

**HOSPITAL INPATIENT AND OUTPATIENT
BILLING GUIDE FOR THE
NOVOSTE™ BETA-CATH™ SYSTEM
INTRAVASCULAR BRACHYTHERAPY DEVICE**



This guide is intended solely for use as a tool to help hospital billing staff resolve reimbursement issues. Any determination about how to seek reimbursement should be made solely by the appropriate members of the hospital in consultation with the physician and in light of the procedure performed on a particular patient. Novoste does not endorse the use of any particular procedure code(s). Also, it is important to note that reimbursement codes and procedures can change. For questions regarding billing of the Beta-Cath™ System call 1-800-NOVOSTE.

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INTRODUCTION AND PRODUCT OVERVIEW

The Beta-Cath™ System intravascular brachytherapy device, occasionally referred to as intracoronary brachytherapy, is a minimally invasive technology intended to deliver beta radiation to the site of successful percutaneous coronary intervention (PCI) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2.7 mm to 4.0 mm. The portable system uses strontium-90 sources to deliver beta radiation through a closed-end lumen catheter. The Beta-Cath™ System is an integrated system comprised of four components: the β -Cath™ Delivery Catheter, the Transfer Device, the Source Train, and the System Accessories. The Beta-Cath™ System is designed so that the Transfer Device and the Delivery Catheter are exclusively compatible. On November 3, 2000, Novoste Corporation received approval from the U. S. Food and Drug Administration (FDA) to begin marketing the Beta-Cath™ System for the indication described above.

This billing guide was developed to assist facilities billing services and procedures associated with the Beta-Cath™ System. This guide should help answer coverage, coding, and reimbursement questions about the Beta-Cath™ System intravascular brachytherapy device (IVBT). The guide is organized into the following sections:

- Coverage
- Diagnosis Coding
- Hospital Inpatient Coding and Reimbursement Overview
- Hospital Outpatient Coding and Reimbursement Overview
- Instructions for Filing Initial Claims and Establishing Medical Necessity
- Frequently Asked Questions
- Glossary of Reimbursement Terms
- Sample Claims Forms

The sections that follow will give you guidance on coding and reimbursement specific to hospitals. The codes listed represent possible coding options. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that were rendered. Before filing claims with the local Medicare contractor or another payer, providers should verify coding requirements with that payer, as well as check any local medical review policies that may exist for using the Beta-Cath™ System.

COVERAGE

Coverage for the Beta-Cath™ System refers to the decision by an insurer organization to provide program benefits for this specific product and/or related medical services. Coverage policies will vary by payer; for example, coverage policies for a specific payer may specify the setting where a service is considered reasonable and necessary, as well as for which indications. The Beta-Cath™ System is currently FDA approved for the treatment of in-stent restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2.7 mm to 4.0 mm.

At this time, there is no national Medicare policy for this procedure. Therefore, each Medicare contractor (carrier or fiscal intermediary) has discretion to determine when the procedure is considered reasonable and necessary. These policies are spelled out in state-specific local medical review policies (LMRPs).

In this guide, we focus on reimbursement by Medicare and private payers.

Many payers, with the exception of Medicare, may require prior authorization or pre-certification before providing hospital services. If so, the hospital will need to contact the patient's health care organization and request permission to perform the procedure before care is initiated. The health care organization will review the prior authorization/pre-certification request and either approve or deny it based upon established criteria including the medical necessity and appropriateness of the procedure.

DIAGNOSIS CODING

ICD-9-CM¹ Diagnosis Codes

All payers require claims to have at least one ICD-9-CM diagnosis code to document patients' diagnoses. These codes should always be identified to the highest level of specificity, and should reflect the patient's condition.

The Beta-Cath™ System is associated with several possible diagnoses. Inclusion of complete and accurate diagnosis codes on the claim will support the medical necessity of performing intravascular brachytherapy and facilitate appropriate claim processing. All diagnoses on the claim must be supported by physician documentation and the codes documented must never be used solely to influence coverage or medical necessity decisions.

The following list includes some, but not all, diagnosis codes that may be appropriate for describing patients who are candidates for treatment with the Beta-Cath™ System:

ICD-9-CM Diagnosis Codes Associated with use of the Beta-Cath™ System

Diagnosis Code	Description
996.72*	Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft, due to other cardiac device, implant and graft.
410.X1	Acute myocardial infarction
411.1	Intermediate coronary syndrome
411.81	Coronary occlusion without myocardial infarction
413.X	Angina pectoris
414.01	Coronary atherosclerosis of native coronary artery

* This code is often interpreted as in-stent restenosis pertaining to the coronary vasculature, and has appeared in several payer policies as the only covered indication specific to the coronary vasculature. Another code, 996.74 describes the peripheral vasculature, and should be reserved to describe in-stent restenosis of non-coronary vasculature.

