BENEFIT HF

Clinical Trial Coding and Billing Guide

Effective as of January 1 2026

Barostim™
Outsmart the heart

Introduction to the BENEFIT-HF Trial

The BENEFIT-HF Trial is an FDA-approved Category B Investigational Device Exemption (IDE) study treating patients who have heart failure with New York Heart Association (NYHA) Functional Class II or III symptoms despite treatment with guideline-directed medical therapies (medications and devices). The objective of the study is to demonstrate that Barostim delivers Baroreflex Activation Therapy for improvement of patient's mortality and heart failure morbidity, heart failure functional status, six-minute hall walk and quality of life. The BENEFIT-HF Trial will randomize up to 2,500 participants at up to 200 sites in the United States and Europe.

Eligible participants will be randomized in a 2:1 ratio to receive Baroreflex Activation Therapy (BAT) with an implanted Barostim System (Device Arm) in addition to usual care medical management or to receive usual care medical management alone with no device implant (Control Arm).

In brief, inclusion criteria and objectives of the trial are below.

Eligible patient criteria:

- LVEF <50%
- NYHA II or III
- On GDMT
- 6 MHW Between 100m–450m
- NT-proBNP ≥ 400 and < 5,000 pg/mL

Or

- Worsening HF event in the prior 6 months and an NT-proBNP < 5,000 pg/mL

Patients from the current US indication (LVEF ≤ 35% and NT-proBNP <1600 pg/mL) ***CAN*** *be included in the trial.*

Primary Objectives

- Safety : MANCE free rate within 180 days
- Effectiveness : All-cause mortality and HF morbidity at 24 months

Secondary Objectives

- NT-proBNP at 12 months
- 6MHW distance at 12 months
- QoL MLWHF questionnaire at 12 months
- Days lost due to death or hospitalization at 24 months
- All-cause mortality at 24 months

Introduction to this coding and billing guide

This guide provides BENEFIT-HF Trial investigators and trial sites with guidelines for preparing and submitting claims during this study.

Medicare and Commercial payers have clinical trial billing compliance requirements. This guide assists with understanding these mandatory claim indicators, and the importance of setting appropriate charges for the Barostim System that reflect each hospital's specific costs.

Accurate reimbursement requires collaboration between the study sponsor and study sites and begins with the clinical trial. To ensure that reimbursement is appropriate for commercial use, the hospital's clinical trial claims must be accurate and reflect the hospital's cost.

The Centers for Medicare and Medicaid Services (CMS) approved coverage for the BENEFIT-HF Trial on January 20, 2026 so that the treatment of Medicare beneficiaries enrolled in this Category B trial can be considered for payment as per Chapter 32 of the Medicare Claims Processing Manual. Medicare approved studies can be found here on the CMS website. Both an extract from the FDA letter approving Category B designation, as well as the CMS approval letter can be found in Appendices A and B.

Trial Name:	**B**arostim-**E**nabled **NE**urohormonal Intervention **F**or **I**mproving **T**reatment of **H**eart **F**ailure (**The BENEFIT-HF Trial**)
NCT Number:	**NCT07232030**
Category B IDE:	**G250077**

Who should receive a copy of this guide?

The clinical trial investigator should distribute this guide to all entities involved in the clinical trial. This typically includes the physician billing office, the study coordinator, the hospital or ASC clinical trial billing coordinator, the patient accounts department, and the revenue cycle department.

Site notification of IDE study participation

Most BENEFIT-HF sites will need to submit a “notification of IDE study participation” email to their local Medicare Administrative Contractor (MAC) in advance of submitting claims so they can set up their system to accept both facility and professional claims. You are not asking for coverage review/approval but rather providing your MAC with physician and facility-specific information.

Appendix C of this guide provides the information needed for each MAC as well as a template you can use.

Medical records documentation

Appropriate documentation of participation in a clinical trial should be included in the patient’s medical record. The billing provider must include the trial name, sponsor, and sponsor-assigned clinical trial protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

Please include the following in your clinical documentation for each participant in the trial:

Trial Name:	**B**arostim-**E**nabled **NE**urohormonal Intervention **F**or **I**mproving **T**reatment of **H**eart **F**ailure (**The BENEFIT-HF Trial**)
NCT Number:	**NCT07232030**
Sponsor Name:	**CVRx, Inc., Minneapolis, MN, USA**
Protocol Number:	**360069-001**

Claim-level billing requirements

Medicare has specific claims filing rules and requirements for Category B IDE studies that must be on each claim. This information should be provided to the internal team responsible for ensuring claims accuracy during clinical trials.

Hospital Outpatient Claims (UB-04)

Clinical Trial Identifiers

- Report the national clinical trial number **NCT07232030**
  - For paper claims, Form CMS-1450 (UB 04) report value code **D4** with the 8-digit clinical trial number **NCT07232030** as the value code amount
  - For electronic claims, the NCT 8-digit number (**07232030**) is entered in 8371- Loop 2300 HI-VALUE INFORMATION segment
- Report Diagnosis Code **Z00.6**, Encounter for examination for normal comparison and control in clinical research program in the secondary position
- Report **Condition Code 30** to indicate a Qualifying Clinical Trial
- On a 0624 revenue code line, bill for the Barostim System using:
  - HCPCS Code **C1825**, Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)
  - Modifier -Q0, Investigational clinical service provided in a clinical research study that is an approved clinical research study
  - the Category B IDE number (**G250077**)
  - charges for the implant procedure billed as covered charges
- On a 0624 revenue code line, bill for the implant of the Barostim System using
  - CPT® Code **64654**, Implantation or replacement of carotid sinus baroreflex activation device; total system
  - Modifier -Q0, Investigational clinical service provided in a clinical research study that is an approved clinical research study
  - the Category B IDE number (**G250077**)
  - charges for the device billed as covered charges

NOTE: Please apply the standard mark-up on the trial device cost that reflects the total cost of the device taking into consideration your cost-to-charge ratio, so that costs submitted during this study are accurate. Your hospital's cost to charge ratio can be requested by emailing **BenefitHF_C-PAS@cvrx.com**

Hospital Inpatient Claims (UB-04)

Clinical Trial Identifiers

- Report 8-digit clinical trial number **NCT07232030**
  - For paper claims, Form CMS-1450 (UB 04) report value code **D4** with the 8-digit clinical trial number **NCT07232030** as the value code amount
  - For electronic claims, the NCT 8-digit number (**07232030**) is entered in 8371- Loop 2300 HI-VALUE INFORMATION segment
- Report Diagnosis Code **Z00.6**, Encounter for examination for normal comparison and control in clinical research program in the secondary position
- Report **Condition Code 30** to indicate a Qualifying Clinical Trial
- Charges for the Barostim System along with the Category B IDE number (**G250077**) should be included in **revenue code 624**.

