



Impella[®] Heart Pump

CODING & BILLING GUIDE

January 2022



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Reimbursement Assistance:

Contact an Abiomed Field Reimbursement Specialist:

reimbursement@abiomed.com

OR

Impella Reimbursement Hotline:

1 (877) 256-0861



SCAN THE QR CODE TO
LEARN MORE, OR VISIT
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Impella 2.5° **Impella CP°**
with SmartAssist°

**Impella 5.0° &
Impella LD°**

**Impella RP° &
Impella RP°**
with SmartAssist°

Impella 5.5°
with SmartAssist°

I. INTRODUCTION

The purpose of this Coding and Billing Guide is to provide coding and billing personnel with information to assist in appropriate coding and billing of Impella procedures. The contents of the Impella Coding and Billing Guide do not replace the policies and procedures of the hospital or physician practice. In the Impella Coding and Billing Guide, readers will find the following information related to hospital and physician reimbursement and coding:

- Hospital ICD-10 PCS Codes
- MS-DRG Mapping
- Documentation Needed for Appropriate Coding
- Physician CPT Codes
- Frequently Asked Questions
- Information Concerning the Appeal Letters and Process

II. WHAT IS AN IMPELLA® HEART PUMP?

Impella 2.5® and Impella CP® with SmartAssist® are minimally invasive, percutaneous catheter-based hemodynamic support devices, designed to provide partial circulatory support and reduce the workload of the heart.

The Impella pump pulls blood from the left ventricle through an inlet area near the tip and expels blood from the catheter into the ascending aorta. The pump can be inserted via a standard catheterization procedure through the femoral artery, into the ascending aorta, across the valve, and into the left ventricle. Angiographic guidance is used to assist with insertion and placement.

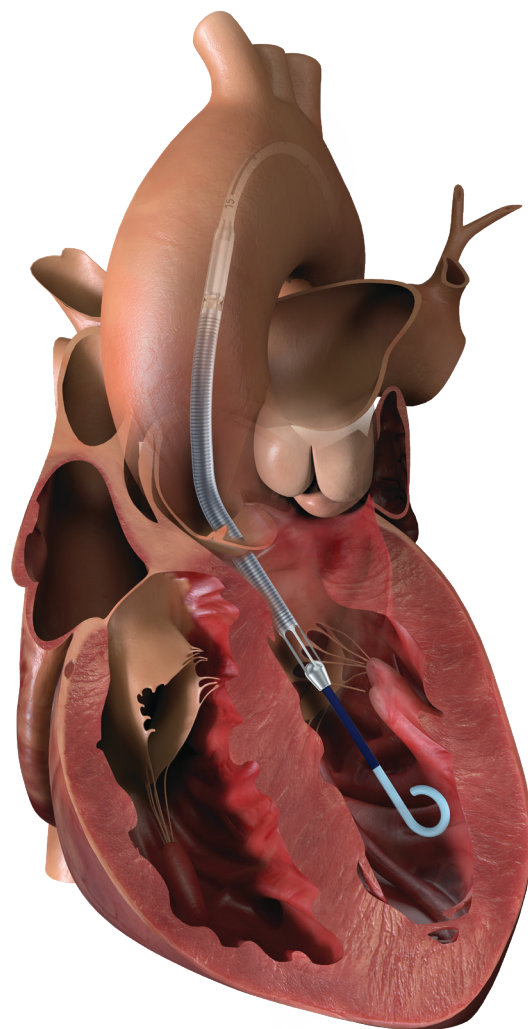
The **Impella 5.0®** heart pump pulls blood from the left ventricle through an inlet near the tip and expels blood from the catheter into the ascending aorta. The pump can be inserted via a femoral artery cutdown, or surgically via axillary approach; the pump is advanced and positioned across the aortic valve into the left ventricle.

The **Impella LD®** heart pump pulls blood from the left ventricle through an inlet area near the tip and expels blood from the catheter into the ascending aorta. The pump is implanted using an open chest procedure. Implanted via a single insertion site in the ascending aorta, the pump is advanced and positioned across the aortic valve into the left ventricle.

The **Impella RP®** heart pump delivers blood from the inlet area, which sits in the inferior vena cava, through the cannula to the outlet opening near the tip of the catheter in the pulmonary artery. The pump can be inserted through a standard catheterization procedure via the femoral vein, into the right atrium, across the tricuspid and pulmonic valves, and into the pulmonary artery.

