



# Circulatory Support System 2007 Reimbursement Guide



BVS® 5000 Blood Pump



AB5000™ Ventricle

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# About This Guide

Abiomed offers this *Reimbursement Guide* to customers as part of a program of reimbursement support services. There have been many changes in the reimbursement for mechanical circulatory support over the past few years in the United States, most recently for Centers for Medicare and Medicaid Services (CMS) Fiscal Year beginning October 1, 2005. As a result of the new policy, there has been an increase of approximately 70% from DRG 525 to DRG 103 with recovery of the native heart on extracorporeal support. Additional increases were included in the CMS Final Rule effective October 1, 2006. Reimbursement from private payers generally follows CMS reimbursement, but please check with individual insurers. Abiomed is committed to providing information that will help obtain insurance reimbursement for AB5000™ Ventricle and BVS® 5000 Blood Pump therapy.

**Disclaimer:** All content in this document is for informational purposes only, and is not intended to provide specific instructions to hospitals or physicians on how to bill for medical procedures. Hospitals and physicians should consult appropriate insurers, including Medicare fiscal intermediaries and carriers, for specific coding, billing and payment levels. This document represents no promise or guarantee by ABIOMED, Inc. concerning medical necessity, levels of payment, coding, billing or coverage issues.

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# Section 1.

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## General Insurance Policies for Cardiac Assist Devices

### ***What are the Current Medicare Coverage Guidelines for Mechanical Circulatory Support?***

Under the Inpatient Prospective Payment System (IPPS), Medicare covers mechanical circulatory support systems for use in Medicare beneficiaries in three conditions:\*

- 1. Support for Recovery**
- 2. Bridge to Transplant**
- 3. Destination Therapy**

In the CMS Final Rule, effective October 1, 2005, CMS outlined increased reimbursement for external ventricular assist devices (VADs) with successful recovery of the native heart as the end goal. This change was made to provide accurate payment to hospitals who identified and treated patients with conditions where native heart function was possible following mechanical support.

In the CMS Final Rule effective October 1, 2006, CMS further expanded the opportunity for centers to be reimbursed for treating patients with potential for heart recovery on external mechanical circulatory support. The coding change will allow hospitals who receive a patient on a BVS® 5000 device and switch to the AB5000™ device to map to the discharge to a higher DRG for increased reimbursement.

The Quality Improvement Organizations (QIOs) associated with CMS are required to assess certain cases; implantable VADs are reviewed to ensure VAD usage is reasonable and necessary and leads to improvement of patient outcomes. With the expanded reimbursement for recovery of the heart, QIOs will also follow recovery cases to document improvement in clinical outcomes.

\* The *Medicare Coverage Issues Manual, Section 20.9, Artificial Hearts and Related Devices*, was revised in October 2003 to read:

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or as destination therapy.

# Section 2.

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## Policies of Specific Types of Insurers

### **Medicare Coding and Payment / Diagnostic Related Group (DRG)**

Medicare reimburses hospital inpatient charges using diagnosis related groups (DRGs) at fixed rates. DRG's are assigned based on ICD-9 diagnoses and procedure codes. The DRG system is an inpatient classification system determined by several factors: principal diagnosis, secondary diagnosis, surgical factors, age, sex, and discharge status. Hospitals are paid a fee for treating patients in a DRG category.

Recent changes to the DRG classification system of cardiac assist devices allow for physicians' best assessment of patient clinical needs and recognition of increased resource utilization for their care, without inappropriate financial penalties to their hospitals.

#### ***Does Medicare Cover AB5000™ Ventricle and BVS® 5000 Blood Pump Implants?***

Yes, Medicare reimburses physicians and institutions for implantation and support of patients on these mechanical circulatory-support devices when medically necessary for the patient and when used consistently with FDA-approved label indications.

#### ***How Does Medicare Determine Reimbursement for Support?***

Medicare uses the Resource Based Relative Value System (RBRVS) and Current Procedural Terminology (CPT) Codes to determine reimbursement levels.

#### ***How Does Medicare Cover Cardiac Assist Devices?***

The tables on the next page depict the specific codes and billing procedures for Abiomed ventricular assist devices, assuming such devices are medically necessary for the specific patient and when used consistently with FDA-approved label indications.