NOTE: Please apply the standard mark-up on the trial device cost that reflects the total cost of the device taking into consideration your cost-to-charge ratio, so that costs submitted during this study are accurate. Your hospital's cost to charge ratio can be requested by emailing **BenefitHF_C-PAS@cvrx.com**

Physician Claims (CMS-1500)

Clinical Trial Identifiers

- Report the clinical trial number **NCT07232030**
  - On the CMS-1500 paper form, place CT05763407 in Field 19
  - For electronic claims, the NCT 8-digit number (**07232030**) is entered in 837P- Loop 2300, REF02, REF01-P4 (on electronic claim do not report "CT") II
- Report the study Category B IDE number **G250077** in Field 23, prior authorization
- Add the **-Q0 modifier**, Investigational clinical service provided in a clinical research study that is an approved clinical research study on the claim line for CPT[1] **64654**
- Add the **-Q1 modifier**, Routine clinical service provided in a clinical research study that is an approved clinical research study with any routine service or procedure performed billed on the same claim, and on all future claims related to study participation
- Report Diagnosis Code **Z00.6**, Encounter for examination for normal comparison and control in clinical research program in the secondary position
- All claims should be reported with **POS 21 Inpatient Hospital** or **POS 20 Outpatient Hospital**

For your reference, sample claim forms can be found in Appendices E, F, and G.

Prior authorization will be done by CVRx

To facilitate enrollment, CVRx Patient Access Support (CPAS) will perform all prior authorizations for all sites.

CPAS is a HIPAA compliant entity that will provide:

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

All sites must enroll in the CPAS prior to starting the trial:
www.cvrx.com/healthcare-professionals/reimbursement

You can then submit patient requests for prior authorizations through this portal.

The CVRx CPAS team will request authorization for inclusion in the BENEFIT-HF Trial for all payer types.

Commercial payers, State Medicaid agencies will require prior authorization prior to enrolling patients into the clinical trial. If a denial is encountered, the CPAS team will pursue an appeal of any denial, including requesting a peer-to-peer review where a clinician from your hospital talks with a physician (preferably cardiologist or cardiovascular surgeon) from the insurance company. If that is unsuccessful, the CPAS team can ask for an external review. The goal is to obtain authorization within the shortest timeframe possible to meet the protocol criteria.

The next section provides the requirements for each payer type, and how the CPAS team will proceed with prior authorization requests.

Traditional Medicare

Traditional Medicare does not require prior authorization on a patient-by-patient basis. CMS has approved this trial for coverage and payment, so no prior authorization is necessary. If the patient has a secondary payer, you do not need to obtain prior authorization; they are, by definition, secondary to the primary payer, so if the primary payer covers, the secondary must cover.

CPAS will verify benefits – no other action required

Medicare Advantage

Medicare Advantage plans are administered by private health plans and are slightly different than Traditional Medicare in the way that they pay for patients enrolling in clinical studies. Medicare Advantage Plans **must cover approved medical device trials for lifesaving technologies** in the same way that traditional Medicare covers and pays for covered device trials. This guidance comes from the **Internet Only Manual (IOM)** for Medicare Advantage Plans, Section 10.7.

IOM Manual Provisions

1. Medicare Advantage Plans are responsible for coverage of **CMS approved**, qualifying clinical trials including provisions for payment. Original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in Medicare Advantage Plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials.
2. Medicare Advantage Plans may not choose the clinical trial or clinical trial items and services to which this policy applies.

Section 10.7.1-10.7.2 of the **Medicare Managed Care Manual**, Chapter 4 states:

> "Medicare Advantage Organizations (MAOs) are responsible for payment of claims related to participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS- approved Category A and Category B IDE Studies. The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage."

This provision also includes reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials.

Medicare Advantage organizations often confuse clinical trial coverage under the September 2000 Clinical Trials National Coverage Determination (NCD) with Medicare's policy on IDE (Investigational Device Exemption) coverage. IDE trials have been covered, at contractor discretion (within CMS's rules and guidelines), since November 1, 1995.

Language from the **Medicare.gov website** below makes it clear that Medicare Advantage plans cannot refuse to allow a Medicare beneficiary to participate in a Medicare-approved clinical trial.

Original Medicare	Medicare Advantage
Original Medicare covers most medically necessary services and supplies in hospitals, doctors' offices, and other health care facilities. Original Medicare doesn't cover some benefits like eye exams, most dental care, and routine exams.	Plans must cover all medically necessary services that Original Medicare covers. Plans may also offer some **extra benefits that Original Medicare doesn't cover** - like certain vision, hearing, and dental services.
You can join a **separate Medicare drug plan** to get Medicare drug coverage (Part D).	**Medicare drug coverage (Part D) is included in most plans.** In most types of Medicare Advantage Plans, you can't join a separate Medicare drug plan.
In most cases, you don't need approval for Original Medicare to cover your services or supplies	In many cases, you may need to get approval from your plan before it covers certain services or supplies.

It is required that you notify your regional Medicare Advantage Plans that you plan to enroll patients in the BENEFIT-HF Trial. A template notification letter is provided as Appendix D.

CPAS will verify benefits

State Medicaid Agencies

As of January 1, 2022, **State Medicaid Agencies** must cover and pay for routine patient costs for patients enrolling in qualifying clinical trials. As a Medicare-covered Category B IDE Study that treats patients with a serious, life-threatening condition, the BENEFIT-HF Trial should meet the qualifications outlined below.

Qualifying Clinical Trial

Section 1905(gg)(2) of the Act defines the term "qualifying clinical trial" for purposes of section 1905(a)(30) of the Act as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition, and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act. Therefore, to meet the statutory definition, the "qualifying clinical trial" must also be one or more of the following:

- A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
    - The National Institutes of Health (NIH);
    - The Centers for Disease Control and Prevention (CDC);
    - The Agency for Health Care Research and Quality (AHRQ);
    - The Centers for Medicare & Medicaid Services (CMS);

Prior authorization/determination will be requested for Medicaid patients enrolling in the BENEFIT-HF Trial; these mandatory requirements mean that any request for treatment in a qualifying study must be expedited and completed within 72 hours.

CMS has created a specific attestation form that is standardized for all State Medicaid Agencies, a copy of which can be found in Appendix H and should be maintained in the patient's financial record.