The codes listed above represent possible coding options. It is always the provider's responsibility to determine and submit appropriate codes to describe the patient condition. The patient's medical record must support all diagnoses on a claim form.

¹ International Classification of Diseases, Ninth Revision, Clinical Modification

HOSPITAL INPATIENT CODING AND REIMBURSEMENT

Hospital Inpatient Coding

ICD-9-CM Procedure Codes

In addition to ICD-9-CM Diagnosis codes, Medicare and private payers also require ICD-9-CM procedure codes on inpatient hospital claim forms. Procedure codes are essential for assigning the proper payment to a patient stay. Some suggested procedure codes for reporting the use of the Beta-Cath™ System and related diagnoses are set forth below. ICD-9 Procedure code 92.27 describes the insertion of the radioactive element, and its use with the appropriate percutaneous transluminal coronary angioplasty (PTCA) procedure code is integral to obtaining the appropriate payment amount. Choose the code that most accurately represents the PTCA procedure performed. You may need to list additional ICD-9-CM procedure codes that describe any other procedures performed.

ICD-9-CM Procedure Codes Associated with use of the Beta-Cath™ System

Procedure Code	Description
36.01	Single vessel percutaneous transluminal coronary angioplasty (PTCA)
92.27	Implantation or insertion of radioactive elements

(See Appendix A for an example of a completed UB-92 claim form for hospital inpatients treated with the Novoste™ Beta-Cath™ System.)

The codes listed above represent possible coding options. It is always the provider's responsibility to determine and submit appropriate codes for the services rendered. Novoste does not recommend the use of any particular procedure code for any particular patient. The patient's medical record must support all procedures on a claim form.

Revenue Codes

All UB-92 facility claim forms must include revenue codes. Revenue codes are three or four digit codes that allow hospitals to attribute supplies and services to specific cost centers within the hospital. Each supply or service provided during the patient's visit must be associated with a revenue code. An example of a revenue code is 360 – *Operating Room*.

Hospital Inpatient Reimbursement

Medicare reimburses for hospital inpatient care using diagnosis-related groups (DRGs). DRGs are assigned based on a patient's diagnoses and the procedures performed during an inpatient stay. Under DRGs, hospitals generally receive a fixed, pre-determined payment for each DRG, regardless of the actual resources used. The DRG payment includes all facility costs associated with the patient's hospital stay, including hospital payment for certain services performed three days prior to admission. A particular hospital's DRG payment is adjusted for many hospital-specific and geographic factors.

The Medicare program has recognized intravascular brachytherapy as a procedure that employs a new technology to treat coronary disease in the inpatient setting, and, as such, warrants a higher payment than PTCA alone. Specifically, the FY 2002 DRG grouper will map a claim to a higher-paying DRG² when PTCA is performed with intravascular brachytherapy (identified by using ICD-9-CM procedure code 92.27, *Implantation or insertion of radioactive elements*). Therefore, we stress the importance of complete and accurate procedure coding on the UB-92 to ensure that the hospital receives appropriate payment for hospital resources, including the Beta-Cath™ System.

Additional DRG-related information specific to the Beta-Cath™ System can be found in the Frequently Asked Questions chapter of this Billing and Reimbursement Guide.

Private insurers may reimburse hospitals for inpatient care using DRGs, a per diem, or case rates. Per diem rates are negotiated prospective payments for each day of care, regardless of the resources used. Per diem rates vary within geographic markets and are plan-specific; payers can use a single per diem for all types of patient services such as surgical and medical services. Case rates, like DRGs, are a pre-determined dollar amount usually defined or categorized by the diagnoses recorded and procedure(s) performed.

² DRG 516, Percutaneous cardiovascular procedure with AMI.

DRG 517, Percutaneous cardiovascular procedure with coronary artery stent without AMI.

HOSPITAL OUTPATIENT CODING AND REIMBURSEMENT

For some patients, it may be clinically appropriate to undergo a cardiac interventional procedure on an outpatient basis. Some payers, however, restrict coverage based on setting. Ultimately, the most appropriate setting of care must be determined by the physician based on the individual patient's clinical needs. The following sections describe the different coding mechanisms and how different payers may reimburse the intravascular brachytherapy procedure, as well as the Beta-Cath™ System, when covered in the hospital outpatient setting.

