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The Impella CP with SmartAssist heart pump is designated as safe and effective by the FDA for use during high-risk PCI procedures and for patients in cardiogenic shock. It is a minimally invasive, temporary heart pump that uses real-time intelligence associated with improved survival and heart recovery. As with any medical treatment, individual results may vary. There are potential risks, these risks need to be discussed with your doctor and recovery takes time. The success of this procedure depends on many factors, including your physical condition and your bodys ability to tolerate the procedure. Use care in the selection of your doctors and hospital, based on their skill and experience. A guide for you, your family and caregivers to learn more about heart disease, heart failure and treatment options to discuss with your doctor. Download PDF Are you a health care professional? 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 Cardiac or Vascular injury (including ventricular perforation). In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. Visit www.abiomed.com/impella and to learn more. Share copy and redistribute the material in any medium or format for any purpose, even commercially. Adapt remix, transform, and build upon the material for any purpose, even commercially. The licensor cannot revoke these freedoms as long as you follow the license terms. Attribution You must give appropriate credit, provide a link to the license, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use. ShareAllike If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original. No additional restrictions You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits. You do not have to comply with the license for elements of the material in the public domain or where your use is permitted by an applicable exception or limitation. No warranties are given. The license may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material. The Impella heart pump is a small pump that a healthcare professional can insert without surgery. It can help maintain blood flow in people who have CAD, are recovering from cardiogenic shock, or are awaiting a heart transplant.Doctors call the Impella a percutaneous ventricular assist device. It keeps the heart working in two situations: during percutaneous coronary interventions (PCI) and following cardiogenic shock. Cardiogenic shock is a life threatening event when the heart cannot pump enough blood to the body.Impella is a brand name, and the manufacturer makes various heart pumps that help with different purposes.Read more to learn about what Impella heart pumps are, the risks and benefits, cost, and more.Share on PinterestJeff Gritchen/Digital First Media/Orange County Register via Getty ImagesThe Impella is a small ventricular assistance device. This means that it supports the functioning of the ventricles. These are the lower chambers of the heart that pump blood out of the heart and to the body. It can help with heart failure and other heart conditions.There are three key reasons why a person may need an Impella. They include: Heart failure: An enlarged and weak heart cannot effectively pump blood throughout the body, but the Impella can help improve blood flow. A doctor may recommend it to someone awaiting heart surgery or a heart transplant. Cardiogenic shock: A heart attack and some other emergencies can cause cardiogenic shock, which hinders the hearts ability to pump blood. The Impella pumps blood through the ventricles, allowing the left ventricle to rest and improving the chances of recovering from cardiogenic shock. PCI: PCI procedures involve surgeons placing stents or balloons to treat blocked arteries. They can save lives, but they can also pose risks for people with heart health issues. The Impella can help sustain blood flow through the organ during these procedures. Unlike some other heart pumps, the Impella does not require heart surgery for insertion. Instead, the doctor makes a small incision in the leg to access the femoral artery. They then thread the pump into the left ventricle via the femoral artery. The heart consists of four chambers.The top two chambers are the atria, which pump blood to the lower two chambers, called the ventricles. The ventricles then pump blood throughout the body. The Impella replaces the function of the left ventricle, pumping blood out of the heart and to the rest of the body. This serves several functions, including:allowing the left ventricle to rest and recover following cardiogenic shockensuring adequate blood flow when the heart is not working wellhelping protect the heart and the organs during certain medical procedures, especially PCIsAdditionally, the Impella sends information to an external console. It tells healthcare professionals about how well the heart is working and how much