## Section 2: Policies of Specific Types of Insurers

Procedure Codes	DRG	Description	Abiomed Device	LOS	Estimated payment for 2007*
37.63 + 37.64 in the same hospital admission	DRG 103	Replacement of an external pulsatile heart assist system + Removal of a heart assist system	AB5000™ Ventricle BVS® 5000 Blood Pump	26	\$135,000
37.65 + 37.64 in the same hospital admission	DRG 103	Implant of an external, pulsatile heart assist system + Removal of a heart assist system	AB5000™ Ventricle BVS® 5000 Blood Pump	26	\$135,000
37.65	DRG 525	Implant of an external, pulsatile heart assist system	AB5000™ Ventricle BVS® 5000 Blood Pump	8	\$86,000
37.63	DRG 525	Replacement and repair of heart assist system, surgical procedure	AB5000™ Ventricle BVS® 5000 Blood Pump	8	\$86,000
37.64	DRG 110	Removal of heart assist system	AB5000™ Ventricle BVS® 5000 Blood Pump	6	\$38,000

CPT® Codes	Description	Abiomed Device	Global Billing Period	Estimated payment for 2007*
33975	Insertion of single extracorporeal ventricular assist device	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$1,200
33976	Insertion of biventricular extracorporeal assist device	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$1,300
33977	Removal of single extracorporeal ventricular assist device	AB5000™ Ventricle BVS® 5000 Blood Pump	90 days	\$1,300
33978	Removal of biventricular extracorporeal assist device	AB5000™ Ventricle BVS® 5000 Blood Pump	90 days	\$1,400

Payment varies with geographical location. Estimates based on eastern metropolitan standard statistical area.

\*Estimate for metropolitan nontransplant center. Teaching hospital payment will be higher; reimbursement varies with wage index and capital expenditure. Please check with your local provider.

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## Section 2: Policies of Specific Types of Insurers

CPT® Codes	Description	Abiomed Device	Global Billing Period	Estimated payment for 2007*
33960	Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial 24 hours	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$1,020
33961	Each additional 24 hours	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$584
99221 99222 99223	Initial hospital care	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$68 \$113 \$157
99231 99232 99233	Subsequent hospital care	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$34 \$56 \$79
99238 99239	Discharge day	AB5000™ Ventricle BVS® 5000 Blood Pump	NA	\$71 \$97

Payment varies with geographical location. Estimates based on eastern metropolitan standard statistical area.

\*Estimate for metropolitan nontransplant center. Teaching hospital payment will be higher; reimbursement varies with wage index and capital expenditure. Please check with your local provider.

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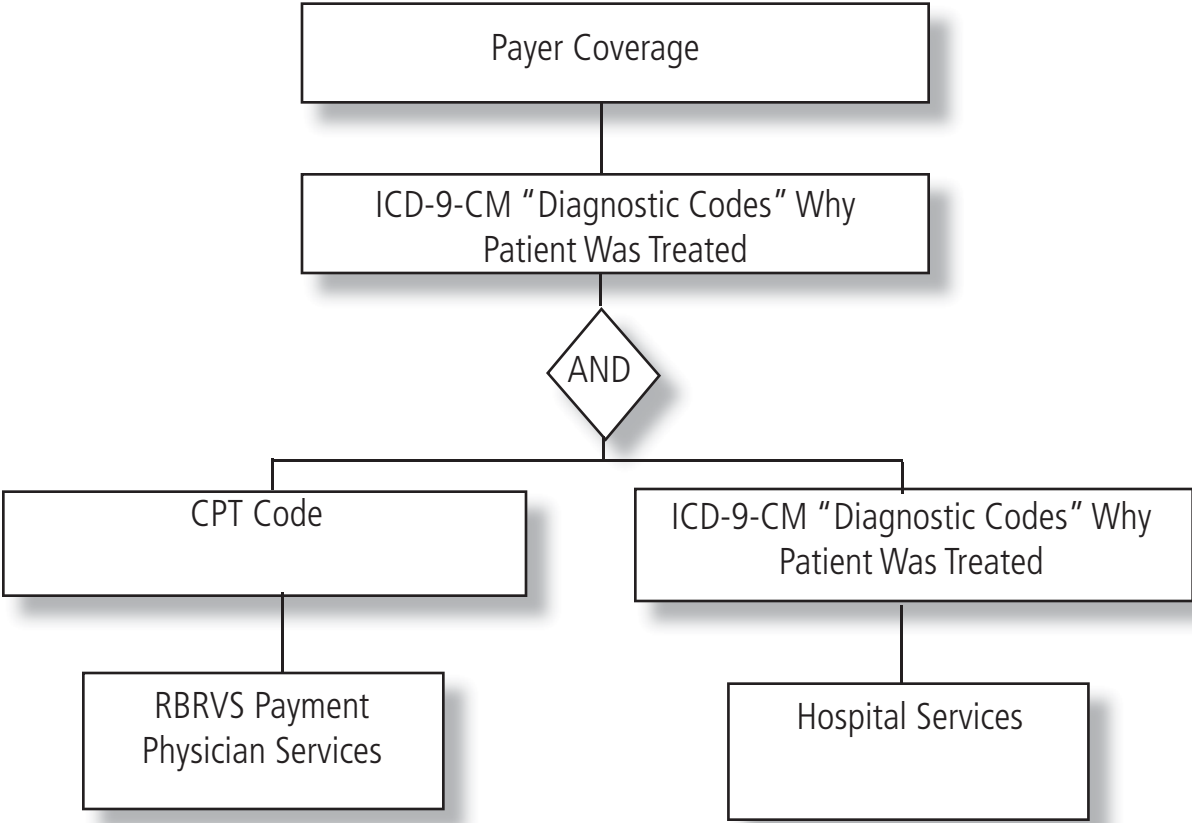
**Section 2: Policies of Specific Types of Insurers**