CPAS will verify benefits and obtain treatment authorization

Private Insurance Coverage

Private insurance policies for clinical trials vary considerably from plan to plan. Many private insurance plans have contract exclusions for "experimental" or "investigational" services and for any directly related services, but that does not preclude them from evaluating IDE Study requests for treatment on a case-by-case basis.

The **Affordable Care Act (section 2709(a))**, has an important provision that requires commercial payers cover and pay the routine costs for patients enrolling in qualifying clinical trials. As a Medicare covered Category B IDE Study that treats patients with serious, life-threatening condition, the BENEFIT-HF Trial meets those requirements for coverage. In other words, commercial insurance companies (1) may not deny the qualified individual participation in an "approved clinical trial" with respect to the treatment of patients with cancer or another life-threatening disease or condition; (2) may not deny the coverage of "routine patient costs" for items and services furnished in connection with participation in the trial. From the CMS website:

Coverage for Individuals Participating in Approved Clinical Trials

In general, PHS Act section 2709(a),[6] as added by the Affordable Care Act, states that if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

A qualified individual under PHS Act section 2709(b) is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either: (1) the referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or (2) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

Q3: Will the Departments be issuing regulations addressing PHS Act section 2709 prior to its effective date?

No. The statutory language of PHS Act section 2709 is self-implementing and the Departments do not expect to issue regulations in the near future. PHS Act section 2709 is applicable to non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

Until any further guidance is issued, group health plans and health insurance issuers are expected to implement the requirements of PHS Act section 2709 using a good faith, reasonable interpretation of the law. The Departments will work together with employers, plans, issuers, states, providers, and other stakeholders to help them come into compliance with the law and will work with families and individuals to help them understand the coverage for clinical trials provision and benefit from it as intended.

For questions about the coverage for clinical trials provision, including complaints regarding compliance with the statutory provision by health insurance issuers, contact your state department of insurance (contact information is available by visiting www.healthcare.gov/using-insurance/managing/consumer-help/index.html) or the Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight at 1-*888-393*-2789. For employment-based group health plan coverage, you also may contact the Department of Labor at www.askebsa.dol.gov or 1-866-444-3272.

Many private insurance plans have not incorporated this requirement into their medical policies and still have contract exclusions for “experimental” or “investigational” services. These exclusions do not apply to the BENEFIT-HF Trial. Even though Commercial payers require pre-determination/prior authorization, they must cover this study.

Both **United Healthcare** and **Aetna** have coverage policies that specifically state that Category B IDE Studies are covered and paid, including the Category B device itself, when specific criteria are met. Relevant policy language for each plan is below.

United Healthcare®

Indications for Coverage

Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act (“PPACA”) requires non-grandfathered health plans to cover “Routine Patient Costs” incurred by a “Qualifying Individual” who is participating in an “Approved Clinical Trial”. Benefits include the reasonable and necessary items and services used to prevent, diagnose, and treat complications arising from participation in a qualifying Clinical Trial. Benefits are available only when the covered person is clinically eligible for participation in the qualifying Clinical Trial as defined by the researcher.

Approved Clinical Trial (Cancer or Life-Threatening Disease)

An “Approved Clinical Trial” is defined as:

- Phase I, Phase II, Phase III, or Phase IV Clinical Trial;
- Being conducted in relation to the prevention, detection, or treatment for cancer or other life-threatening disease or condition; **and**
- Meets the requirements under Criteria for Approved Clinical Trials

For purposes of this benefit, a “life-threatening disease or condition” is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Coverage Limitations and Exclusions

Benefits for Clinical Trials do not include:

- The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following:
  - Certain Category B Devices. Only certain FDA-designated Category B Devices are covered. In order to be covered, all of the following criteria must be met:
    - The device must be used within the context of an FDA-approved clinical trial
    - The device must be used according to the clinical trial's approved protocols
    - Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines
    - The device is medically necessary for the member, and the amount, duration and frequency of use or application of the service is medically appropriate
    - The device is furnished in a setting appropriate to the member’s medical needs and condition

CPAS will verify benefits and obtain prior authorization

aetna™

This Clinical Policy Bulletin addresses clinical trials, coverage of routine patient care costs.

I. **Policy Limitations and Exclusions**

A. Consistent with Centers for Medicare & Medicaid Services (CMS) policy and Patient Protection and Affordable Care Act (PPACA) requirements, Aetna covers medically necessary routine patient care costs in clinical trials (in the same way that it reimburses routine care for members not in clinical trials) according to the limitations outlined below. All of the following limitations apply to such coverage:

1. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; *and*
2. All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; *and*
3. Members must meet all applicable plan requirements for precertification, registration, and referrals; *and*
4. To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to Aetna, but Aetna can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s).

B. Aetna covers costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials.

C. Aetna does not cover the following clinical trial costs:

1. Costs of data collection and record keeping that would not be required but for the clinical trial; *and*
2. Items and services provided by the trial sponsor without charge; *and*
3. The experimental intervention itself (except medically necessary Category B investigational devices and promising experimental and investigational interventions for terminal illnesses in certain clinical trials according to Aetna's terminal illness policy (see benefit plan descriptions for details)); *and*
4. Travel, lodging and meals; *and*
5. Other services to clinical trial participants necessary solely to satisfy data collection needs of the clinical trial (i.e., "protocol-induced costs").

Coding and Payment

All payers use administrative codes to determine coverage and payment. Below are code suggestions for you to discuss with your reimbursement/revenue cycle team.

Diagnosis Coding

Possible diagnosis codes used in all settings of care. Not a comprehensive list.

ICD-10 CM CODE	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

Physician Coding

Possible coding for physician services in all settings of care.

Modifiers

When billing during a clinical trial, the following HCPCS code modifiers should be added to

MODIFIER	DESCRIPTOR
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

Barostim evaluations

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
93306	**Transthoracic Echo**: Echocardiography, transthoracic, real time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, with color flow Doppler echocardiography	1.42	$198
93308	**Transthoracic Echo, Limited**: Echocardiography, transthoracic, real time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study	0.52	$1012
93880	**Carotid Artery Duplex Scan**: Duplex scan of extracranial arteries; complete bilateral study	0.78	$190
93882	**Carotid Artery Duplex Scan, Limited**: Duplex scan of extracranial arteries; unilateral or limited study	0.49	$125
83880	**NT-ProBNP**: N-Terminal pro B-Type Natriuretic Peptide	n/a	$39
94618	**Six-Minute Hall Walk Test**: Pulmonary stress testing (eg, Six-Minute Hall Walk Test), including measurement of heart rate, oximetry, and oxygen titration, when performed	0.47	$37

Barostim System implant

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
64654	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	11.00	$562

Barostim generator or lead replacement

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	11.3	$648
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	8.01	$429

Barostim programming and interrogation

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
93145	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation 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); without programming	0.65	$55
93146	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation 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); with programming, including optimization of tolerated therapeutic level setting	0.90	$83

Possible principal diagnosis codes for interrogation and programming. Possible secondary diagnosis codes for interrogation and programming are Heart Failure diagnosis codes (see page 14)

ICD-10 CM DIAGNOSIS CODE	DIAGNOSIS 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

Follow up visits or services may be billed independently from the Barostim device interrogation (with or without programming). Please choose the appropriate evaluation and management (E&M) CPT code that is supported by your documentation in addition to a device evaluation code.

