



IMPELLA® PERCUTANEOUS CARDIAC SUPPORT SYSTEM

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Overview

The Impella® Recover® LP 2.5 Percutaneous Cardiac Support System (Abiomed, Inc., Danvers, MA) is a ventricular assist device (VAD) that may be used to provide short-term (up to 6 hours) circulatory support to high-risk patients during percutaneous coronary intervention (PCI) procedures. This device will add an additional 2.5 liters/minute of blood pumped to the body from the left ventricle.

Results of published studies provide preliminary evidence that the Impella® Recover® LP 2.5 may be an effective and safe method of providing cardiac support during high-risk PCU procedures. However, all of these studies (N=5) for this indication were small (N< 30) and uncontrolled. At this time, reliable evidence evaluating the safety and efficacy of the Impella® Recover® LP 2.5 Percutaneous Cardiac Support System is lacking.

Clinical trials are underway to evaluate this device. The largest of these studies is a randomized controlled trial (Protect II) that plans to enroll 654 patients and is designed to compare the Impella® Recover® LP 2.5 Percutaneous Cardiac Support System to the intra-aortic balloon pump (IABP) in the support of high-risk patients undergoing PCI.

Definitions

Percutaneous coronary intervention -- The placement of an angioplasty guide wire, balloon, or other device into a coronary artery for the purpose of coronary revascularization.

Ventricular Assist Device -- a mechanical device that helps the heart pump blood through the body.

Policy

FCHP considers any use of the Impella® Recover® LP 2.5 Percutaneous Cardiac Support System (Abiomed, Inc., Danvers, MA) experimental/investigational. FCHP does not provide coverage for experimental/investigational services.

Note: FCHP covers patient care services related to qualified clinical trials for commercial plan members. Clinical trials related to the use of the Impella® Recover® LP 2.5 Percutaneous Cardiac Support System are not qualified clinical trials, thus patient care services related to these trials are not covered services.



Coding

There is no specific code for the insertion or removal of the Impella® Recover® LP 2.5 Percutaneous Cardiac Support System.

Codes	Number	Description
CPT	33999	Unlisted procedure, cardiac surgery

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

References

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Committee review dates:

Technology Assessment Subcommittee: 10/27/09

Technology Assessment Committee: 12/16/09

IMPORTANT NOTE:

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.