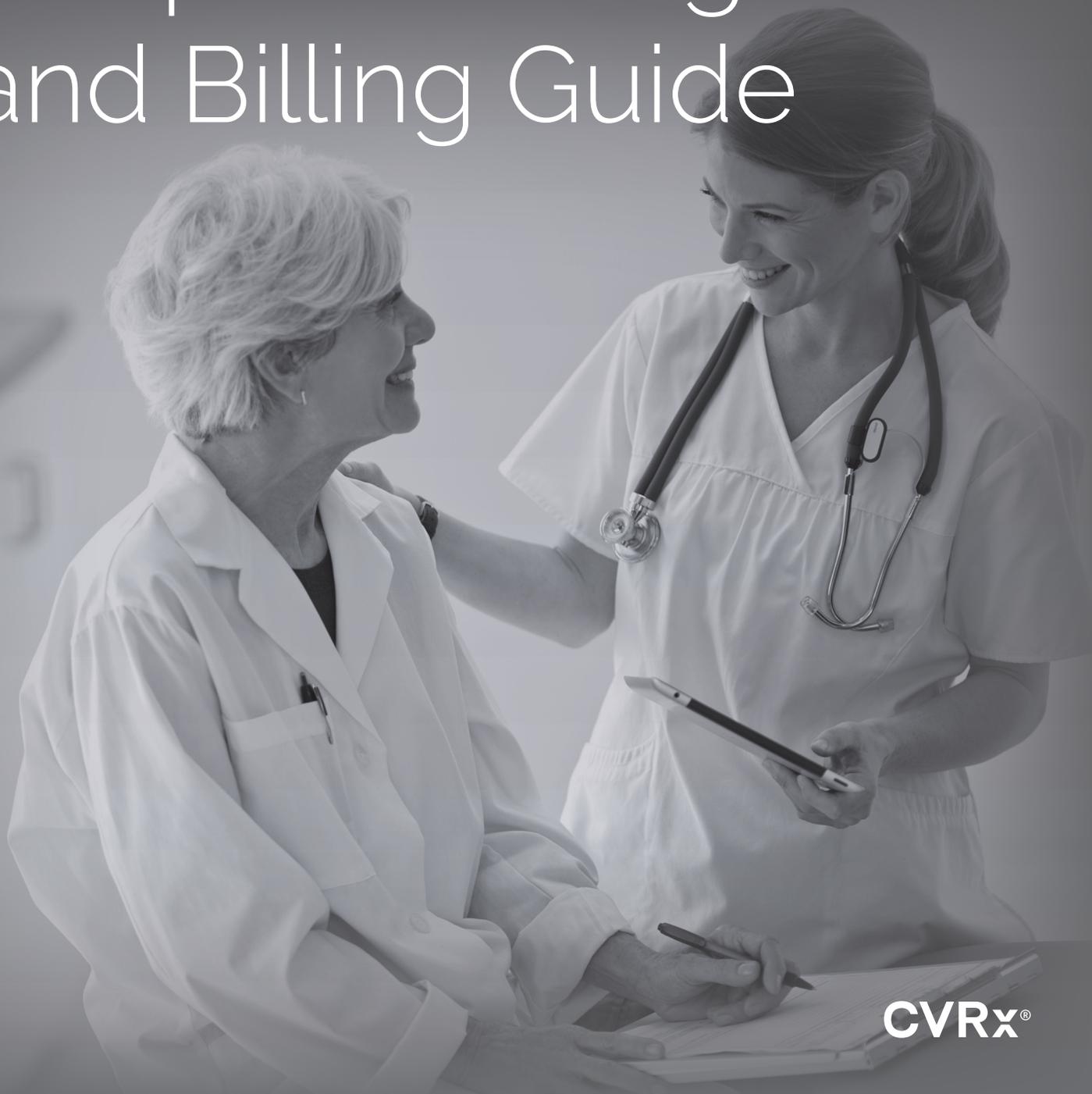




BAROSTIM  
THERAPY™

The BAROSTIM NEO™ System

# Hospital Coding and Billing Guide



CVRx®

# BAROSTIM NEO™ System Hospital Billing Guide

This Hospital Billing & Coding Guide provides information for physicians and healthcare facilities for BAROSTIM NEO System procedures.