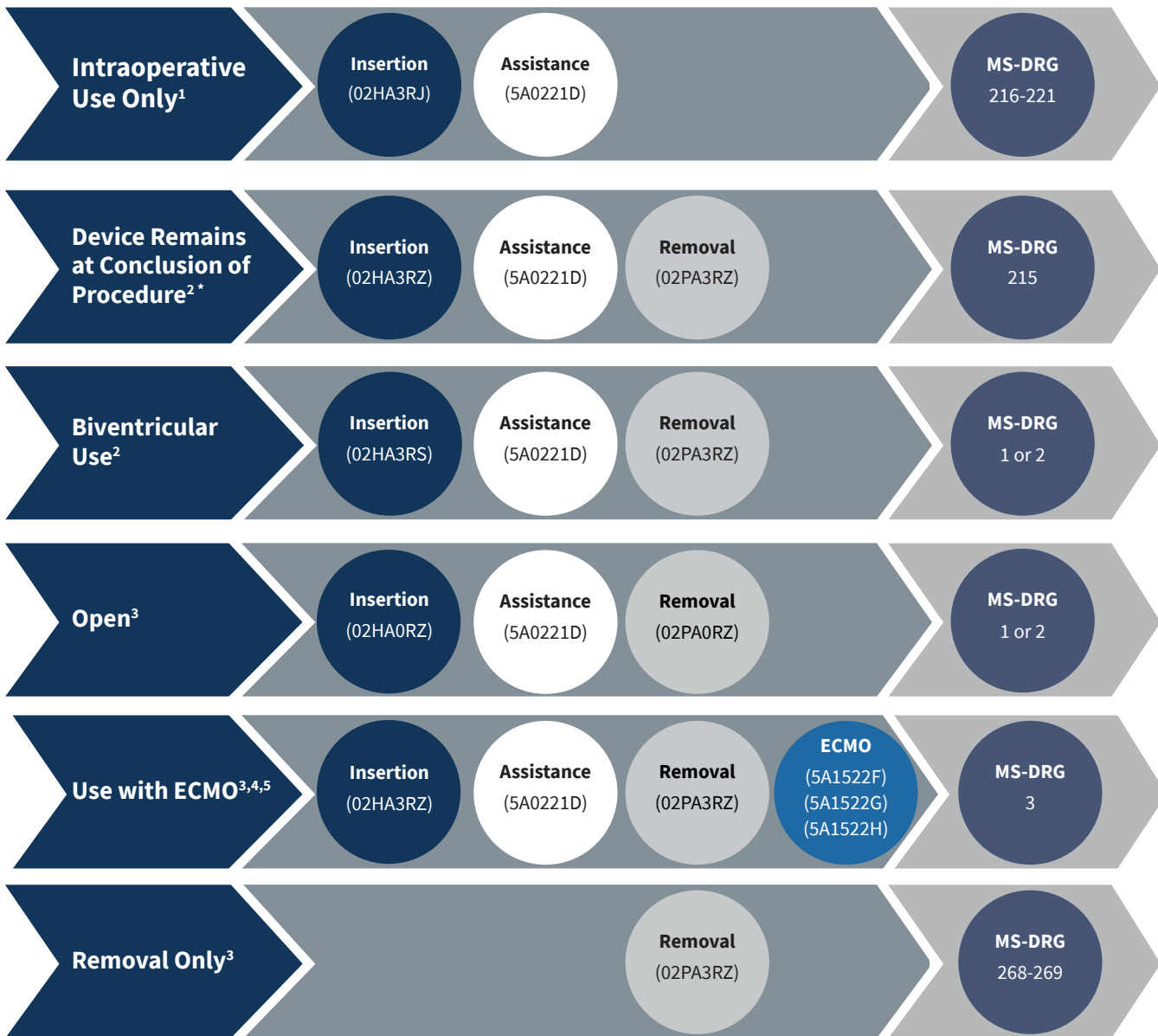
The **Impella 5.5® with SmartAssist®** heart pump pulls blood from the left ventricle through an inlet near the tip and expels blood from the catheter into the ascending aorta. The pump is inserted via axillary approach or open chest procedure via a single insertion site in the ascending aorta. It is positioned across the aortic valve into the left ventricle. Hemodynamic sensor technology allows for repositioning in the ICU without the need for imaging*.

**For ventricularized pumps*



III. HOSPITAL ICD-10 PCS PROCEDURE CODING

January 2022



According to ICD-10 PCS Official Guideline B6.1a, a device is coded only if a device remains after the procedure is completed. If no device remains, the device value No Device is coded. In limited root operations, the classification provides the qualifier values Temporary and Intraoperative, for specific procedures involving clinically significant devices, where the purpose of the device is to be utilized for a brief duration during the procedure or current inpatient stay.

The ICD-10 PCS device removal code may be used when the hospital that receives the patient only monitors care and removes the Impella device prior to patient discharge. If escalation of care therapy occurs, use the appropriate ICD-10 PCS code that corresponds to the therapy or services that are provided.

* For repositioning, report 02WAXRZ (The repositioning of the Impella device is consistent with the root operation “Revision,” which includes correcting the displaced device. AHA Coding Clinic, Volume 5, Number 1, First Quarter 2018)

1. AHA Coding Clinic, Volume 4, Number 4, Fourth Quarter 2017
2. AHA Coding Clinic, Volume 4, Number 1, First Quarter 2017
3. AHA Coding Clinic, Volume 3, Number 4, Fourth Quarter 2016
4. ICD-10 MS-DRG Definitions Manual Files v39 (Updated September 2021)
5. FY 2022 IPPS/LTCH PPS final rule CMS -1735-F

IV. DOCUMENTATION

An accurate description of the patient's condition should always be included to clearly document the Major Complication or Comorbid Conditions (MCCs) and Complication or Comorbid Conditions (CCs) that are present. Common MCCs and CCs associated with the use of hemodynamic support are provided in **Appendix B on page 17**.

Physician procedure note:

- Indicate the medical necessity of the Impella device
- Establish the risk profile of the patient
- Provide pertinent case history and condition prior to the procedure
- Describe the hemodynamic status of the patient
- Document **diagnostic catheterization and MCCs and CCs** present
- Document insertion and removal of the Impella device

Charge capture:








- Charge for Impella device separate from procedure
- Removal code when performed during separate session than the insertion
- Reposition code when performed under radiographic guidance and during separate session than insertion
- Critical care services when time is documented at the bed side

V. HOSPITAL INPATIENT STATUS

Impella procedures are listed on the Medicare "Inpatient Only List," and are therefore, excluded from the Two-Midnight Inpatient Stay Rule.

The Impella devices do not have a separate HCPCS (C-Code) because it is only used in the inpatient setting.