Hospital Outpatient Coding

CPT and HCPCS Codes

In addition to ICD-9-CM Diagnosis codes, Medicare and some private payers require Current Procedural Terminology (CPT)³ and Healthcare Common Procedural Coding System (HCPCS) codes on hospital outpatient UB-92 claim forms. These codes describe procedures and services performed, as well as supplies provided, and are essential for assigning proper payment. Some suggested codes for reporting the use of the Beta-Cath™ System are set forth below.

Revenue Codes

All UB-92 facility claim forms must include revenue codes. Revenue codes are three or four digit codes that allow hospitals to attribute supplies and services to specific cost centers within the hospital. Each supply or service provided during the patient's visit must be associated with a revenue code. An example of a revenue code is 360 – *Operating Room*.

³ Current Procedural Terminology (CPT), Copyright 2001, American Medical Association.

Hospital Outpatient Reimbursement

Under the Medicare program, all services are assigned to ambulatory payment classification (APC) groups based on the CPT and Healthcare Common Procedural Coding System (HCPCS) codes noted on the facility UB-92 claim, making accurate procedure coding essential. The APC does not appear on the claim; rather it is assigned by the fiscal intermediary during claims processing.

For dates of service from July 1, 2001 until April 1, 2002, Medicare assigned a New Technology Procedure/Service HCPCS C-code, C9702, to allow hospital outpatient facilities to bill Medicare for intravascular brachytherapy with the Beta-Cath™ System. After April 1, 2002, C9702 will be deleted, and hospitals will no longer use this C-code to identify IVBT services.

For services performed after April 1, 2002, Medicare recognizes CPT code 92974, *Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy*, as the appropriate code for this service. When assigning this procedure to an APC for payment purposes, CMS considered all the costs to the hospital associated with performing IVBT, including the delivery catheter and the brachytherapy seeds. Therefore, the hospital will not use any other codes to receive appropriate Medicare reimbursement for intravascular brachytherapy with the Beta-Cath™ System. Other services that are performed, such as PTCA, can be billed separately.

CPT Code Associated with use of the Beta-Cath™ System

HCPCS Code	Description	New Technology APC
92974	Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy	0981

(See Appendix B for an example of a completed UB-92 claim form for hospital outpatients treated with the Novoste™ Beta-Cath™ System.)

Non-Medicare payers also likely will use the new CPT code for IVBT in the hospital outpatient setting.

The codes listed above represent possible coding options. It is always the provider's responsibility to determine and submit appropriate codes for the services rendered. Novoste does not recommend the use of any particular procedure code for any particular patient. The patient's medical record must support all procedures on a claim form.

ADDITIONAL CODING AND REIMBURSEMENT GUIDANCE

Medical Physicist

A medical physicist may be part of the team that performs an IVBT treatment with the Novoste™ Beta-Cath™ System. If the Medical Physicist is a salaried hospital employee, the hospital will be able to bill for the services provided during the encounter using code 77370. For the service of a Medical Physicist practicing independently from the hospital, the facility can charge for the services rendered by the physicist if the hospital incurs a cost (for example, the hospital may pay the physicist a consultant fee).

INSTRUCTIONS FOR FILING CLAIMS

Checklist for Successful Claim Submission

To facilitate timely and appropriate reimbursement, hospital staff members should ensure that coding and documentation is complete and accurate. Included below are some checklist items for successful claim submission. Use this checklist as a guide when submitting claims for intravascular brachytherapy procedures using the Novoste™ Beta-Cath™ System.

- ❑ Obtain prior authorization or pre-certification, when appropriate, prior to the procedure.
- ❑ Verify that the patient's identification number and all other information is correctly entered.
- ❑ Ensure appropriate documentation exists in the medical record to support the diagnosis and procedure codes submitted on the claim.
- ❑ Use the most appropriate ICD-9-CM diagnosis and procedure codes. Ensure they are coded to the highest level of specificity.
- ❑ Use the correct CPT or HCPCS codes and modifiers where and when appropriate.
- ❑ Use accurate revenue codes for the services rendered.
- ❑ Ensure that all outpatient claims have accurate dates, ICD-9, CPT, HCPCS, and Revenue codes.
- ❑ File the claim in a timely fashion.