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
93145	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation 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); without programming	0.65	$55

Barostim removal

CPT® CODE[1]	DESCRIPTOR	WORK RVUs	2026 MEDICARE AVG PAYMENT
64657	Removal of baroreflex activation device (BAT) modulation system; total system, including lead and pulse generator	12.13	$635
64658	Removal of baroreflex activation device (BAT) modulation system; lead only	8.95	$478
64659	Removal of baroreflex activation device (BAT) modulation system; pulse generator only	8.23	$444

Outpatient Hospital Coding

Barostim System chargemaster set up

For an initial Barostim system implant (full device; generator and lead at the same time) use the item number 100069-202

For replacement of any single part, use one of the following item numbers:
- 100065-202 (IPG only)
- 100063-212 (Lead only)

Create your chargemaster line items using the following CPT and HCPCS codes that correspond with the item number below.

CPT CODE	DESCRIPTOR	CPT® CODE[1]	HCPCS CODE*	ITEM NUMBER
Initial Barostim System Implant (Kit) *De novo implant only*	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	64654	C1825	100069-202 Barostim Neo2 Neurostimulator System IPG Model CSL **Combo Kit**
Battery replacement only	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	64656	C1767 L8686	100065-202 Barostim Neo2 Model 2104 (**IPG only**)
Lead replacement only	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	64655	C1778 L8680	100063-212 Barostim Neo2 Model CSL Kit Model 1036 SH (**lead only**)

*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.

Barostim System coding and ambulatory payment classification (APC) assignment

Possible codes used to report hospital outpatient services.

Barostim System implant

CPT® CODE[1]	DESCRIPTOR	STATUS INDICATOR	APC	2026 MEDICARE UNADJUSTED PAYMENT
64654	Initial open implantation of baroflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	S	1580	$45,000
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	n/a	2030	

Barostim Generator or Lead replacement

CPT® CODE[1]	DESCRIPTOR	STATUS INDICATOR	APC	2026 MEDICARE UNADJUSTED PAYMENT
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	J1	5461	$3,572
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	J1	5465	$31,526

Device codes for Barostim Generator and leads

The following HCPCS codes should be used for cost reporting purposes when reporting Barostim generator 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

*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.

Barostim removal

CPT® CODE[1]	DESCRIPTOR	STATUS INDICATOR	APC	2026 MEDICARE UNADJUSTED PAYMENT
64657	Removal of baroreflex activation device (BAT) modulation system; total system, including lead and pulse generator	Q2	5432	$3,490
64658	Removal of baroreflex activation device (BAT) modulation system; lead only	J1	5461	$3,572
64659	Removal of baroreflex activation device (BAT) modulation system; pulse generator only	J1	5461	$3,572

Hospital Outpatient Status Indicators:

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.

Ambulatory Surgery Center (ASC) coding

Barostim System chargemaster set up

For an initial Barostim system implant (full device; generator and lead at the same time) use the item number 100069-202

For replacement of any single part, use one of the following item numbers:
- 100065-202 (IPG only)
- 100063-212 (Lead only)

Create your chargemaster line items using the following CPT and HCPCS codes that correspond with the item number below.

CPT CODE	DESCRIPTOR	CPT® CODE[1]	HCPCS CODE*	ITEM NUMBER
Initial Barostim System Implant (Kit) *De novo implant only*	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	64654	C1825	100069-202 Barostim Neo2 Neurostimulator System IPG Model CSL **Combo Kit**
Battery replacement only	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	64656	C1767 L8686	100065-202 Barostim Neo2 Model 2104 (**IPG only**)
Lead replacement only	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	64655	C1778 L8680	100063-212 Barostim Neo2 Model CSL Kit Model 1036 SH (**lead only**)

*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.

Barostim System coding and payment

Possible codes used to report ASC services.

Barostim System implant

CPT® CODE[1]	*DESCRIPTOR*	STATUS INDICATOR	MULTIPLE PROCEDURE DISCOUNT?	2026 MEDICARE UNADJUSTED PAYMENT
64654	Initial open implantation of baroflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (ie, total system), and intraoperative interrogation and programming	J8	NO	$41,787
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	n/a		

Barostim Generator or Lead replacement

CPT® CODE[1]	DESCRIPTOR	STATUS INDICATOR	MULTIPLE PROCEDURE DISCOUNT?	2026 MEDICARE UNADJUSTED PAYMENT
64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only	J8	YES	$2,538
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only	J8	YES	$27,566

Device codes for Barostim Generator and leads

The following HCPCS codes should be used for cost reporting purposes when reporting Barostim generator 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

*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.

Barostim removal

CPT® CODE[1]	DESCRIPTOR	STATUS INDICATOR	MULTIPLE PROCEDURE DISCOUNT?	2026 MEDICARE UNADJUSTED PAYMENT
64657	Removal of baroreflex activation device (BAT) modulation system; total system, including lead and pulse generator	G2	NO	$2,177
64658	Removal of baroreflex activation device (BAT) modulation system; lead only	G2	YES	$2,003
64659	Removal of baroreflex activation device (BAT) modulation system; pulse generator only	G2	YES	$2,003

ASC Status Indicators:

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.

G2 Paid under OPPS; Addendum B displays APC assignments when services are separately payable.

Inpatient Hospital Coding

A Barostim implant is reported with a cluster of two ICD-10 PCS codes. Below are possible codes used to report hospital inpatient services.

Barostim System implant

ICD-10 PCS CODE	DESCRIPTOR
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach
OR	
03HK3MZ	Insertion of stimulator lead into right internal carotid artery, percutaneous approach
OR	
03HL3MZ	Insertion of stimulator lead into left internal carotid artery, percutaneous approach

MS-DRG Assignment

Each hospital admission maps to an inpatient MS-DRG, and payment varies by payer. Medicare updates their national average payment amount annually, based on charges submitted by hospitals, and it is adjusted for each hospital based on the geographic wage index, any indirect medical education, and the amount of uncompensated care provided.