VI. CLINICAL DOCUMENTATION GUIDE

	<p>CLINICAL INDICATIONS Severe Coronary Artery Disease with Depressed Left Ventricular Ejection Fraction, Cardiogenic Shock Following Acute Myocardial Infarction</p>
	<p>CLINICAL PROFILE NYHA Class I-IV, CCS Class, Ejection Fraction, Past Medical History and Physical Exam</p>
	<p>OTHER COMORBIDITIES Cardiac Disease, Diabetes, Renal Dysfunction, Pulmonary Disease, Immunosuppression, Arrhythmia, MCC/CC</p>
	<p>CORONARY ANATOMY Unprotected Left Main Disease, Triple-Vessel Coronary Artery Disease, Severe Calcification, Documentation of Catheterization</p>
	<p>USE OF ADJUNCTIVE DEVICES Orbital/Rotational Atherectomy, Stenting and Angioplasty, IVUS</p>
	<p>HEMODYNAMIC PROFILE Shock Hypotension, Severely Elevated EDP, Severely Elevated PCWP, RA/RV/PCWP (Right Heart Catheterization Measurements), PA Catheter</p>
	<p>SURGICAL CANDIDACY e.g. Prohibitive Risk for Surgical Revascularization Following Evaluation by Heart Team</p>

VII. PHYSICIAN CPT CODING

The CPT Codes listed in the following table should be used to report the insertion, removal, repositioning and critical care time for the Impella device.

CPT	Description	Total RVUs ¹	Work RVUs ¹	Medicare National Avg. ²
Insertion				
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart , arterial access only	10.60	6.75	\$367
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart , venous access only	10.59	6.75	\$366
Removal				
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion	5.54	3.55	\$192
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion	4.71	3.00	\$163
Repositioning				
33993*	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion	4.87	3.10	\$169
Critical Care Monitoring				
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes	6.33	4.50	\$219
+99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes	3.18	2.25	\$110
Surgical Insertion				
33975	Insertion of ventricular assist device; extracorporeal, single ventricle	38.11	25.00	\$1,319
Surgical Removal				
33977	Removal of ventricular assist device; extracorporeal, single ventricle	32.79	20.86	\$1,135
Axillary Cutdown				
+34715**	Open axillary/subclavian artery exposure for delivery of endovascular prosthesis, by infraclavicular or supraclavicular incision, unilateral	8.76	6.00	\$303
+34716**	Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral	10.86	7.19	\$376
Femoral Cutdown				
+34812**	Open femoral artery exposure for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral	6.03	4.13	\$209
+34714**	Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral	7.88	5.25	\$273

CPT	Description	Total RVUs ¹	Work RVUs ¹	Medicare National Avg. ²
Angioplasty				
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	15.53	9.85	\$537
+92921	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch; each additional branch of a major coronary artery	0.00	0.00	\$0
Atherectomy				
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	18.51	11.74	\$641
+92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery	0.00	0.00	\$0
Stenting				
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	17.28	10.96	\$598
+92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery	0.00	0.00	\$0
Atherectomy, Stenting & Angioplasty				
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	19.38	12.29	\$671
+92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery	0.00	0.00	\$0

CPT	Description	Total RVUs ¹	Work RVUs ¹	Medicare National Avg. ²
Diagnostic Catheterization				
93460-26	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	10.95	7.10	\$379
IVUS				
92978-26	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel	2.77	1.80	\$96
+92979-26	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel	2.21	1.40	\$76
Miscellaneous				
93750	Interrogation of ventricular assist device (VAD), in person, review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	1.17	0.75	\$40

Multiple Procedure Payment Reduction (MPPR) on the Professional Component may apply.

+ CPT® code designated by the +symbol is listed in addition to the primary code to provide additional information about the procedure.

RVU, Relative Value Units. RVUs are measures of the physician's work, time and intensity of the procedure and are used to calculate payments for physicians

1. CMS 2022 Physician Fee Schedule, released December 2021
2. 2022 payment calculated using 2021 conversion factor of \$34.61

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Questions? email: reimbursement@abiomed.com

VIII. ADDITIONAL PHYSICIAN CODING GUIDANCE

Guidance
Removal and Repositioning
CPT code 33992 (removal) and CPT code 33993 (repositioning) may be billed and paid for in addition to CPT code 33990 (insertion) if performed during a separate session. Medicare's definition of a separate session is that the services be performed during a different patient encounter. Payers may require the use of a modifier to report multiple procedures by the same physician on the same day.
Radiology and Imaging
CPT Codes 33990 and 33993 include radiology or imaging guidance in their description. This indicates to some payers that the imaging and radiology procedures are included in the primary procedure and are not eligible for separate payment.
Other Procedural Activities
When using an unlisted procedure code, it is important to submit a copy of the procedure to explain the services performed. It is strongly recommended that the freeform field of the claim form (Field 19, "Reserved For Local Use,") be used to document a crosswalk to another procedure believed to be fairly equivalent. You should also indicate in Field 19 an expected payment amount for the payer's reference. It is important to check with each payer regarding their specific coding policy, if covered, obtain instruction as to how to report the service (i.e., code 33999 or another CPT code).
*When repositioning the Impella CP with SmartAssist without using imaging guidance, it is recommended that unlisted, cardiac surgery procedure code 33999 is used.
**When insertion and cutdown performed by different physicians, it is recommended to report 33799 with a crosswalk to the appropriate CPT code – 34714, 34715, 34716, 34812

Multiple Procedure Payment Reduction (MPPR) on the Professional Component may apply

Relative Value Units (RVUs), are measures of the physician's work, time and intensity of the procedure and are used to calculate payments for physicians

1. CPT® 2022 Codebook Professional Edition
2. CMS 2022 Physician Fee Schedule, released December 2021
2022 payment calculated using 2021 conversion factor of \$34.61

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IX. REIMBURSEMENT RESOURCES

1. Third-Party Customer Reimbursement Hotline

- Resource for Impella coding, coverage and payment questions
- Copies of Impella Coding and Billing Guide
- Toll Free Number: 1-877-256-0861
- Available: Monday - Friday
8:00 AM–5:00 PM Central Time
- Third-Party Reimbursement Resource
- Staffed: Certified hospital and physician coders
- 24-hour turnaround time for inquiries during business hours

2. ABIOMED Reimbursement Email

- Resource for contacting ABIOMED reimbursement staff
- Email Address: reimbursement@abiomed.com
- Staffed: Regular business hours

3. Reimbursement Materials

- Coding and Billing Guide for all Impella devices
- Impella 5.5 with SmartAssist Coding Guide
- Physician Pocket Coding Guide
- ICD-10 PCS Coding Guide

4. Webinar Wednesday

- Register Here
<https://events.heartrecovery.com/>

X. FREQUENTLY ASKED QUESTIONS (FAQ)

1. Which Revenue Code should the Impella device be mapped to in the Charge Master?

Answer: Revenue Code 278 (Medical/Surgical Supplies and Devices; Other Implants) best describes the Impella device.