***What is the Medicare Payment Process?***

Medicare utilizes the Resource Based Relative Value System (RBRVS) and Current Procedural Terminology (CPT) Codes to determine reimbursement levels.

The Medicare payment process begins with physician documentation and ends with the assignment of payment by Medicare. The steps in this process include:

- 1. Physician Documentation**
- 2. Billing/Coding Information Based on Physician Documentation (Including Selection of Appropriate Diagnosis and Procedure Codes)**
- 3. Review of Coding and Physician Documentation to Determine Medical Necessity**
- 4. Medicare Payment to Hospital or Physician**



## Section 2: Policies of Specific Types of Insurers

### ***How Does the New Medicare Reimbursement Framework Apply to Open-Heart Centers and Transplant Hospitals?***

Reimbursement for open-heart centers and transplant centers who utilize external, pulsatile ventricular assist systems has changed in recent years. Effective October 1, 2005, an implant and explant during the same admission was significantly changed to map to DRG 103. Effective October 1, 2006, a replacement and explant is also mapped to DRG 103.

### **Open-Heart Hospitals**

The CMS guidelines for FY2006 change how open-heart hospitals receive payment for VAD patients. A patient that receives both an implant (37.65) and explant (37.64) of an AB5000™ Ventricle or a BVS® 5000 Blood Pump during a single hospital stay will now map to a different payment in DRG 103.

The procedure code for an AB5000™ Ventricle or a BVS® 5000 Blood Pump (37.65) will continue to trigger assignment to DRG 525 if a patient is implanted with an AB5000™ Ventricle or a BVS® 5000 Blood Pump (37.65), then transferred to a transplant hospital.

### **Transplant Hospitals**

CMS will make payments of DRG 103 to transplant hospitals for patients who are both implanted with an external VAD system (37.65) and explanted (37.64) during the same admission. Effective October 1, 2006, CMS is also reimbursing at DRG 103 for the replacement of an external ventricular support system (37.63) and explant (37.64) during the same admission.

Reimbursement received for AB5000™ Ventricle or a BVS® 5000 Blood Pump implantation (37.65) and ensuing cardiac transplantation (37.51) will continue to map to DRG 103.

Should a patient be on an AB5000™ Ventricle or a BVS® 5000 Blood Pump (37.65) and then be transferred to a new implantable or internal system (37.66), the assigned DRG will continue to be DRG 103.

Similar to the open-heart hospital scenario, a patient implanted with an AB5000™ Ventricle or a BVS® 5000 Blood Pump (37.65) that expires will generate assignment of DRG 525, as it has done historically.

## Section 2: Policies of Specific Types of Insurers

### ***How Does Medicare Reimbursement Work for Transfer Patients?***

#### **Open-Heart Hospitals**

If a patient is implanted with an AB5000™ Ventricle or a BVS® 5000 Blood Pump (37.65) and is transferred to a transplant hospital, the open-heart hospital will continue to assign the discharge code "4" (discharged/transferred to an Acute Care Hospital) and fall under DRG 525.

The open-heart hospital then receives a prorated portion of DRG 525. The proration factor is equal to the length of stay (LOS) plus one, divided by the average length of stay (currently eight days).

The payment to the open-heart hospital is the hospital's DRG rate multiplied by the proration factor.