MS-DRG	DESCRIPTOR	2026 MEDICARE AVG PAYMENT
276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator	$43,709

Note, other MS-DRGs could be assigned depending upon what else is performed during the admission.

Appendix A: FDA approval letter

November 14, 2025

CVRx Inc.
% Nikita Basandra
Director, Regulatory Affairs
9201 West Broadway Ave.
Suite 650
Minneapolis, Minnesota 55445

Re: G250077/S002
Trade/Device Name: Barostim System
Dated: October 17, 2025
Received: October 17, 2025
CMS Category: B
Annual Report Due: April 26, 2026

Dear Nikita Basandra:

The Food and Drug Administration (FDA) has reviewed the supplement to your Investigational Device Exemption (IDE) application regarding your pivotal study (BENEFIT-HF) for a significant risk device proposing updates to the protocol and SAP in response to study design considerations. FDA has determined you have provided sufficient data to support continuation of your human clinical study; this means that there are no subject protection concerns that preclude continuation of the investigation. Your supplement is therefore approved, and you may implement that change in your study. Your investigation is limited to 200 US institutions and 3600 US subjects.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/about-fda/cdrh-offices/division-industry-and-consumer-education) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

FDA believes the study design provided in your submission is adequate and may support a future marketing approval or clearance, if it is successfully executed and meets its stated endpoints without raising unforeseen safety concerns.

We note that you have designed this protocol to collect safety and effectiveness data to support submission of a future PMA application.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Regarding the statistics to be presented in the PMA, we expect analysis of the primary dataset to contain one line per unit (e.g., person, sample, observation) with clinical outcomes and baseline covariates. You should also provide the statistical program code which produces the above analyses and which clearly documents variable definitions and coding schemes, as well as the data, in an electronic format (e.g., SAS, S-Plus or R, Excel, ASCII).

If approved, it is likely that a post-approval study (PAS) may be requested as a Condition of Approval (CoA). As the original IDE cohort can sometimes be used to gather long-term safety and effectiveness data after market approval, we suggest you consider obtaining patient informed consent and IRB approval at the initiation of the study so that enrolled subjects will be followed for a period of at least 5 years. FDA believes this may reduce patient loss to follow-up during the marketing application review process and keep many subjects available to participate in such a PAS if ordered. In addition, please note that other clinical studies apart from continued follow-up of IDE subjects, including prospective studies which enroll new patients, may also be required as CoA should a future marketing application be approved.

Future correspondence concerning this application should be identified as an IDE supplement referencing the IDE number above, and can be submitted as a complete eCopy or eSTAR file, electronically through the CDRH portal. For more information about the eCopy program, please visit https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-medical-device-submissions. For more information about the eSTAR program, please visit https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any minor clarification questions concerning the contents of the letter, please contact Kimberly Crowley at 301-796-6017 or Kimberly.Crowley@fda.hhs.gov.

Sincerely,

Hetal B. Odobasic -S

Hetal Odobasic
Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Additional Recommendations and Considerations

Appendix B: CMS approval letter

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Nikita Basandra
Director, Regulatory Affairs
CVRx Inc.
9201 West Broadway Ave.
Suite 650
Minneapolis, Minnesota 55445

January 20, 2026

Dear Ms. Basandra:

Thank you for submitting your Medicare coverage Category B IDE study review request. We have completed our review of the IDE study protocol entitled *Barostim-Enabled NEurohormonal Intervention For Improving Treatment of Heart Failure (BENEFIT-HF)* [G250077-NCT07232030]. CMS believes that the IDE study is consistent with the conditions specified in the IDE regulations (42 CFR 405 Subpart B). The device as well as the related and routine items and services are approved for purposes of Medicare coverage. We will post limited information about this study on the CMS IDE webpage at http://www.cms.gov/Medicare/Coverage/IDE/index.html.
While CMS is approving this IDE study, the study design and results may not be sufficient to result in a positive coverage determination after the device comes to market. For additional information, please refer to the guidance documents available at https://www.cms.gov/medicare-coverage-database/reports/national-coverage-medicare-coverage-documents-report.aspx?docTypeId=1&status=all.

Because this study is approved for purposes of Medicare coverage across all Medicare Administrative regions, study sites are not required to obtain approval from local Medicare Administrative Contractors (MACs). However, MACs may require additional documentation. To facilitate Medicare reimbursement, we suggest you provide your study sites with appropriate billing instructions. Additional information is available on the CMS IDE webpage at http://www.cms.gov/Medicare/Coverage/IDE/index.html and in a MLNMatters article at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/MLNMattersArticles/Downloads/MM8921.pdf.

Please contact clinicalstudynotification@cms.hhs.gov if you have any questions or need additional information.