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**CVRx offers reimbursement hotline support and prior authorization services to all providers. Contact the CVRx Reimbursement Hotline at 763-416-2344 or [Reimbursement@cvrx.com](mailto:Reimbursement@cvrx.com).**

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# BAROSTIM THERAPY Overview

## BAROSTIM NEO System

Heart failure is a condition where the heart cannot pump enough blood to meet the body's needs. Symptoms include shortness of breath, general fatigue or weakness and fluid retention. BAROSTIM NEO is an implantable neuromodulation therapy for the treatment of heart failure symptoms. The minimally invasive BAROSTIM NEO System uses CVRx's patented carotid baroreflex activation therapy (BAROSTIM THERAPY) technology to trigger the body's main cardiovascular reflex, thereby addressing the underlying causes of the progression of heart failure.

In clinical studies, BAROSTIM THERAPY has shown to significantly improve patient-centered symptomatic endpoints of quality of life score and exercise capacity. These results are supported by objective evidence of significant improvement of NT-proBNP.<sup>1</sup>

## Indication<sup>1</sup>

The BAROSTIM NEO 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  $\leq$  35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

## Contraindications<sup>1</sup>

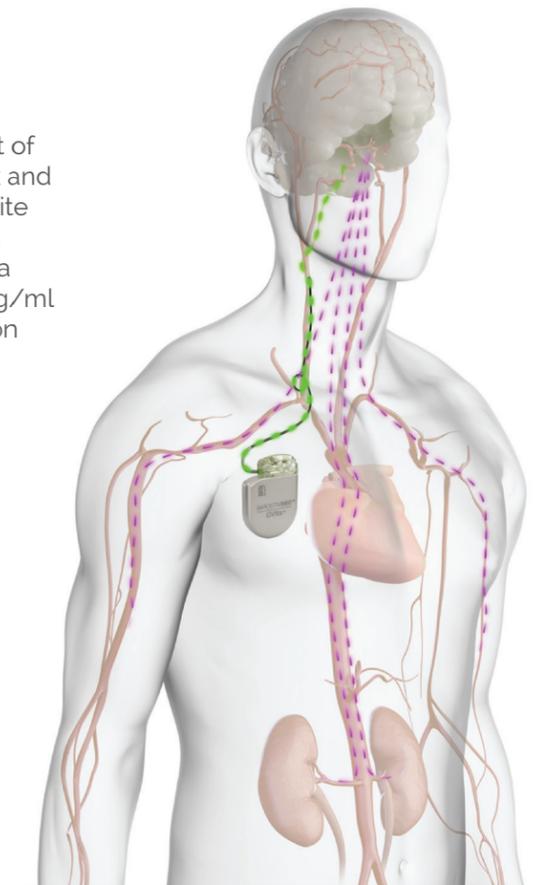
Patients are contraindicated if they have:

- Been assessed to have bilateral carotid bifurcations located above the level of the mandible
- Baroreflex failure or autonomic neuropathy
- Uncontrolled, symptomatic cardiac bradyarrhythmia
- 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

## System Implant Procedure Overview

*This document is for reference purposes only and does not replace physicians' medical documentation.*

An incision is made in the neck and carotid artery is exposed. A lead is connected to the implantable pulse generator (IPG). The lead is mapped and sutured. The lead is then disconnected from the IPG. A pocket is created and tunneling to the lead is performed. The strain relief loop is created. The lead is re-connected to the IPG. IPG is secured and incisions are closed.