#### **Transplant Hospitals**

The admission diagnosis at the transplant hospital determines the DRG assignment. The transplant hospital receives the full DRG payment, unless the hospital discharge code is "4". Effective October 1, 2006, patients transferred from an open-heart hospital on a BVS5000 Blood Pump who are subsequently switched (i.e., "repair/replace," code 37.63) to an AB5000 Ventricle and recover will map to DRG 103.

Transferred patients from open-heart hospitals that expire without explant at transplant hospitals will continue to be slotted under a DRG based on diagnosis only.

- i.e., cardiogenic shock: DRG 127
- i.e., AMI: DRG 122

Patients transferred from open-heart hospitals with an AB5000™ Ventricle or a BVS® 5000 Blood Pump and who then receive cardiac transplantation (37.51) will be assigned to DRG 103.

For case examples, please refer to ***Section 4, Reimbursement Case Study.***

## Section 2: Policies of Specific Types of Insurers

### Private Payers

#### *Will Private Payers Cover Cardiac Assist Devices?*

In general, patients with acute heart failure who have conditions likely to result in recovery of native heart function are younger and often covered by private insurance. It is estimated that 60% of recovery patients are non-Medicare patients<sup>1</sup>. All major carriers in the U.S. cover external ventricular assist device technology to some extent, and may make case-by-case assessments to determine the level of coverage and reimbursement. These coverage levels vary by carrier, region, and hospital negotiated contracts. Private payers may establish reimbursement under a number of different mechanisms, including:

- Payment of a percentage of charges
- A DRG-like system
- Payment on a per-diem basis
- Special device carve-outs that assure device cost recovery

<sup>1</sup>ABIOMED, Inc. Data Registry, October 2006.

# Section 3.

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## Claims, Denials, and Appeals

### Submitting the Claim

If a claim needs to be submitted, there are several steps necessary to ensure a timely response from the carrier. To submit the claim, call the patient's insurance company and obtain the name of a clinical case manager who reviews inpatient claims. Send the following documents (in paper form, if possible) to the attention of that person:

- The bill
- A copy of the operative report
- A clinical profile of the patient that explains the decision to employ the AB5000™ Ventricle/BVS® 5000 Blood Pump
- A brief description of the AB5000™ Ventricle/BVS® 5000 Blood Pump and its indications for use

Follow-up on the claim should be done with the same contact person.

### Denials and Appeals

#### ***What are the Most Common Reasons a Claim is Denied?***

There are times when a claim is denied by a carrier. There may be a variety of reasons behind the denial and there are actions to take for appeal. A claim may be denied for a variety of reasons, including:

- Clerical errors (misspellings and transposed numbers)
- Omission of an accurate description of services
- Inaccurate or missing information

### Section 3: Claims, Denials, and Appeals

#### ***What are the Options Available if a Patient's Claim is Denied?***

All insurers have a process for appealing denied claims. When a claim is returned, the reason is stated in the accompanying explanation of benefits (EOB). Often, returned claims simply require additional information, such as a diagnosis or procedure code.

The *first step* in an appeal is to resubmit the denied claim with the requested information. Most well-documented follow-up submittals are successful with persistence.

If the resubmitted claim is not approved, the next step is to call the insurer's Claims Manager or Medical Director to obtain a review or hearing. For this type of appeal, submit the following:

- A copy of the bill and the insurance company denial letter or EOB.
- A copy of the operative report.
- A clinical profile of the patient that explains the decision to employ the AB5000™ Ventricle/BVS® 5000 Blood Pump.
- A brief description of the AB5000™ Ventricle/BVS® 5000 Blood Pump and its indications for use.
- A review of the complexity of the case: a description of the time, skill, and procedures involved in implanting and explanting the device and in caring for the patient while on support.
- A description of the clinical result, focusing on the clinical contribution of the AB5000™ Ventricle/BVS® 5000 Blood Pump to the patient outcome.
- A statement that outlines the CPT and ICD-9 Codes relevant to the procedure.

Please refer to ***Appendix A, Sample Appeal Letter to Insurance Company*** for a sample format for appealing a denied claim.

This information should help with understanding insurers' policies. However, using this information does not ensure success in obtaining insurance payment. Third-party payment for medical products and service is affected by numerous factors, many of which are beyond the scope of the matters discussed in this document.