blood the Impella is pumping. It is important to note that the Impella is only suitable for use in hospital settings. This means that it is a short-term solution for most people, usually as they recover from a cardiovascular event or await a longer-term treatment, such as a heart transplant or open heart surgery. Impella heart pumps are expensive, but medical insurance often fully or partially covers this treatment.A 2019 study found that, after the introduction of Impella pumps, the cost of treating people with mechanical devices rose from \$47,000 to \$51,000 per person. The actual cost an individual pays depends on their insurance, the hospital they are at, and any other care they need. Some people may pay nothing or a small copay, while others may pay close to the full cost of the device. If a person is unsure about whether or not a medical device is eligible for coverage, they should contact their insurance provider.Generally, people who need an Impella have serious health complications such as heart failure. These complications can make inserting the device difficult and may also increase the dangers of infections and other side effects. Therefore, it is important to discuss the risks and benefits of the procedure with a doctor. Some potential risks include: bleeding that may become life threateningdamage to the blood vesselsdamage to the heart liver failurekidney failuredangerously low blood pressureinfection, including life threatening sepsisdeathheart attackdangerous heart arrhythmias, or an irregular heartbeatThe Impella is not the only heart pump available. There may be safer alternatives depending on a persons needs and medical condition, so it is important to ask a doctor for guidance about the best option. It is possible for a doctor to insert the Impella while a person is awake. This may be ideal for people who cannot safely go under anesthesia or those who prefer to be awake. If a person is awake during the procedure, a doctor will usually give them pain medication and drugs to help them feel groggy and relaxed. Some people can have general anesthesia, meaning they will be asleep and have no memory of the procedure. To insert the Impella, a doctor makes a small cut in the upper thigh, near the groin. They then thread the device up to the heart through a long thin catheter. Once the device is in the heart, a doctor removes the catheter. LVADs are devices that help the ventricles pump blood to the rest of the body. The Impella is a type of LVAD, but many other types of these devices are available. Some, such as the Impella, provide short-term support, while others offer longer-term aid. Some other LVADs include: HeartwareHeartmate 3Synchrony Total Artificial Heart Several observational studies suggest that the Impella may reduce the risk of death following cardiogenic shock, but randomized controlled trials have not proven this claim. Overall, a persons prognosis depends on the reason they need the Impella and other treatment options that become available. For example, someone who needs and eventually gets a heart transplant may have a better outcome than an individual who continues to wait for a transplant. When the Impella enables a person to wait longer for a necessary procedure, it can improve outcomes. However, there is no specific data showing the Impellas overall role in cardiovascular health or heart failure outcomes. People can ask a doctor about risks, benefits, and the outlook for their specific condition. The Impella can help the heart rest and maintain health as they await surgery or a heart transplant. For some people, it is a life changing or life-saving treatment. However, like any medical procedure, it poses some risks. It is important to speak with a doctor about the risks and benefits of the pump, treatment goals, alternative options, and the long-term prognosis. Heart DiseaseCardiovascular / Cardiology DANVERS, Mass.--(BUSINESS WIRE)--Nov. 14, 2019– To mark the five year anniversary of the study by Stretch, et al., on cost and outcomes trends for short-term mechanical circulatory support, Abiomed announces a comprehensive publication review of cost and comparative effectiveness of Impella in high-risk PCI and cardiogenic shock. The data, from a robust body of US and European evidence from 2004 - 2019, includes the PROTECT II FDA randomized controlled trial, data from the Centers for Medicare & Medicaid Services MedPAR database and more than 20 peer-reviewed clinical publications on cost-effectiveness. It demonstrates that Impella use in high-risk PCI (Protected PCI) and cardiogenic shock, when compared to intra-aortic balloon pump (IABP) or other therapies, is associated with improved patient outcomes and reduced costs. The review will be presented at upcoming meetings of interventional cardiologists and cardiac surgeons in Munich, Germany, and Phoenix, Arizona. This press release features