# Hospital Coding and Billing Overview

The purpose of this document is to provide information on reporting of the BAROSTIM NEO baroreceptor activation neuromodulation procedure to physicians and their coding teams for purposes of coding and billing. It is the provider's responsibility to choose diagnosis codes that accurately describe the patient's condition and CPT codes reflecting the procedure performed. The medical record must contain the appropriate information to support medical necessity.

For questions regarding reimbursement and prior authorization, please call the CVRx Reimbursement Hotline at **763-416-2344** or email questions to [Reimbursement@cvrx.com](mailto:Reimbursement@cvrx.com).

## DIAGNOSIS CODES

BAROSTIM NEO is used to treat the symptoms of heart failure patients with reduced EF  $\leq 35\%$ , NYHA Class III or II with a recent heart failure hospitalization, NtProBNP  $< 1600$  pg/ml and who are not indicated for cardiac resynchronization therapy as stated in the AHA/ACC guidelines.

When a patient with heart failure is implanted with BAROSTIM NEO, the following ICD-10-CM diagnosis may be reported. For those patients with a stated or implied causal relationship with hypertension, heart failure should be sequenced as a secondary diagnosis.

### Initial System Implant or Battery (IPG) Replacement ICD-10-CM

ICD-10-CM <sup>2</sup>	Descriptor
<b>I50.1</b>	<b>Left ventricular failure, unspecified</b>
<b>I50.2</b>	<b>Systolic (congestive) heart failure</b>
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
<b>I50.3</b>	<b>Diastolic (congestive) heart failure</b>
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
<b>I50.4</b>	<b>Combined systolic (congestive) and diastolic (congestive) heart failure</b>
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
<b>I50.8</b>	<b>Other heart failure</b>
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
<b>I50.9</b>	<b>Heart failure, unspecified</b>

When a patient is seen for routine interrogation and programming, Z45.42 should be listed as the primary diagnosis with the underlying condition of the patient (ie, heart failure) listed as a secondary diagnosis

### Follow Up Interrogation Device Evaluation CD-10-CM

ICD-10-CM <sup>2</sup>	Descriptor
Z45.42	Encounter for adjustment and management of neurostimulator

## HOSPITAL OUTPATIENT CODES

For hospital outpatient payments, Medicare assigns each CPT code to a specific Ambulatory Payment Classification (APC). Each APC has a fixed payment amount which includes the cost of any devices. Hospitals report outpatient procedures using CPT codes. The BAROSTIM NEO System CPT codes are Category III CPT codes.

### Implant Procedure

The BAROSTIM NEO system implant procedure is reported with the following CPT code and is mapped into the corresponding APC payment:

CPT <sup>®</sup> Code <sup>3</sup>	Descriptor	Status Indicator	APC	National Medicare Rate <sup>*</sup>
<b>Implant procedure</b>				
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)	J1	5464	\$29,115

\*Medicare rate for 2020

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 Level II Device Codes

The following HCPCS Level II codes should be used for cost reporting purposes when reporting procedures involving the BAROSTIM NEO System. HCPCS Level II device codes are assigned to identify the device itself. 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 <sup>5</sup> Code	Descriptor
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

## Interrogation and Device Programming

In a separate encounter, the BAROSTIM NEO device will require interrogation device evaluation with or without programming. These procedures are reported with the following codes. Whenever programming is performed, it is essential that physicians individually document the specific parameters changed for coding purposes.

CPT® Code <sup>3</sup>	Descriptor	Status Indicator	APC	National Medicare Rate*
<b>Interrogation device evaluation</b>				
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	\$138
<b>Interrogation device evaluation with programming</b>				
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	\$138

S- Procedure or Service, Not Discounted When Multiple; \*Medicare rate for 2020

## Revision, Removal, Replacement Procedures

At some time during its lifecycle, the BAROSTIM NEO device may require revision, removal, or replacement. These procedures are reported with the following codes:

CPT® Code <sup>3</sup>	Descriptor	Status Indicator	APC	National Medicare Rate*
<b>Lead replacement</b>				
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461	\$3,148
<b>Battery replacement</b>				
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5464	\$29,116
<b>System explant (remove device and lead)</b>				
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	\$5,508
<b>Lead removal / lead repair</b>				
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461	\$3,148

## Device explant / device revision

CPT® Code <sup>3</sup>	Descriptor	Status Indicator	APC	National Medicare Rate*
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5461	\$3,148

\*Medicare rate for 2020

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".