# Section 4.

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## Reimbursement Case Study

### Open-Heart and Transplant Center System

#### Open-Heart Hospital

A patient is admitted for coronary artery bypass at a New York City Metro Hospital. The patient develops postcardiotomy cardiogenic shock (PCCS) as a result of surgery. The decision is made to implant an AB5000™ Ventricle.

#### *Scenario 1*

On postoperative day 5 the decision is made to transfer the patient to a New York City Teaching Hospital (transplant hospital).

- The physicians' documentation of the VAD implant procedure leads the hospitals' coding department to assign Procedure Code 37.65 (implant of external, pulsatile heart assist system).
- Procedure Code 37.65 for the open heart center yields DRG 525.
- The proration factor is 6/8 (length of stay [LOS] plus 1, divided by the average length of stay [ALOS]).
- Medicare payment for DRG 525 is prorated at approximately \$67,000 ( $\$86,000 * (6/8)$ )<sup>1</sup>.

<sup>1</sup>For informational purposes only.

## Section 4: Reimbursement Case Study

### Scenario 2

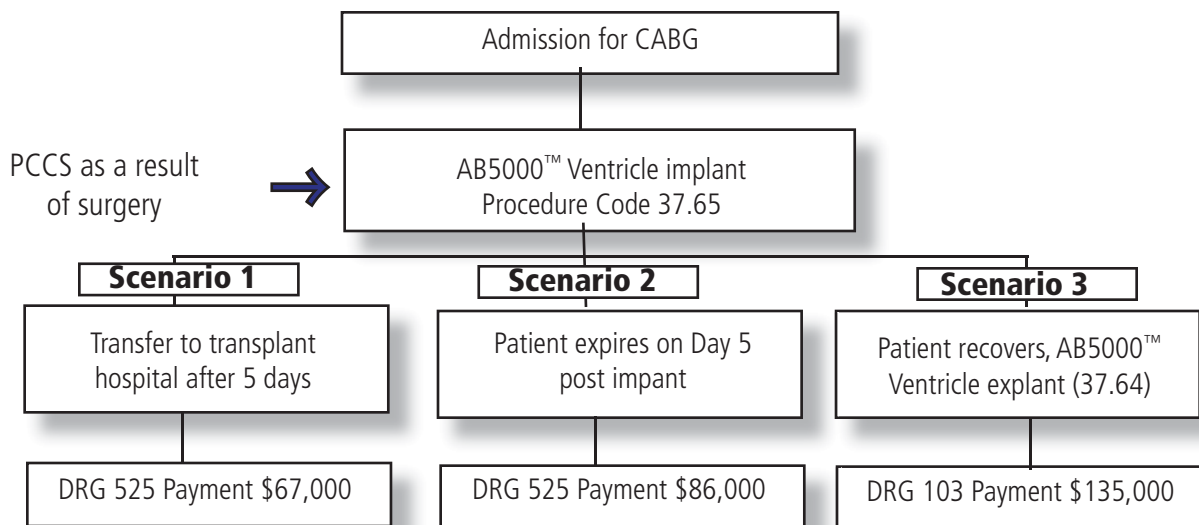
On postoperative day five, the patient expires.

- The physician's documentation of the VAD implant procedure leads the hospital's coding department to assign Procedure Code 37.65 (implant of external, pulsatile heart assist system).
- Procedure Code 37.65 for this hospital yields DRG 525.
- Medicare payment for DRG 525 is \$86,000.\*

### Scenario 3

The patient's heart recovers function. The AB5000™ Ventricle is explanted Day 26 and the patient discharged home with their native heart.

- The physician's documentation of the VAD implant procedure leads the hospital's coding department to assign Procedure Code 37.65 (implant of external, pulsatile heart assist system) and explant Procedure Code 37.64 (removal of a heart assist system).
- Procedure Codes 37.65 and 37.64 yields DRG 103.
- Medicare payment for DRG 103 is \$135,000.\*



\* For informational purposes only. Based on estimated reimbursement rates for specific institutions. Payment varies by institution based on geographic location and other elements of CMS payment calculations. Prorated approximate amounts.

## Section 4: Reimbursement Case Study

### Transplant Hospital

Patient is admitted from an open-heart hospital after undergoing CABG and an AB5000™ Ventricle implant.