2. Is there a separate HCPCS or C-Code for the Impella device?

Answer: No. Use of an Impella heart pump is an inpatient only procedure and reporting of a HCPCS code for billing purposes is not required as it is with many outpatient procedures or devices.

3. When should the Inpatient order be written for the patient receiving a procedure using an Impella heart pump?

Answer: Follow your facility's internal policy regarding appropriateness of writing the Inpatient Order. As with any other order, it should be written at the time that the procedure is indicated along with appropriate medical documentation. The inpatient order must be updated prior to the patient being discharged from the hospital. Use of Impella devices is excluded from the Medicare Two-Midnight Stay Rule.

4. Our hospital has had a denial for the care of a patient receiving an Impella heart pump. How can we find out why there was a denial and what we can do to appeal it?

Answer: Denials are not common. In the appendix of the Impella Coding and Billing Guide, a sample appeal letter has been attached to assist you. Please contact a Field Reimbursement Manager at reimbursement@abiomed.com for further assistance.

5. What constitutes a cardiac catheterization?

Answer: Cardiac catheterization includes invasive recording of intracardiac and intravascular pressures, tracing, blood sampling, and cardiac output. If these tests are performed for diagnostic purposes or further evaluation, they may be coded and reported, since they are not inherent to the procedure.

APPENDIX SECTION

A-E

APPENDIX: A**Cardiac Cath Lab ICD-10 PROCEDURE CODES**

✓	ICD-10 PCS Code	Description	✓	ICD-10 PCS Code	Description
	4A023N6	Measurement of Cardiac Sampling and Pressure, Right Heart, Percutaneous Approach		B2020ZZ	Plain Radiography of Single Coronary Artery Bypass Graft using High Osmolar Contrast
	4A023N7	Measurement of Cardiac Sampling and Pressure, Left Heart, Percutaneous Approach		B2021ZZ	Plain Radiography of Single Coronary Artery Bypass Graft using Low Osmolar Contrast
	4A023N8	Measurement of Cardiac Sampling and Pressure, Bilateral, Percutaneous Approach		B202YZZ	Plain Radiography of Single Coronary Artery Bypass Graft using Other Contrast
	4A023FZ	Measurement of Cardiac Rhythm, Percutaneous Approach		B2030ZZ	Plain Radiography of Multiple Coronary Artery Bypass Graft using High Osmolar Contrast
	4A020N6	Measurement of Cardiac Sampling and Pressure, Right Heart, Open Approach		B2031ZZ	Plain Radiography of Multiple Coronary Artery Bypass Grafts using Low Osmolar Contrast
	4A020N7	Measurement of Cardiac Sampling and Pressure, Left Heart, Open Approach		B203YZZ	Plain Radiography of Multiple Coronary Artery Bypass Grafts using Other Contrast
	4A020N8	Measurement of Cardiac Sampling and Pressure, Bilateral, Open Approach		B2040ZZ	Plain Radiography of Right Heart using High Osmolar Contrast
	4A027FZ	Measurement of Cardiac Rhythm, Via Natural or Artificial Opening		B2041ZZ	Plain Radiography of Right Heart using Low Osmolar Contrast
	4A027N6	Measurement of Cardiac Sampling and Pressure, Right Heart, Via Natural or Artificial Opening		B204YZZ	Plain Radiography of Right Heart using Other Contrast
	4A027N7	Measurement of Cardiac Sampling and Pressure, Left Heart, Via Natural or Artificial Opening		B2050ZZ	Plain Radiography of Left Heart using High Osmolar Contrast
	4A027N8	Measurement of Cardiac Sampling and Pressure, Bilateral, Via Natural or Artificial Opening		B2051ZZ	Plain Radiography of Left Heart using Low Osmolar Contrast
	4A028FZ	Measurement of Cardiac Rhythm, Via Natural or Artificial Opening Endoscopic		B205YZZ	Plain Radiography of Left Heart using Other Contrast
	4A028N6	Measurement of Cardiac Sampling and Pressure, Right Heart, Via Natural or Artificial Opening Endoscopic		B2060ZZ	Plain Radiography of Right and Left Heart using High Osmolar Contrast
	4A028N7	Measurement of Cardiac Sampling and Pressure, Left Heart, Via Natural or Artificial Opening Endoscopic		B2061ZZ	Plain Radiography of Right and Left Heart using Low Osmolar Contrast
	4A028N8	Measurement of Cardiac Sampling and Pressure, Bilateral, Via Natural or Artificial Opening Endoscopic		B206YZZ	Plain Radiography of Right and Left Heart using Other Contrast
	B2000ZZ	Plain Radiography of Single Coronary Artery using High Osmolar Contrast		B2070ZZ	Plain Radiography of Right Internal Mammary Bypass Graft using High Osmolar Contrast
	B2001ZZ	Plain Radiography of Single Coronary Artery using Low Osmolar Contrast		B2071ZZ	Plain Radiography of Right Internal Mammary Bypass Graft using Other Contrast
	B200YZZ	Plain Radiography of Single Coronary Artery using Other Contrast		B2080ZZ	Plain Radiography of Left Internal Mammary Bypass Graft using High Osmolar Contrast
	B2010ZZ	Plain Radiography of Multiple Coronary Arteries using High Osmolar Contrast		B2081ZZ	Plain Radiography of Left Internal Mammary Bypass Graft using Low Osmolar Contrast
	B2011ZZ	Plain Radiography of Multiple Coronary Arteries using Low Osmolar Contrast		B208YZZ	Plain Radiography of Left Internal Mammary Bypass Graft using Other Contrast
	B201YZZ	Plain Radiography of Multiple Coronary Arteries using Other Contrast		B20F0ZZ	Plain Radiography of Other Bypass Graft using High Osmolar Contrast