## HOSPITAL INPATIENT CODES

ICD-10-PCS is the system of codes used by hospitals to classify and report procedures and services provided in the inpatient setting. Each inpatient stay is assigned to a specific Medicare Severity-Diagnosis-Related Group (MS-DRG) based on the ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes reported for an individual inpatient stay. Only one MS-DRG is assigned for each inpatient stay, regardless of the number of procedures performed. When more than one procedure is reported, MS-DRG assignment is based on the highest-ranked code. Each MS-DRG has a fixed payment amount which includes the cost of any devices.

The BAROSTIM NEO procedure involves the following ICD-10-PCS codes which may be mapped to the MS-DRGs as outlined below.

ICD-10-PCS <sup>2</sup> Procedure Code	Descriptor	Typical MS-DRG Assignment	National Medicare Rate 2020
<b>Insertion of Complete System</b>			
0JH60MZ	Insertion of Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach	252 with MCC	\$20,531
And			
03HK0MZ	Insertion of Stimulator Lead on to Left Internal Carotid Artery, Open Approach	253 with CC	\$16,314
OR			
03HLOMZ	Insertion of Stimulator Lead on to Right Internal Carotid Artery, Open Approach	254 without CC/MCC	\$11,391

The distinction between MS-DRG 252, 253 and 254 is the presence or absence of secondary diagnosis codes designated by Medicare as MCCs or CCs. MCC refers to secondary diagnosis codes designated as major complications or comorbidities. CC refers to secondary diagnosis codes designated as other (non-major) complications or comorbidities. MS-DRGs 252 and 253 require that at least one of the secondary diagnosis codes is a CC or an MCC. If none of the secondary diagnosis codes is a CC or MCC, then the MS-DRG 254 is assigned.

## BILLING REQUIREMENTS

### Hospital Outpatient Billing

Medicare has specific instructions for submitting hospital outpatient claims related to implantable devices. Hospitals are strongly encouraged to separately bill devices using a device category C-code or other appropriate HCPCS code for implantable devices, along with the charge for the device. Complete and accurate reporting of the codes and charges for implanted devices is critical to ensure the relative weights for the services are accurate. This will ensure proper payments to hospitals for the procedures that use implanted devices.

This means for Medicare claims, device charges on the UB-04 listed under Column 47 - Total Charges that are on the same line as a C-Code and an acceptable revenue code are billed correctly, accurately capturing the charges for use in future payment rate calculations.

The most appropriate revenue code for BAROSTIM NEO is 0278, Medical/Surgical Supplies: Other Implants. This revenue code was developed to separate high-cost implants from low-cost supplies, which improves charge consistency when creating revenue-code-specific cost-to-charge ratios. Charges for the procedure to implant the device are reported under revenue code 0360, Operating Room Services.

Alternately, device charges listed in Column 47 on the same line of the UB-04 as CPT code 0266T, using revenue code 0360, Operating Room Services, are also acceptable and support future payment-rate calculations. A review of EOBs shows various private payers accepting each of these approaches.

Billing that does not support appropriate cost capture and will lead to undervalued future payments includes:

- incorrectly listing the device on the UB-04 as a non-covered charge (Column 48)
- using an undesignated revenue code
- failing to markup the device in keeping with the hospital's applicable cost-to-charge ratio

The latter may occur with revenue code 0360, which can include service charges and a mix of low-cost and high-cost supplies.