#### Scenario 1

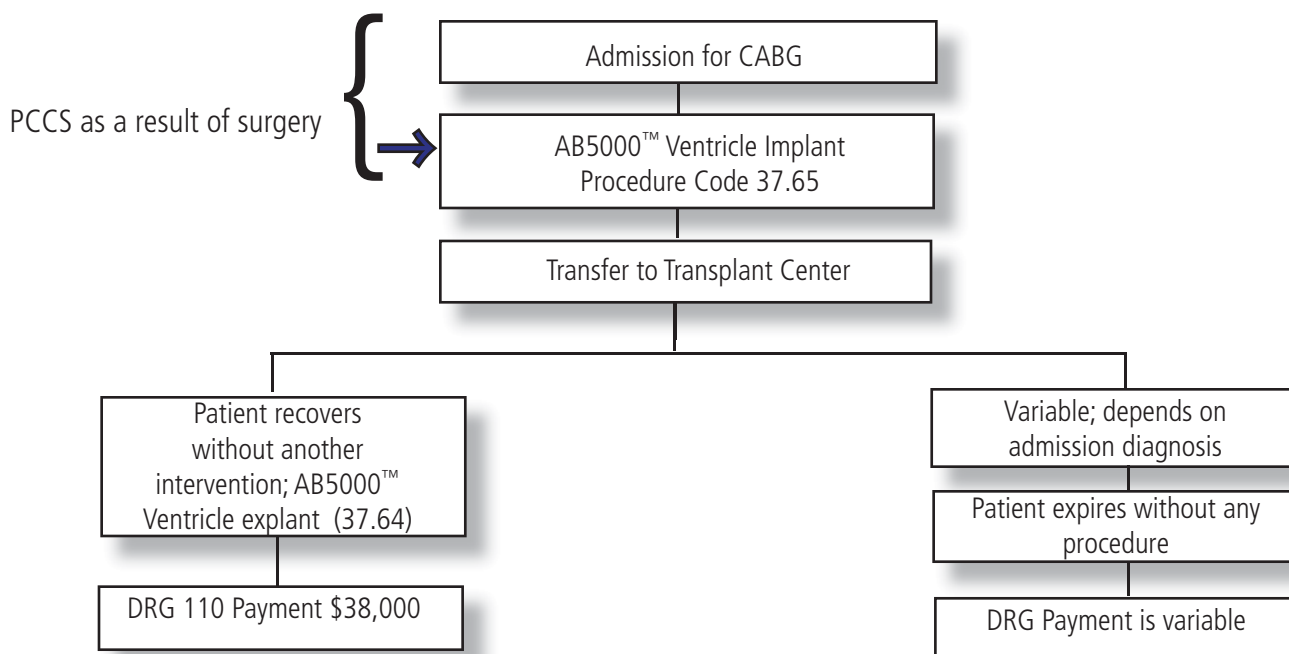
The patient recovers, the AB5000™ Ventricle is explanted, and the patient is discharged home.

- The physician's documentation of the explant procedure leads to Procedure Code 37.64 (removal of heart assist system).
- Procedure Code 37.64 for this hospital yields DRG 110.
- Medicare payment for DRG 110 is \$38,000.\*

#### Scenario 2

The patient expires with an AB5000™ Ventricle from the open-heart hospital in place.

- Review of the patient's hospital course yields DRG 127.
- Medicare payment for DRG 127 at this hospital is \$10,000.\*