Cardiac Cath Lab ICD-10 PROCEDURE CODES

(Check all procedures performed)

✓	ICD-10 PCS Code	Description	✓	ICD-10 PCS Code	Description
	B20F1ZZ	Plain Radiography of Other Bypass Graft using Low Osmolar Contrast		B214YZZ	Fluoroscopy of Right Heart using Other Contrast
	B20FYZZ	Plain Radiography of Other Bypass Graft using Other Contrast		B2150ZZ	Fluoroscopy of Left Heart using High Osmolar Contrast
	B2100ZZ	Fluoroscopy of Single Coronary Artery using High Osmolar Contrast		B2151ZZ	Fluoroscopy of Left Heart using Low Osmolar Contrast
	B2101ZZ	Fluoroscopy of Single Coronary Artery using Low Osmolar Contrast		B215YZZ	Fluoroscopy of Left Heart using Other Contrast
	B210YZZ	Fluoroscopy of Single Coronary Artery using Other Contrast		B2160ZZ	Fluoroscopy of Right and Left Heart using High Osmolar Contrast
	B2110ZZ	Fluoroscopy of Multiple Coronary Arteries using High Osmolar Contrast		B2161ZZ	Fluoroscopy of Right and Left Heart using Low Osmolar Contrast
	B2111ZZ	Fluoroscopy of Multiple Coronary Arteries using Low Osmolar Contrast		B216YZZ	Fluoroscopy of Right and Left Heart using Other Contrast
	B211YZZ	Fluoroscopy of Multiple Coronary Arteries using Other Contrast		B2170ZZ	Fluoroscopy of Right Internal Mammary Bypass Graft using High Osmolar Contrast
	B2120ZZ	Fluoroscopy of Single Coronary Artery Bypass Graft using High Osmolar Contrast		B2171ZZ	Fluoroscopy of Right Internal Mammary Bypass Graft using Low Osmolar Contrast
	B2121ZZ	Fluoroscopy of Single Coronary Artery Bypass Graft using Low Osmolar Contrast		B217YZZ	Fluoroscopy of Right Internal Mammary Bypass Graft using Other Contrast
	B212YZZ	Fluoroscopy of Single Coronary Artery Bypass Graft using Other Contrast		B2180ZZ	Fluoroscopy of Left Internal Mammary Bypass Graft using High Osmolar Contrast
	B2130ZZ	Fluoroscopy of Multiple Coronary Artery Bypass Grafts using High Osmolar Contrast		B2181ZZ	Fluoroscopy of Left Internal Mammary Bypass Graft using Low Osmolar Contrast
	B2131ZZ	Fluoroscopy of Multiple Coronary Artery Bypass Grafts using Low Osmolar Contrast		B218YZZ	Fluoroscopy of Left Internal Mammary Bypass Graft using Other Contrast
	B213YZZ	Fluoroscopy of Multiple Coronary Artery Bypass Grafts using Other Contrast		B21F0ZZ	Fluoroscopy of Other Bypass Graft using High Osmolar Contrast
	B2140ZZ	Fluoroscopy of Right Heart using High Osmolar Contrast		B21F1ZZ	Fluoroscopy of Other Bypass Graft using Low Osmolar Contrast
	B2141ZZ	Fluoroscopy of Right Heart using Low Osmolar Contrast		B21FYZZ	Fluoroscopy of Other Bypass Graft using Other Contrast

The accurate documentation of procedures performed is essential to appropriate DRG coding and reimbursement. The purpose of this sample ICD-10 PCS Catheterization Codes sheet is to assist the user in the identification of catheterization procedures that were performed. The use of this tool does not guarantee payment or DRG assignment nor should it replace the coding policies and procedures of the hospital. Accurate coding of all procedures and patient treatment is ultimately the responsibility of the treating facility.