multimedia. View the full release here: Multiple studies, including systematic reviews of multiple cost-effectiveness publications, demonstrate that Impella use is associated with a reduction in length of stay for patients, with a greater opportunity for benefit as the illness level increases. Key evidence of Impella's cost-effectiveness includes data on how: Impella reduces mortality and cost Impella reduces length of stay and readmissions Impella reduces long-term health care costs Impella Reduces Mortality and Cost Several studies show that the use of percutaneous ventricular assist devices (PVADs), including Impella, is particularly cost-effective in cases of cardiogenic shock: A study conducted by Yale University colleagues Stretch, et al., found that in cases of cardiogenic shock in coronary atherosclerosis and other heart disease, PVADs reduced costs by \$45,000 and \$54,000 per case, respectively, and reduced mortality by 58% (Stretch, et al., Journal of the American College of Cardiology, 2014) For patients in cardiogenic shock requiring emergent hemodynamic support, PVAD therapy (and Impella 2.5 in particular) resulted in better outcomes, shorter length of stay, lower costs and a survival benefit when compared with surgical hemodynamic support alternatives (Maini, et al., Journal of Catheterization and Cardiovascular Interventions, 2014) Research by Vetrovec, et al, found that use of PVADs, including Impella, is associated with reduced mortality rates, shorter length of stay and lower hospital costs compared to ECMO. Their data showed that PVAD use compared to ECMO resulted in total episode-of-care (EOC) savings of \$54,571 (Vetrovec, et al., Journal of Catheterization and Cardiovascular Interventions, 2019) Impella Reduces Length of Stay and Readmissions Several studies, including systematic reviews of multiple cost-effectiveness publications, demonstrate that Impella use is associated with a reduction in length of stay for patients, with a greater opportunity for benefit as the illness level increases1. According to peer-reviewed published data, Impella use is associated with: A 52% reduction in repeated admission for revascularization at 90 days, as demonstrated in an independent economic analysis of the PROTECT II Randomized Controlled Trial (Gregory, et al., American Health & Drug Benefits Journal, 2013) A reduction in hospital stays ranging from 2-12 days (Maini, et al., Expert Review of Pharmacoeconomics & Outcomes Research, 2014) Shorter ablation times and reduced hospital length of stay in patients with atrial fibrillation (Aryana, et al., Heart Rhythm Society, 2014) A reduction in acute kidney injury, with average cost savings of \$22,023 per case (Silver, et al., Journal of Hospital Medicine, 2016) These findings are consistent in the United States and Europe. A retrospective cost-effectiveness analysis based on the USPELLa and Europella databases concluded that Impella is a cost-effective intervention compared with IABP for high-risk PCI patients (Roos, et al., Journal of Medical Economics, 2013). As an example of Impellas cost-effectiveness, the United Kingdoms National Institute for Health Care and Excellence (NICE), one of the worlds most conservative regulatory bodies, confirmed the use of Impella in certain high-risk PCI patients. Sometimes trying to save costs by avoiding or delaying the use of innovative technologies sounds good, but you delay safe and effective therapy. Then the patients are sicker, and their outcomes are worse, which ends up being more costly for the patient and healthcare system. Using a better therapy up front can give you a better long-term outcome while reducing total costs, said George Vetrovec, MD, professor, emeritus, at Virginia Commonwealth University. Case Studies: Impella Reduces Long-term Health Care Costs Because Impella enables the heart to rest and recover - while helping to restore native heart function - it may prevent the need for an implantable left ventricular assist device (LVAD) or a heart transplant, leading to an estimated \$887,000 reduction in hospital charges over the period from 30 days pre-transplant to 180 days post-transplant discharge2. This makes native heart recovery one of the most cost-effective therapies in healthcare. The case of Adam Millar illustrates the real-world benefit of native heart recovery. In 2018, Millar was 18 years old when Nima Agihli, MD, an interventional cardiologist at St. Anthonys Central in Lakewood, Colorado, placed an Impella CP and Impella RP to recover Adams heart after he was diagnosed with atrial fibrillation and developed cardiogenic shock. At the time, Millar was a junior hockey player, and native heart recovery proved to be the best outcome for his health and future quality of life. Adams treatment was covered by United Healthcare. Before Impella recovered my heart, physicians considered me as a