Sincerely,

Recoverable Signature

X Andrew Ward

Andrew Ward

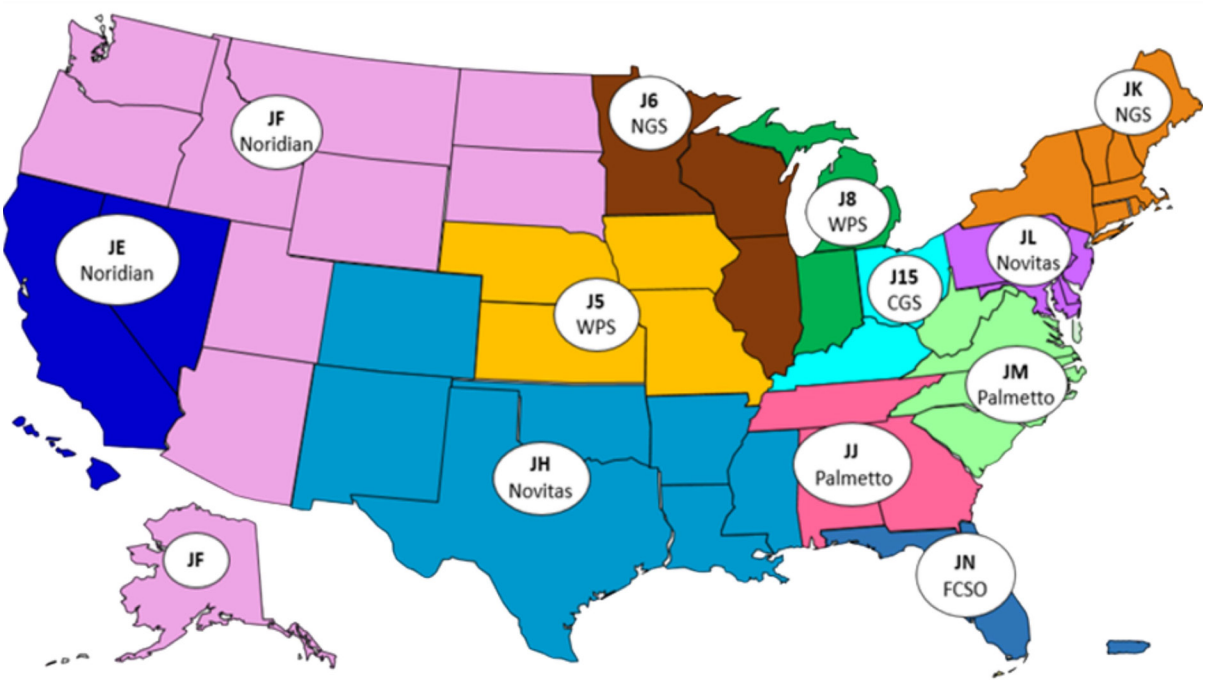
Signed by: ANDREW C. WARD -A

Andrew Ward – Ph.D, Ph.D. MPH
Director, Evidence Development Division
Coverage and Analysis Group

Appendix C: MAC Notification of IDE Study Participation

The following table summarizes the Part A/B MACs requiring individual sites to submit a "Notification of IDE Study Participation". This process is in addition to central CMS' coverage approval. A/B MAC IDE policies frequently change. All Sites should verify current local MAC policies regardless of jurisdiction.

A template notification email is included below.



MAC	IDE Policy Details	Policy/Form Links
CGS (J15)	CGS requires you send: • Local IRB Approval • CMS Approval letter provided to the sponsor • PTAN of the facility • Name(s) of the principal investigator w/ NPI #s • Names of the sub-investigators with NPI #s Send to: **J15IDE@cgsadmin.com**	**https://www.cgsmedicare.com/partb/pubs/news/2014/1214/cope27849.html**
FCSO (JN) and **Novitas** (JH, JL)	Novitas and FCSO both require you send: • CMS Approval letter provided to the sponsor • National Clinical Trial Number • Name of the Part A facility and address where the services will be performed • Name(s) of the principal investigator • Point of contact name and email address • Agency for Health Care Administration (AHCA) facility number found on their website. Send to **medicalafairs@guidewellsource.com** with "Part A IDE Submission" in the subject line	**https://medicare.fcso.com/medical-affairs/investigational-device-exemption-ide-studies**

MAC	IDE Policy Details	Policy/Form Links
Noridian (JE, JF)	Noridian requires you send: • Notice of participation in the trial • IDE number assigned by FDA • National Clinical Trial Number • PTAN of the facility • Name(s) of the principal investigator with NPI number(s) • Names of the sub-investigators with NPI number(s) Send to **iderequests@noridian.com**	**https://med.noridianmedicare.com/**
NGS (J6, JK)	NGS requires you send: • CMS Approval letter provided to the sponsor • IDE number • Name and UPIN of the facility where services will be provided • Name(s) of the principal investigator with NPI number(s Send to **NGSIDERequests@elevancehealth.com**	**https://www.ngsmedicare.com/NGS_LandingPage/**
Palmetto (JJ, JM)	*Palmetto does not require notification for CMS approvals.*	
WPS (J5, J8)	WPS requires you send: • Notice of participation in the trial • IDE number assigned by FDA • National Clinical Trial Number • PTAN of the facility • Name(s) of the principal investigator with NPI number(s) • Names of the sub-investigators with NPI number(s) Send to: **IDE.mailbox@wpsic.com**	**https://www.wpsgha.com/guides-resources/view/19**

Sample email to send to your Medicare Administrative Contractor:

Subject Line: Part A/b IDE Submission: **BENEFIT-HF Trial**

To Whom it May Concern,

I am writing to notify you of our intent to enroll patients in the clinical trial referenced above. The **B**arostim-**E**nabled **NE**urohormonal Intervention **F**or **I**mproving **T**reatment of **H**eart **F**ailure (**The BENEFIT-HF Trial**) has been given Category B Investigational Device Exemption (IDE) status by the Food and Drug Administration and is approved for coverage by Medicare as of January 20, 2026. Medicare approved studies can be found here on the CMS website.

The information required for you to process claims is as follows:

- **BENEFIT-HF Trial** National Clinical Trial (NCT) identifier: **NCT07232030**
- **BENEFIT-HF Trial** Category B IDE Number: **G250077**
- Name and PTAN of the facility:
- Name(s) of the principal investigator with NPI number(s)
- Names of the sub-investigators with NPI number(s)
- CPT Code for implant procedure: **64654**

Other information you may require is attached to this email. We are one of the sites in the U.S. enrolling patients in this important clinical trial. Please confirm receipt of this email at your earliest convenience, so we may begin to submit claims.

Appendix D: Sample Medicare Advantage Plan Notification Letter

BENEFIT-HF Trial Sample Medicare Advantage Plan Notification Letter
Please complete items in Orange AND put on your hospital's letterhead before sending

[Date]

[Medicare Advantage Plan Address]

RE:

Trial Name:	**B**arostim-**E**nabled **NE**urohormonal Intervention **F**or **I**mproving **T**reatment of **H**eart **F**ailure (**The BENEFIT-HF Trial**)
NCT Number:	**NCT07232030**
Category B IDE:	**G250077**
CPT Code:	

To whom it may concern,

I am writing to notify you of our intent to enroll patients in the clinical trial referenced above. The BENEFIT-HF Trial has been given Category B Investigational Device Exemption (IDE) status by the Food and Drug Administration and is covered by Medicare as of January 20, 2026.

Medicare approved studies can be found here on the CMS website.
Per the Medicare Internet Only Manual (IOM) for Medicare Advantage Plans, Chapter 4, Sections 10.7.1 and 10.7.2, Medicare Advantage plans must cover and pay for Category B IDE studies

> **10.7.2 – Payment for Investigational Device Exemption (IDE) Studies**
> ***(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)***
>
> MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A and Category B *IDE studies*. *The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.*

We are one of the sites in the U.S. enrolling patients in this important clinical trial. This endorses our belief in the efficacy of this device, and we likely will enroll patients covered by your Medicare Advantage Plan.

If you require additional information, do not hesitate to contact me at [Insert phone number and email address].