**Please ensure the Prior Authorization number is included on every claim submitted to commercial insurance providers.**

### Hospital Inpatient Billing

Medicare instructions for submitting hospital-inpatient claims related to implantable devices utilize the same revenue codes reported above, as well as Column 47 for device charges. C-codes for the devices are not used for inpatient billing. Further, a CPT code for the procedure is not posted to revenue code 0360. Instead, ICD-10-PCS codes are posted to FL 74 at the bottom of the UB-04.

*Note:* The revenue codes shown on the examples are just that: examples. In general, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.

## Claim Submission

### Traditional Medicare Insurance

Traditional Medicare plans are administered by Medicare Administrative Contractors (MACs). MACs usually do not require prior authorizations. When submitting a claim to the MACs the following information may be needed:

1. BAROSTIM NEO FDA approval letter
2. BAROSTIM NEO pivotal trial publication
3. CVRx BAROSTIM CFS (one page summary of all BAROSTIM NEO clinical trials)
4. UB-04 (outpatient or inpatient) or electronic equivalent

### Commercial Insurance (Medicare Advantage and Commercial Plans)

Commercial payers often require prior authorization for an elective procedure such as BAROSTIM NEO implantation. When submitting a claim to the commercial insurance the following information may be needed:

1. BAROSTIM NEO FDA approval letter
2. BAROSTIM NEO pivotal trial publication
3. **Please ensure the Prior Authorization number is included in every claim submitted to commercial insurance providers**
4. UB-04 (outpatient or inpatient) or electronic equivalent

CVRx will provide BAROSTIM NEO clinical and FDA evidence materials. For questions regarding claim submission materials, please call the CVRx Reimbursement Hotline at **763-416-2344** or email questions to [Reimbursement@cvrx.com](mailto:Reimbursement@cvrx.com).

# Medicare Appeal Process

To receive assistance with filing appeals or reconsideration request, contact the CVRx Reimbursement Hotline at 763-416-2344 or email [reimbursement@cvrx.com](mailto:reimbursement@cvrx.com).

Medicare Claims are typically processed within 30 days of submission. If denied – The physician must file a request for redetermination within 120 days from the date of receipt of the Provider's Remittance Advice (PRA).

- Medicare requires a signature on each appeal—please sign the appeal letter and the redetermination form and send to the address provided with:
  - Copy of the Explanation of Benefit (EOB)
  - Patient pre-op notes and surgical consult
  - Prior authorization number (if obtained)
  - Copy of completed patient selection checklist
  - Operative report notes
  - Clinical articles and coding information on BAROSTIM Therapy

Medicare Administrative Contractors (MACs) generally issue a decision within 60 days of receipt of the request for redetermination. If denied – The physician must file a request for reconsideration within 180 days of receipt of the decision.

- Medicare requires a signature on each appeal – please sign the appeal letter and reconsideration form and send to the address provided with:
  - Copy of the EOB
  - Patient pre-op notes
  - Copy of completed patient selection checklist
  - Op-notes
  - Clinical articles and coding information included in the packet
- Generally, a qualified independent contractor sends a decision to all parties within 60 days of receipt of the request for reconsideration

## BAROSTIM NEO™ Brief Summary for Physicians

The BAROSTIM NEO™ 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  $\leq$  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.

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.

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician. See System Reference Guide 950120-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events.

## References:

- 1 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050>
- 1 Current Procedural Terminology 2020, American Medical Association, Chicago, IL 2019. 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 2020. American Medical Association, Chicago, IL 2019.
- 3 2020 IPPS Final Rule. CMS-1716-F.
- 4 2020 OPPS and ASC Final Rule. CMS-1717-FC, CMS-1715-F, CMS-1715-IFC.
- 5 2020 HCPCS Level II Expert. AAPC, Salt Lake City, UT 2019.

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CAUTION: Federal law restricts this device to sale by or on the order of a physician. For a list of all potential benefits and risks go to [www.cvr.com/benefit-risk-analysis/](http://www.cvr.com/benefit-risk-analysis/)

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