candidate for an implantable LVAD and a heart transplant. Both would have drastically decreased my quality of life, said Millar. If I received a heart transplant, I would have had a long recovery and taken auto-immune medication to avoid the rejection of the transplant for the rest of my life. Impella also enables high-risk PCI patients to improve their native heart function through Impella-supported Protected PCI. The story of Jim Hoag illustrates how Protected PCI with Impella and complete revascularization enable better outcomes and improved quality of life for patients. Jim, a 67-year-old grandfather, struggled with such extreme weakness and fatigue that he could barely walk from the parking lot to the athletic field to watch his grandsons play sports. He went to Spectrum Health in Grand Rapids, Michigan, where a diagnostic catheterization revealed severe blockages and poor heart function with an ejection fraction of 25%. Jim was referred to the advanced heart failure clinic where he was identified by the heart team as an appropriate candidate for Protected PCI. Drs. David Wohns and Kevin Wolschleger implanted the Impella 2.5 to support Jim's weak heart while they placed multiple stents. Jim was discharged home one day later, and within two months his heart function had returned to near normal with an ejection fraction of 55%. Jim's treatment was reimbursed by Medicare. Today, Jim feels better than he has in years, attended Abiomed's patient summit in Danvers, Massachusetts, this summer, and now climbs to the top of the stands to cheer on his grandchildren. Cost- Effectiveness Compared to Other Therapies Impellas cost-effectiveness when compared to other related treatments, including LVADs, is validated based on an incremental cost-effectiveness ratio -- or ICER. ICER is a standard economic metric that represents the additional cost of one unit of a healthcare outcome, such as a quality-adjusted life year, gained by a healthcare intervention or strategy when compared with the next best alternative or standard of care. Amounts less than \$100,000 are considered cost effective in the U.S., and less than \$50,000 in most other countries. Impellas ICER shows a reduction in costs of \$135,000 per year in an emergent population3. 1.Nalluri, et al, Expert Review of Medical Devices, 2017; Aryana, et al, Heart Rhythm Society, 2014; Krenn, et al, SCAI, 2014; Maini, et al, Journal of Catheterization and Cardiovascular Interventions, 2014; Maini, et al, Expert Review of Pharmacoeconomics & Outcomes Research, 2014; Wohns et al, International Society for Minimally Invasive Cardiothoracic Surgery, 2014; Gregory, et al, American Health & Drug Benefits Journal, 2013; Gregory, et al, Journal of Managed Care Medicine, 2013; O'Neill, et al, Journal of American College of Cardiology, USPELLa, 2013; Roos, et al, Journal of Medical Economics, 2013; Lamarque, et al, Journal of Thoracic and Cardiovascular Surgery, 2010 2.Millman 2017 US Organ and Tissue Transplant Cost Estimates and Discussion 3 Maini et al, Journal of Catheterization and Cardiovascular Interventions, 2014 ABOUT IMPELLA HEART PUMPS The Impella 2.5 and Impella CP devices are U.S. FDA PMA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI) such as stenting or balloon angioplasty, to re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella LD, and Impella 5.5 with Smart Assist are U.S. FDA approved heart pumps used to treat heart attack or cardiomyopathy patients in cardiogenic shock, and have the unique ability to enable native heart recovery, allowing patients to return home with their own heart. The Impella RP is U.S. FDA approved to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Impella is the most studied mechanical circulatory support device in the history of the FDA with real world clinical data on more than 100,000 patients and more than 550 peer-reviewed publications. In Europe, the Impella 2.5, Impella CP and Impella CP with SmartAssist are CE marked for treatment of high-risk PCI and AMI cardiogenic shock patients for up to 5 days. Impella 5.0 and Impella LD are CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 10 days. The Impella 5.5 with Smart Assist is CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 30 days. The Impella RP is CE marked to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, open-heart surgery, or refractory ventricular arrhythmia. To learn more about the Impella platform of heart pumps, visit www.abiomed.com/impella or call 1-800-451-1111. Impella is a registered trademark of Abiomed, Inc. and its subsidiaries. Impella, the Impella logo, and the Impella heart pump design are trademarks of Abiomed, Inc. in the United States and other countries. Impella is also a registered trademark of Abiomed, Inc. in the United Kingdom, Germany, France, Italy, Spain, and other countries. 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