Sincerely,
[Insert name and signature]

Appendix E: Sample outpatient hospital / ASC claim form

1	2	3a PAT. CNTL #		4 TYPE OF BILL
		b. MED. REC. #		
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM: XXXX2026 THROUGH: XXXX2026	7

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

10 BIRTHDATE	11 SEX	12 ADMISSION DATE: XXXX2026	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18 CONDITION CODES: 30	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30

	31 OCCURRENCE CODE	31 OCCURRENCE DATE	32 OCCURRENCE CODE	32 OCCURRENCE DATE	33 OCCURRENCE CODE	33 OCCURRENCE DATE	34 OCCURRENCE CODE	34 OCCURRENCE DATE	35 OCCURRENCE SPAN CODE	35 OCCURRENCE SPAN FROM	35 OCCURRENCE SPAN THROUGH	36 OCCURRENCE SPAN CODE	36 OCCURRENCE SPAN FROM	36 OCCURRENCE SPAN 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 D4	NCT072332030				
	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	0624	IDE G250077	C1825 Q0	01012026	1	$XXXXX XX			5
6	0360	IDE G250077	64654 Q0	01012026	1	$XXXXX XX			6
7	0370	ANESTHESIA			#	$XXXXX XX			7
8	0710	RECOVERY ROOM			#	$XXXXX XX			8
9									9
10									10
11									11
12									12
13									13
14									14
15									15
16									16
17									17
18									18
19									19
20									20
21									21
22					#	$XXXXX XX			22
23		*PAGE ____ OF ____*		*CREATION DATE*					23

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57 OTHER PRV ID	
A									A
B									B
C									C

	58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A					A
B					B
C					C

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A	ABC1234567		A
B			B
C			C

66 DX	A	B	C	D	E	F	G	H	68
XXX.XX	Z00.6								
	I	J	K	L	M	N	O	P	Q

69 ADMIT DX	70 PATIENT REASON DX	a	b	c	71 PPS CODE	72 ECI	a	b	c	73

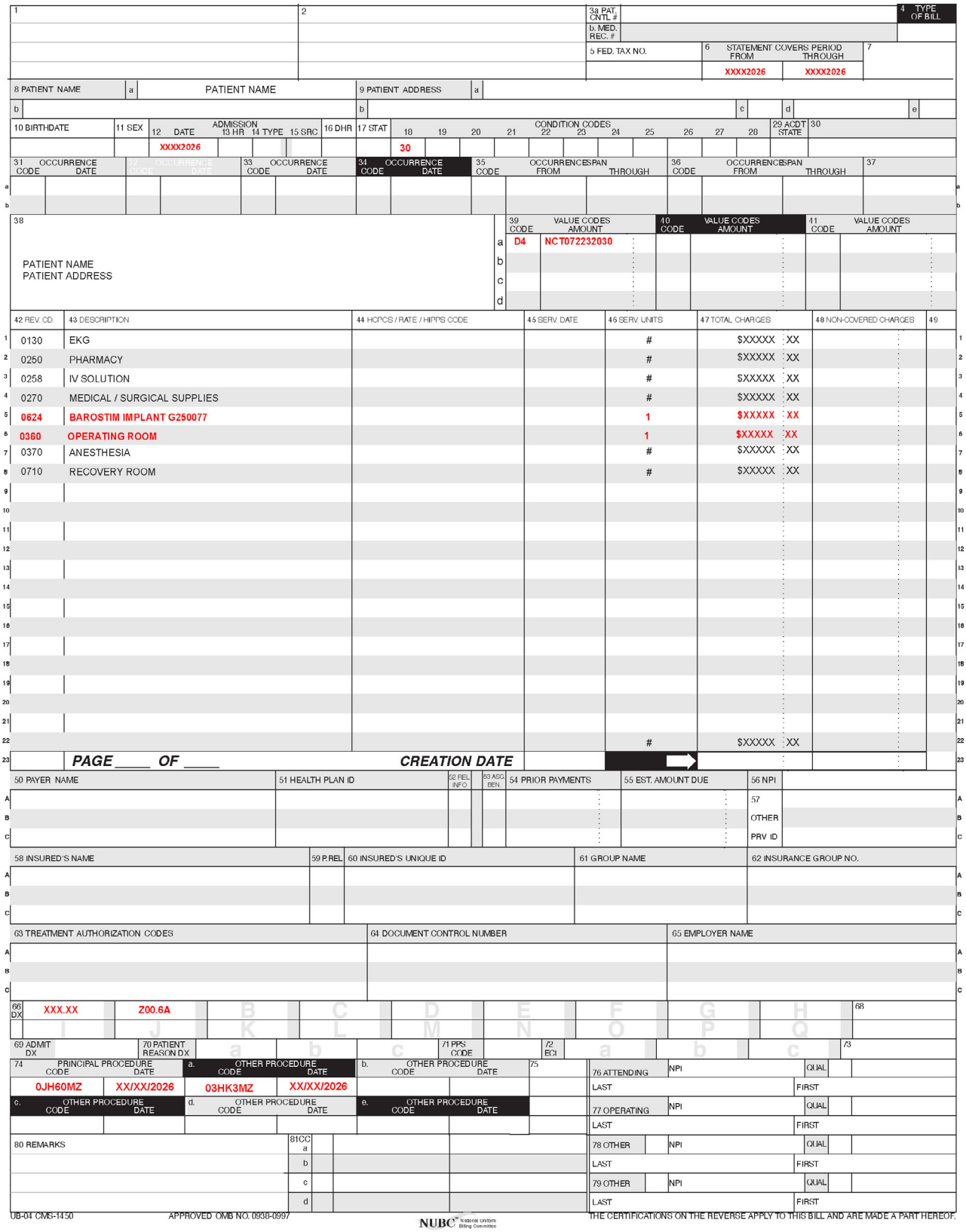
74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

80 REMARKS	81CC		
	a		
	b		
	c		
	d		

76 ATTENDING	NPI	QUAL	
LAST		FIRST	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER	NPI	QUAL	
LAST		FIRST	
79 OTHER	NPI	QUAL	
LAST		FIRST	

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.