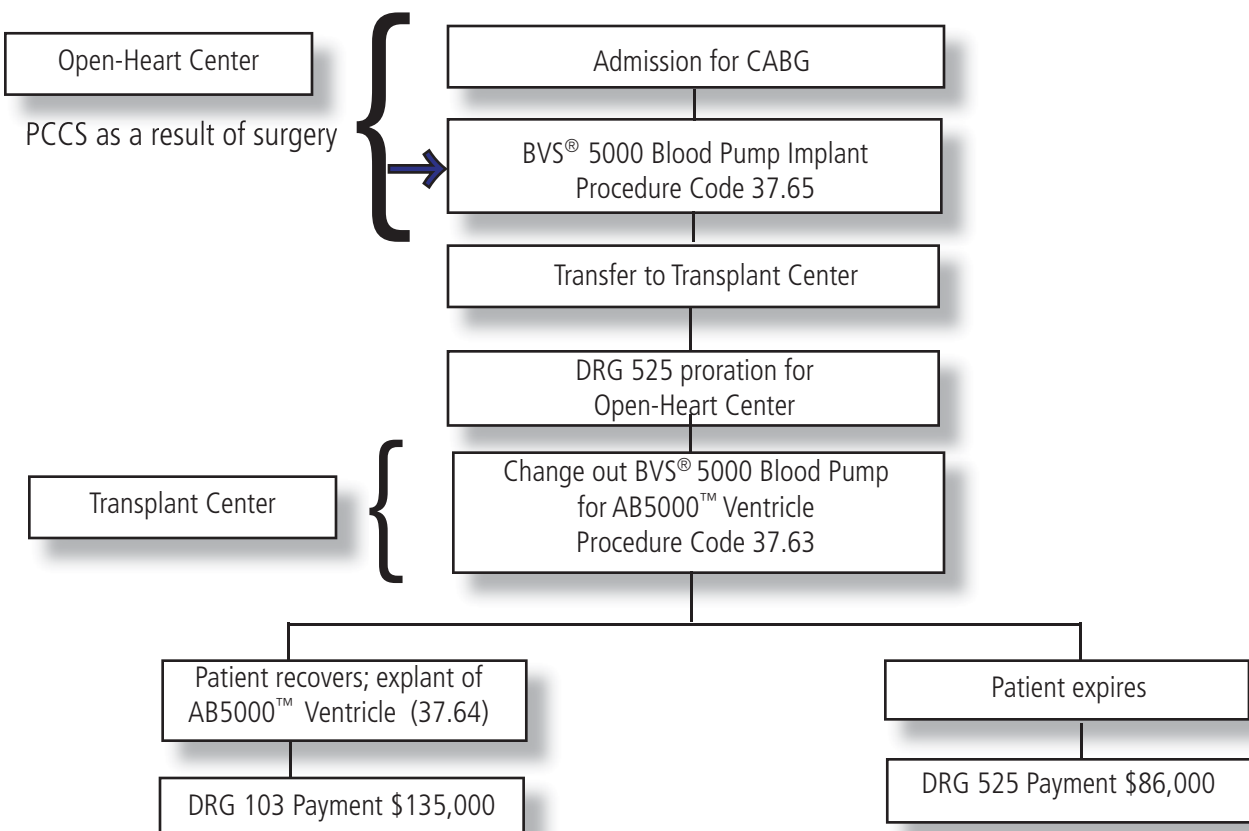
\* For informational purposes only. Based on estimated reimbursement rates for specific institutions. Payment varies by institution based on geographic location and other elements of CMS payment calculations.

## Section 4: Reimbursement Case Study

### Scenario 3

The patient is admitted from an open-heart hospital after undergoing CABG and a BVS<sup>®</sup> 5000 Blood Pump implant. The decision is made to change out the BVS<sup>®</sup> 5000 Blood Pump and implant an AB5000<sup>™</sup> Ventricle. This procedure is done in the operating room. Effective October 1, 2006, if the patient recovers in the same admission after the AB5000 replacement, the transplant center can code for DRG 103.

- Procedure Code 37.63 applies to the change out procedure (replacement and repair of heart assist system, surgical procedure).
- Procedure Code 37.63 for this hospital yields DRG 525.
- Medicare payment for DRG 525 is \$86,000.\*
- Procedure Code 37.63 (replace/repair) plus code 37.64 (explant) during same admission maps to DRG 103.



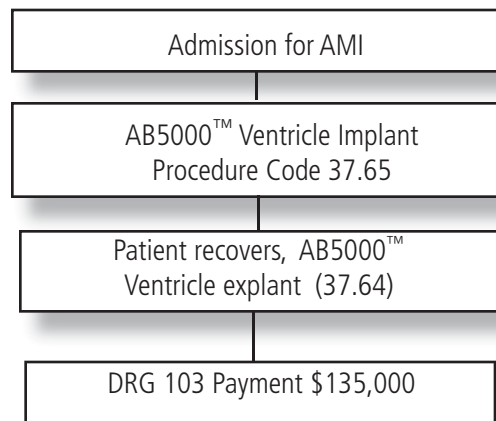
\* For informational purposes only. Based on estimated reimbursement rates for specific institutions. Payment varies by institution based on geographic location and other elements of CMS payment calculations.

## Section 4: Reimbursement Case Study

### Scenario 4

A patient presents to the transplant hospital. He/she has suffered an AMI and decompensates rapidly. The decision is made to initiate early VAD support. This patient subsequently recovers his/her native heart function, is explanted, and discharges.