Impella® Heart Pump Sample MCC Sheet

DIAGNOSIS CODES COMMON WITH IMPELLA PROCEDURES

MCC	ICD-10 CM Code	Description	MCC	ICD-10 CM Code	Description
MCC	I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall	MCC	I40.9	Acute myocarditis, unspecified
MCC	I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery	MCC	I41	Myocarditis in diseases classified elsewhere
MCC	I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall	MCC	I46.2	Cardiac arrest due to underlying cardiac condition
MCC	I21.29	ST elevation (STEMI) myocardial infarction involving other sites	MCC	I46.8	Cardiac arrest due to other underlying condition
MCC	I21.3	ST elevation (STEMI) myocardial infarction of unspecified site	MCC	I46.9	Cardiac arrest, cause unspecified
MCC	I21.4	Non-ST elevation (NSTEMI) myocardial infarction	MCC	I49.01	Ventricular fibrillation
MCC	I21.9	Acute myocardial infarction, unspecified	MCC	I49.02	Ventricular flutter
MCC	I21.A1	Myocardial infarction type 2	MCC	I50.21	Acute systolic (congestive) heart failure
MCC	I21.A9	Other Myocardial infarction type	MCC	I50.23	Acute on chronic systolic (congestive) heart failure
MCC	I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall	MCC	I50.31	Acute diastolic (congestive) heart failure
MCC	I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction	MCC	I50.33	Acute on chronic diastolic (congestive) heart failure
MCC	I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites	MCC	I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
MCC	I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site	MCC	I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
MCC	I25.42	Coronary artery dissection	MCC	I51.1	Rupture of chordae tendineae, not elsewhere classified
MCC	I26.09	Other pulmonary embolism with acute cor pulmonale	MCC	I51.2	Rupture of papillary muscle, not elsewhere classified
MCC	I26.90	Septic pulmonary embolism without acute cor pulmonale	MCC	I71.00	Dissection of unspecified site of aorta
MCC	I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale	MCC	O90.3	Peripartum cardiomyopathy
MCC	I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale	MCC	R57.0	Cardiogenic shock
MCC	I26.99	Other pulmonary embolism without acute cor pulmonale	MCC	R57.1	Hypovolemic shock
MCC	I33.0	Acute and subacute infective endocarditis	MCC	R57.8	Other shock
MCC	I40.0	Infective myocarditis	MCC	R65.21	Severe sepsis with septic shock
MCC	I40.1	Isolated myocarditis	MCC	T81.11XA	Postprocedural cardiogenic shock, initial encounter
MCC	I40.8	Other acute myocarditis	MCC	T81.19XA	Other postprocedural shock, initial encounter

Impella® Heart Pump Sample CC Sheet

DIAGNOSIS CODES COMMON WITH IMPELLA PROCEDURES

CC	ICD-10 CM Code	Description
CC	A36.81	Diphtheritic cardiomyopathy
CC	A38.1	Scarlet fever with myocarditis
CC	B26.82	Mumps myocarditis
CC	B33.22	Viral myocarditis
CC	I01.2	Acute rheumatic myocarditis
CC	I09.0	Rheumatic myocarditis
CC	I09.81	Rheumatic heart failure
CC	I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
CC	I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
CC	I20.0	Unstable angina
CC	I20.1	Angina pectoris with documented spasm
CC	I24.0	Acute coronary thrombosis not resulting in myocardial infarction
CC	I24.1	Dressler's Syndrome
CC	I24.8	Other forms of acute ischemic heart disease
CC	I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
CC	I25.3	Aneurysm of heart
CC	I42.0	Dilated cardiomyopathy
CC	I42.1	Obstructive hypertrophic cardiomyopathy
CC	I42.2	Other hypertrophic cardiomyopathy
CC	I42.3	Endomyocardial (eosinophilic) disease
CC	I42.4	Endocardial fibroelastosis
CC	I42.5	Other restrictive cardiomyopathy
CC	I42.6	Alcoholic cardiomyopathy

CC	ICD-10 CM Code	Description
CC	I42.7	Cardiomyopathy due to drug and external agent
CC	I42.8	Other cardiomyopathies
CC	I42.9	Cardiomyopathy, unspecified
CC	I43	Cardiomyopathy in diseases classified elsewhere
CC	I44.2	Atrioventricular block, complete
CC	I50.1	Left ventricular failure
CC	I50.20	Unspecified systolic (congestive) heart failure
CC	I50.22	Chronic systolic (congestive) heart failure
CC	I50.30	Unspecified diastolic (congestive) heart failure
CC	I50.32	Chronic diastolic (congestive) heart failure
CC	I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
CC	I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
CC	I97.130	Postprocedural heart failure following cardiac surgery
CC	I97.131	Postprocedural heart failure following other surgery
CC	R57.9	Shock, unspecified
CC	T81.10XA	Postprocedural shock unspecified, initial encounter

The accurate documentation of MCC/CCs is required to document the patient condition. All patients should have MCC/CCs documented in the medical record. The purpose of this sample MCC/CC documentation sheet is to assist the user in the identification of common secondary MCCs and CCs that are often present during a procedure where an Impella device is used under the practice of medicine.

The use of this tool does not guarantee payment or DRG assignment nor should it replace the coding policies and procedures of the hospital. Accurate coding of all procedures and patient treatment is ultimately the responsibility of the treating facility.

APPENDIX: C

PCS Code Descriptors

PCS Code ¹	Description
Insertion Codes	
02HA3RZ	Insertion of Short-term External Heart Assist System into Heart, Percutaneous Approach
02HA0RJ	Insertion of Short-term External Heart Assist System into Heart, Intraoperative, Open Approach
02HA3RJ	Insertion of Short-term External Heart Assist System into Heart, Intraoperative, Percutaneous Approach
02HA0RZ	Insertion of Short-term External Heart Assist System into Heart, Open Approach
02HA0RS	Insertion of Biventricular Short-term External Heart Assist System into Heart, Open Approach
02HA3RS	Insertion of Biventricular Short-term External Heart Assist System into Heart, Percutaneous Approach
Assistance Codes	
5A0221D	Assistance with Cardiac Output using Impeller Pump, Continuous
Removal Codes	
02PA0RZ	Removal of Short-term External Heart Assist System from Heart, Open Approach
02PA0RS	Removal of Biventricular Short-term External Heart Assist System from Heart, Open Approach
02PA3RZ	Removal of Short-term External Heart Assist System from Heart, Percutaneous Approach
02PA3RS	Removal of Biventricular Short-term External Heart Assist System from Heart, Percutaneous Approach
Revision Codes	
02WAXRZ	Revision of Short-term External Heart Assist System in Heart, External Approach

1. ICD-10-CM/PCS-DRG v.39.0 Definitions Manual

APPENDIX: D

Payer Denials and Appeal Process

Payer denials for use of Impella heart pumps are not common. In the event that your hospital or physician received a denial for a claim regarding a patient treated with an Impella device, follow your organization's internal policy regarding appeals. You may also want to consider the following prior to requesting a review of the initial determination:

- If there has been a clerical error or if a procedure was miscoded, contact the payer review unit to find out how the procedure should be coded.
- If there is an issue regarding medical necessity substantiation, request a review of claims for payment. This will require that the provider substantiate the service based on the patient's clinical presentation, diagnosis, and standard of practice as it relates to the diagnosis. If the claim was denied due to the service not being covered, contact the payer's medical director to discuss the coverage issue.