FREQUENTLY ASKED QUESTIONS

1. Will the hospital be separately reimbursed for use of the Beta-Cath™ System used during an inpatient hospital stay?

Under Medicare DRGs, reimbursement for devices used in a procedure are included in the diagnosis-related group (DRG) payment assigned for that patient admission. Starting October 1, 2001, the Medicare program will assign claims for PTCA with IVBT to the DRG for PTCA with stenting to help offset the additional costs involved in performing IVBT compared with PTCA alone.

Private payers may use similar DRG payments for inpatient stays or they may use another payment mechanism. In either case, the device likely will not be separately reimbursed. However, to understand better how private payers will provide coverage, providers should contact a patient's insurer to ensure they are being reimbursed appropriately.

2. What DRG is typically expected for patients who undergo intravascular brachytherapy with the Beta-Cath™ System?

Typically, one would expect the patient's case to group according to the patient's diagnoses and procedure(s) performed during an inpatient admission. For example, Medicare has decided that PTCA with IVBT will map to the DRG as if a PTCA with stent was performed:

- *DRG 517: PTCA with insertion of stent, without AMI.*

If a patient is discharged with a diagnosis of an AMI, the admission may be grouped into the following DRG, regardless of which procedure is performed:

- *DRG 516: PTCA with AMI*

In order to receive appropriate reimbursement for use of the Beta-Cath™ System, hospitals must be certain to bill all relevant ICD-9 procedure codes performed during the procedure. Reporting of these codes will ensure mapping to an appropriate DRG that reflects the level of service performed. Please be sure to report placement of the radiation source train (92.27) to reflect use of the Novoste™ Beta-Cath™ System in addition to the PTCA procedure performed.

3. For Medicare patients, what other codes can I bill for IVBT in addition to 92974 (Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy)?

Novoste has received specific guidance from CMS that HCPCS code 92974 is intended to represent the IVBT procedure, including the cost of the device. Therefore, it is neither necessary nor appropriate to bill additional codes for the procedure or the Beta-Cath™ System. Of course, other procedures performed on the same day, such as PTCA, can be billed separately.

GLOSSARY OF REIMBURSEMENT TERMS

Allowable Charge. The maximum amount an insurer will allow for a specific supply or service. The amount the insurer pays is typically 80 percent of this amount and the patient is responsible for the remainder.

Ambulatory Payment Classification (APC). The basis for grouping and assigning payment to services under the Medicare hospital outpatient prospective payment system (OPPS). APC groups are similar clinically and with regard to resource use.

The Centers for Medicare and Medicaid Services (CMS). The federal agency, formerly known as the Health Care Financing Administration (HCFA), that administers the Medicare, Medicaid, and State Child Health Insurance Programs.

CMS-1500 (previously known as HCFA-1500). This is a standard claim form required by Medicare and other payers for billing physician services.

Current Procedural Terminology, (CPT). A listing of descriptive terms and codes for reporting medical services and procedures performed by physicians. The American Medical Association maintains this coding system.

Diagnosis-related Group (DRG). A method of grouping inpatient hospital stays by medical diagnoses, procedures, patient age, patient sex, and discharge status. These groupings are used in the Medicare inpatient hospital prospective payment system to establish the predetermined fixed payment for each inpatient episode of care (regardless of the resources utilized).

Explanation of Benefits (EOB). Also called explanation of medical benefits (EOMB). The statement sent to covered persons by their health plan listing services provided, amount billed, and payment made.

Healthcare Common Procedure Coding System (HCPCS). CMS-assigned alpha-numeric billing codes for services and supplies not represented by a CPT code. Intravascular brachytherapy is currently billed with a HCPCS C-code.

International Classification of Disease, 9th Edition, Clinical Modifications (ICD-9-CM). A coding system used to describe both patient diagnoses in all settings and surgical and medical procedures performed in a hospital setting.

Medically Necessary. A medically necessary service is one that is reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Medicare. A federally funded program that provides health insurance benefits to the elderly (aged 65 or older), disabled Americans, and patients with end stage renal disease. Medicare is administered by the Centers for Medicare and Medicaid Services.

Prior Authorization. An administrative procedure whereby a health provider seeks to confirm patient coverage by a third party payer before treatment is initiated.

Revenue Codes. A coding system used for categorizing and billing hospital services maintained by the National Uniform Billing Committee.

UB-92 or CMS-1450 (previously known as HCFA-1450). This is a standard claim form required by Medicare and other payers for billing hospital services.