- Procedure Code (37.65) refers to the initial placement of VAD support; associated is Procedure Code (37.64) because the patient was explanted during his/her hospital stay.
- Dual Procedure Codes (37.65 and 37.64) during the same hospital admission map to DRG 103.
- Medicare payment for DRG 103 is \$135,000.\*



*\* For informational purposes only. Based on estimated reimbursement rates for specific institutions. Payment varies by institution based on geographic location and other elements of CMS payment calculations.*



# Appendix A.

## Sample Appeal Letter to Insurance Carrier

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*(Provider Letterhead)*

Re: *(Patient, ID #, Dates of Service)*  
*(Diagnosis)*

Dear \_\_\_\_\_:

The enclosed claim is being submitted as an appeal. We have attached a copy of your denial letter, and per your request have provided additional clinical information. *(Patient Name)* suffered from postcardiotomy ventricular dysfunction. She had undergone successful bypass surgery (CABG x 4) and subsequently developed low cardiac output. She could not be weaned from cardiopulmonary bypass despite application of all conventional measures, and *(an AB5000 Ventricle/a BVS 5000 Blood Pump)* was inserted to support her left ventricle and circulation. The *(AB5000 Ventricle/BVS 5000 Blood Pump)* is an external, pulsatile ventricular assist device used in patients suffering from reversible ventricular dysfunction. A copy of the operative report is attached.

Based upon *(Dr. Name)* evaluation of this patient, it was his professional judgement that the BVS support was medically necessary to provide *(Patient Name)* circulatory support and allow her stunned myocardium to recover. Implantation of the device was urgent and emergent, thus prior authorization for the device was not possible. *(Dr. Name)* participated in ABIOMED's *(AB5000 Ventricle/BVS 5000 Blood Pump)* training course, which included a classroom didactic session. Insertion of the device in *(Patient Name)* took approximately 60 additional minutes.

The implantation of the *(AB5000 Ventricle/BVS 5000 Blood Pump)* in *(Patient Name)* began with the patient on cardiopulmonary bypass. The tip of the atrial cannula was inserted into the left atrium through purse-string sutures. An incision was made in the ascending aorta, and the graft on the arterial cannula was sutured to the incision. The external blood pump was primed and attached to the cannulae. Flow was initiated and the patient's chest was closed.

(continued on next page)

The patient remained in the ICU during and immediately following mechanical circulatory support. Monitoring was particularly intense during the first 24 to 48 hours of support. Hemodynamics and hematology/blood chemistry parameters were frequently measured during this time. Following 60 hours of left ventricular support, the patient was able to be weaned from the device. *(Patient Name)* was returned to the operating room where the chest was reopened and flow was discontinued. The cannulae were withdrawn, clamped, and oversewn. The chest was then closed and the patient returned to the ICU for observation.

Following mechanical circulatory support, the patient's hemodynamics were restored to normal ranges and myocardial recovery was evident. *(Patient Name)* was discharged from the hospital on the eighth postoperative day and is currently undergoing outpatient cardiac rehabilitation. *(Dr. Name)* noted that the *(AB5000 Ventricle/BVS 5000 Blood Pump)* provided the patient the opportunity to rest, heal, and recover her native heart, thus resulting in such a favorable patient outcome.

The prompt processing of this appeal would be greatly appreciated. If you have any questions, please do not hesitate to contact me, *(Name)*, at *(phone)* or *(Dr. Name)* at *(phone)*.

Sincerely yours,

Enclosures

# Appendix B.

## Reimbursement Resources

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ABIOMED, INC.  
[www.abiomed.com](http://www.abiomed.com)

\*Advanced Medical Technology Association (AdvaMed)  
[www.advamed.org](http://www.advamed.org)

CPT Code Manager  
[www.codemanager.com](http://www.codemanager.com)

CMS: Intermediary-Carrier Directory  
[www.cms.hhs.gov/contracts/incardir.asp](http://www.cms.hhs.gov/contracts/incardir.asp)

CMS: Medicare Learning Network  
[www.cms.hhs.gov/medlearn](http://www.cms.hhs.gov/medlearn)

Code of Federal Regulations (CFR)  
[www.gpoaccess.gov/cfr](http://www.gpoaccess.gov/cfr)

\*FDC Reports  
[www.fdcreports.com](http://www.fdcreports.com)

Medicare Coverage Database  
[www.cms.hhs.gov](http://www.cms.hhs.gov)

Medicare Part-B News  
[www.partbnews.com](http://www.partbnews.com)

Patient Advocacy  
[www.patientadvocate.org](http://www.patientadvocate.org)

\*The Gray Sheet  
[www.thegraysheet.com](http://www.thegraysheet.com)

\*These sites may require a subscription or registration to view some information.



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