Suggested Steps for Appeals Process:

- Obtain documentation in writing from the payer regarding
 - » Reimbursed rates
 - » Reason for non-coverage
 - » All reference materials used to support this decision
- The physician, facility and patient impacted by the decision should write a letter to the payer. If applicable, the patient should also write a letter to their Employee Benefits Manager to log a concern about the employer's health plan.
- The facility and physician should write for a formal Appeals Letter to the Payer's Medical Director. The following information should be enclosed with this correspondence:
 - » Technical work value of the physician
 - » Clinical benefits to patient
 - » Peer-reviewed clinical journal articles
 - » Comparative data and benefits of Impella to medical management or other procedure
 - » Evidence of coverage and payment during clinical trials
 - » List of other payers who are paying for the procedure/technology
 - » Letters of support from other providers, if applicable
- Overnight mail the letter to the Medical Director and follow-up with a call twenty-four hours after receipt.
- During your call, request a Peer-to-Peer meeting with the Medical Director to discuss your patient's specific case, as this step has been the most beneficial. The request for a Peer-to-Peer conversation should be your first step.

The Reimbursement Hotline at 1-877-256-0861 is available Monday-Friday, 8:00 am to 5:00 pm, CT to assist your organization. Additionally, you may email the Abiomed Reimbursement Field Team at reimbursement@abiomed.com for assistance.

APPENDIX: E

Appeal Letter

This document is not intended for promotional purposes and should be modified to accurately describe the patient's specific clinical situation.

[DATE]

[Payer Contact Name]

[Payer Contact Title]

[Payer Company Name]

[Payer Street Address]

[City, ST, Zip code]

Re: Request for Coverage Reconsideration of Denied Claim for **[INSERT URGENT OR ELECTIVE]** High-risk Percutaneous Coronary Intervention (PCI) or **[Cardiogenic Shock]** Patient At Time of Admission

AN APPEAL FOR MEDICALLY NECESSARY AND REASONABLE CARE

Patient Treated with Adjunctive Impella® Percutaneous VENTRICULAR ASSIST device (pVAD)

Patient name: [First and last name]

Patient date of birth: [XX/XX/XXXX]

SS # [XXX-XX-XXXX]

Insurance ID # [XXXXXXXXXXXXXXXXXX]

Group # [XXXXXXXXXX]

Date of Service: [XX/XX/XXXX]

CPT® Code (s):

ICD-10-CM Diagnosis Code (s):

I10-PCS Code (s):

Dear **[Payer contact name]**:

The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

DELETE/EDIT THIS SECTION FOR HIGH-RISK-PCI

On [LIST ADMISSION DATE and PATIENT'S FULL NAME], underwent an [INSERT URGENT OR ELECTIVE] [LIST PCI PROCEDURE (s)]. For select cardiac cases, I use percutaneous ventricular assist devices when there is or where there exists the potential for acute cardiac instability.

Because of [INSERT PATIENT'S FULL NAME] high cardiac risk, I inserted the FDA approved percutaneous cardiac assist device Impella® [INSERT 2.5, CP, 5.0, 5.5] to ensure continuous hemodynamic support, preserve myocardial perfusion, and to maintain end organ perfusion and prevent mortality during [INSERT PATIENT'S FULL NAME] [LIST TYPE OF PCI PROCEDURE (s)] procedure.

Despite early revascularization and IABP support, mortality rates remain high for patients such as [INSERT PATIENT'S FULL NAME]. Because pVADs provide critically needed circulatory support and can quickly restore hemodynamics, they stabilize these patients resulting in successful revascularization.

DELETE/EDIT THIS SECTION FOR CARDIOGENIC SHOCK:

On [LIST ADMISSION DATE and PATIENT'S FULL NAME], was admitted to our facility with cardiogenic shock and treated with the Impella heart pump.

I have learned that our claim has been denied for the Impella heart pump procedure for this plan member. Based on [INSERT PATIENT'S FULL NAME] clinical condition and a review of the supporting documentation, I am confident you will agree that Impella, which is explicitly indicated for this condition, was medically necessary, reasonable, and thus an appropriate treatment option to reduce the risk of mortality in [INSERT PATIENT'S FULL NAME] case.

The decision to deny payment for this patient's Impella procedure is inconsistent with current medical practice. Clinical guidelines from ACCF/AHA/SCAI in 2011¹ and ACCF/AHA in 2013² recommend the use of pVADs for both high-risk PCI and cardiogenic shock, in addition to the AHA/ACC in 2014³ and the 2015 Clinical Expert Consensus Statement on the use of pVADs from SCAI, ACC, HFSA and STS.⁴ In addition, the FDA indications for use includes both high risk PCI and cardiogenic shock.⁵ It is also important to note, other payers, including Aetna, Humana, HCSC, BCBS-Michigan, and Highmark follow these clinical guidelines and cover pVADs for the FDA indications. Furthermore, the American Hospital Association, in conjunction with CMS, has published coding guidelines for pVADs which included the expanded indications for use and the appropriate ICD-10-PCS codes for this procedure.

Please reconsider your denial of coverage in light of the patient's clinical need, as well as the evidence for this technology, including peer-reviewed publications and FDA approval. Not only do Impella's FDA indications for use include both high-risk PCI and cardiogenic shock, CMS and numerous other commercial health plans cover Impella for these FDA indications.