Appendix F: Sample inpatient hospital claim form



1		2		3a PAT. CNTL #				4 TYPE OF BILL			
				b. MED. REC. #							
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM	THROUGH	7			
						XXXX2026	XXXX2026				
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 CONDITION CODES 22 23 24 25 26 27 28		29 ACDT STATE	30
		XXXX2026					30				

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 D4	NCT072232030				
	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	0624	BAROSTIM IMPLANT G250077			1	$XXXXX XX		5
6	0360	OPERATING ROOM			1	$XXXXX XX		6
7	0370	ANESTHESIA			#	$XXXXX XX		7
8	0710	RECOVERY ROOM			#	$XXXXX XX		8
9								9
10								10
11								11
12								12
13								13
14								14
15								15
16								16
17								17
18								18
19								19
20								20
21								21
22					#	$XXXXX XX		22
23		PAGE____ OF ____	CREATION DATE					23

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI		
A							57		A
B							OTHER		B
C							PRV ID		C

	58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A					A
B					B
C					C

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A			A
B			B
C			C

66 DX												68
	XXX.XX	Z00.6A	B	C	D	E	F	G	H		
	I	J	K	L	M	N	O	P	Q		

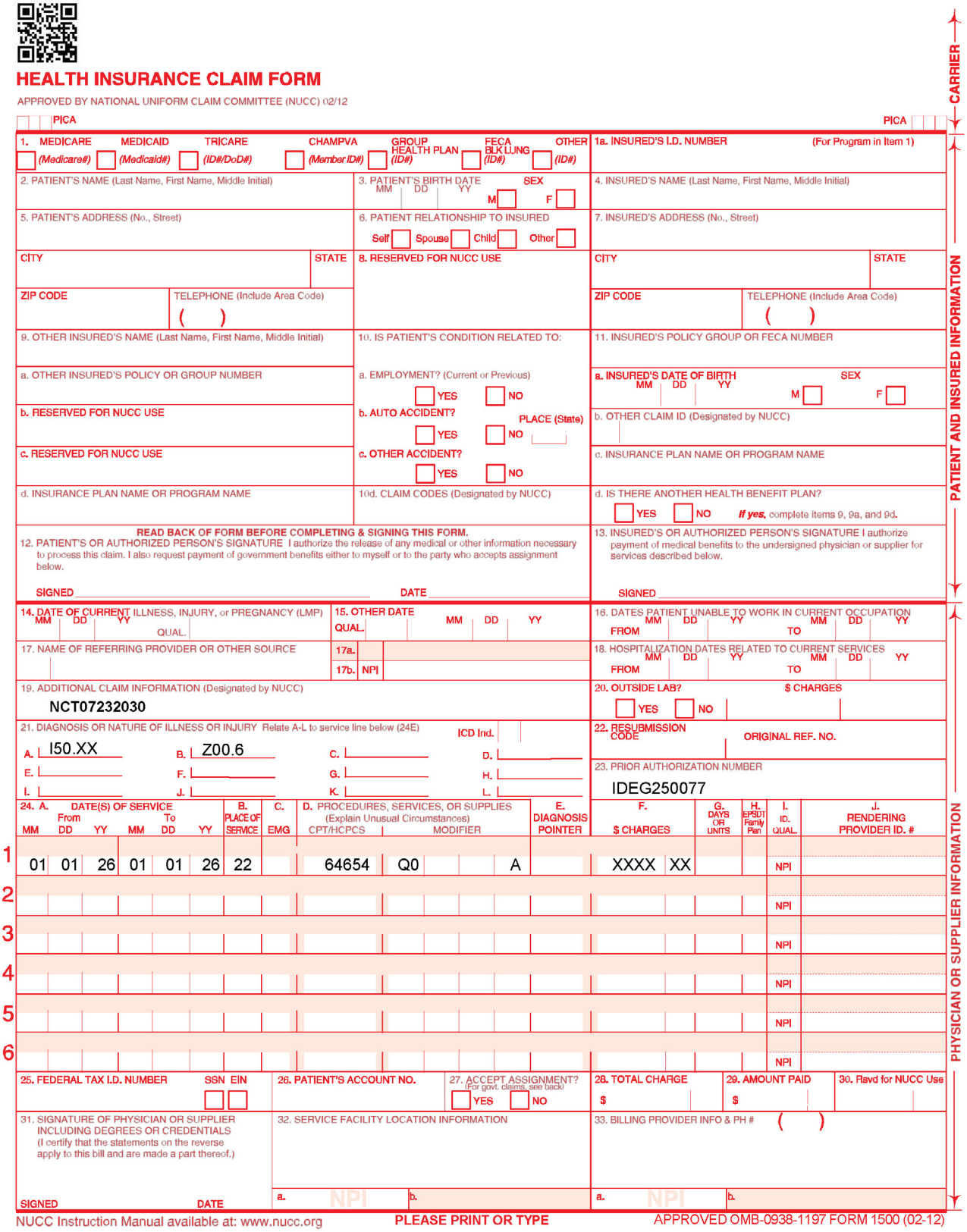
69 ADMIT DX	70 PATIENT REASON DX	a	b	c	71 PPS CODE	72 ECI	a	b	c	73

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75	76 ATTENDING	NPI	QUAL	
0JH60MZ	XX/XX/2026	03HK3MZ	XX/XX/2026				LAST		FIRST	
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE		77 OPERATING	NPI	QUAL	
							LAST		FIRST	

80 REMARKS	81CC			78 OTHER	NPI	QUAL	
	a			LAST		FIRST	
	b			79 OTHER	NPI	QUAL	
	c			LAST		FIRST	
	d						

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.

Appendix G: Sample physician claim form



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes,* complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

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)

NCT07232030

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. I50.XX B. Z00.6 C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

IDEG250077

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	26	01	01	26	22		64654	Q0	A	XXXX	XX		NPI	
2															NPI	
3															NPI	
4															NPI	
5															NPI	
6															NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Appendix H: Medicaid attestation form on the appropriateness of the qualified clinical trial

Participant
Participant Name: _____

Medicaid I.D.: _____

Qualified Clinical Trial
National Clinical Trial Number (from clinicaltrials.gov): **NCT07232030**

Principal Investigator Attestation
Principal Investigator Name: _____

- I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.
- The Principal Investigator is also the Health Care Provider and hereby attests to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(signature of principal investigator) (month, day, year)

Health Care Provider Attestation

Health Care Provider Name: _____

- I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(signature of health care provider) (month, day, year)

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-0193. Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

CVRx contacts

Technical support (24/7)

Phone: 763-416-2343

Reimbursement support

Phone: 763-416-2354

Fax: 763-207-1965

Email: BenefitHF_C-PAS@cvrx.com

Prior authorization

Phone: 763-416-2354

Fax: 763-207-1965

Email: BenefitHF_C-PAS@cvrx.com

Disclaimer and Sources

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.

References:

1. *Instructions for Use 900133-001 available at www.cvrx.com/ifu.*
2. *ICD-10-PCS and ICD-10-CM 2025. American Medical Association, Chicago, IL.*
3. *Current Procedural Terminology 2025, 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. *2026 Physician Final Rule CMS -1832-F.*
6. *2026 OPPS and ASC Final Rule CMS 1834-FC.*
7. *2026 IPPS Final Rule CMS-1833-F.*


Barostim™
Outsmart the heart