References:

1. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention Journal of the American College of Cardiology Vol. 58, No. 24, 2011
2. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction, Journal of the American College of Cardiology Volume 61, Issue 4, January 2013;
3. 2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes, Journal of the American College of Cardiology Volume 64, Issue 24, December 2014
4. https://www.sts.org/sites/default/files/documents/pdf/expertconsensus/Expert_Consensus_Statement_Percutaneous_MCS.pdf
5. Appendix A: FDA Indications for Use

To further substantiate my request, please note that Impella was medically necessary for this patient, and whose clinical profile I have outlined below:

EDIT THIS SECTION TO GUIDE CLINICAL RATIONALE

- Establish the risk profile of the patient - Detailed patient history with description of patient's status including diagnosis, complaints, physical examination results, e.g., if patient was a surgical turndown, Coronary anatomy risk (RCA, LAD, triple vessel disease, etc.). Any and all correlating diagnostic test results, other clinician's notes and level of impairment. Note if other hemodynamic support alternatives were used and if patient is refractory to these interventions. List all additional MCC's and CC's to support the need for hemodynamic support
- Describe functional impairments, and how the patient's condition has impacted his/her activities of daily life, e.g., XXX, XXX, XXX, etc.
- Severity of the signs and symptoms exhibited by the patient, e.g., XXX, XXX, XXX
- Previous treatments and interventions - noting procedures, medications, and/or therapies attempted; include outcome of each treatment to include trauma, e.g., XXX, XXX, XXX, etc.
- The medical necessity and rationale for Impella; clinical specifics substantiating why this procedure was an appropriate medical option at the time in the patient's care; note therapeutic goals and anticipated outcomes, and risk to patient if procedure were not performed.
- Severity of the signs and symptoms exhibited by the patient
- Medical predictability of something adverse happening to the patient should be documented]

As explained above, I believe that in this case the Impella device was medically necessary for your member and as such this service should be granted coverage and paid for by your organization accordingly.

Please let me know if I can provide any additional information, and thank you for your attention.

Sincerely,

[Physician's name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone number]

Enclosures (suggested): Appeal form (if provided by the plan)
Chart notes, tests results, fragility studies, etc.

APPEAL LETTER BIBLIOGRAPHY

1. O'Neill W.W., et al. The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the Upsella Registry *J of Interv Cardiol* 2014 Feb;27(1):1-11
2. Lemaire A., et al. The Impella Device for Acute Mechanical Circulatory Support in Patients in Cardiogenic Shock *Annals of Thoracic Surgery*; 2014 Jan; 97(1):133-138
3. Griffith B.P., et al. The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support *J Thorac Cardiovasc Surg* 2013 Feb;145(2):548-54
4. Seyfarth M., et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction *J Am Coll Cardiol* 2008 Nov 4;52(19):1584-8
5. Burkhoff, D., et al. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock *American Heart Journal* 2006 Sep;152(3):469e1-469e8
6. Thiele H., et al. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock *European Heart Journal* 2005 Feb 25;26(13):1276-1283.
7. Cheng R., et al. Complications of extracorporeal membrane oxygenation for treatment of cardiogenic shock and cardiac arrest: a meta-analysis of 1,866 adult patients *Ann Thorac Surg* 2014;97(2):610-616
8. O'Neill W.W., et al. A prospective randomized clinical trial of hemodynamic support with Impella 2.5 versus intraaortic balloon pump in patients undergoing high-risk percutaneous coronary intervention (The PROTECT II Study) *Circulation* 2012 Oct 2;126(14):1717-27
9. Dangas G., et al. Impact of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump on prognostically important clinical outcomes in patients undergoing high-risk percutaneous coronary intervention (From the PROTECT II Randomized Trial) *American Journal of Cardiology* 2014 Jan 15;113(2):222-228
10. Cohen, M., et al. Optimizing Rotational Atherectomy in High Risk Percutaneous Coronary Interventions. (Insights from the PROTECT II Study) *Catheterization and Cardiovascular Interventions* 2014 Jun 1;83(7):1057-64.
11. Stretch R., et al. National Trends in the Utilization of Short-Term Mechanical Circulatory Support. *J Am Coll Cardiol*. 2014;64(14): 1407-1415

High-Risk PCI

The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, “Impella® System Therapy”), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

EMERGENCY USE AUTHORIZATION

Impella Left Ventricular (LV) Support Systems (Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Important Risk Information for Impella devices

CONTRAINDICATIONS

The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm² or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

*** This condition is a contraindication for the cardiogenic shock indication only.**

POTENTIAL ADVERSE EVENTS

Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

Right-Side Support

PMA APPROVED INDICATION

The Impella RP® System and Impella RP with SmartAssist® are indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m², who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

EMERGENCY USE AUTHORIZATION

Only the Impella RP System is authorized to be used by healthcare providers (HCP) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m², for the treatment of acute right heart failure or decompensation caused by complications related to Coronavirus Disease 2019 (COVID-19), including pulmonary embolism (PE). The Impella RP has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Important Risk Information for Impella RP System and Impella RP with SmartAssist

CONTRAINDICATIONS

The Impella RP System and Impella RP with SmartAssist are contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP devices. Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve. Mural thrombus of the right atrium or vena cava. Anatomic conditions precluding insertion of the pump. Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

POTENTIAL ADVERSE EVENTS

The potential adverse effects (e.g., complications) associated with the use of the Impella RP System and Impella RP with SmartAssist: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.

Learn more visit: www.abiomed.com/important-safety-information

Reimbursement Hotline:

Monday-Friday, 8:00am - 5:00 pm CT

1-877-256-0861

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit:

www.abiomed.com/important-safety-information

Questions? email: reimbursement@abiomed.com



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