Percutaneous Ventricular Assist Device

Policy Number: MMP240.16
Last Committee Approval Date: September 10, 2025
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➲ Instructions for Use

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Coverage Rationale

Overview

Percutaneous insertion of an endovascular cardiac assist device is reasonable and necessary under limited conditions.

CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for Percutaneous Ventricular Assist Device.

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist, and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Percutaneous Ventricular Assist Device.

For states/territories with no LCDs/LCAs, refer to the criteria below.

Until the literature clearly demonstrates the efficacy of the treatment approach, percutaneous insertion of an endovascular cardiac assist device is considered reasonable and necessary only in the following three life-threatening situations and only when external counterpulsation (intra-aortic balloon pump, IABP) is not expected to be sufficient:

- Cardiogenic shock; or
- Severe decompensated heart failure with threatening multi-organ failure; or
- Complications/disturbances of the circulatory system intra-operatively or postoperatively.

This service will only be considered reasonable and necessary when the FDA approval guidelines are adhered to strictly.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

Diagnosis Code	Description
I5A	Non-ischemic myocardial injury (non-traumatic)
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.84	End stage heart failure
I50.9	Heart failure, unspecified
I51.4	Myocarditis, unspecified
I51.9	Heart disease, unspecified
I97.0	Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.111	Postprocedural cardiac insufficiency following other surgery
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery
I97.710	Intraoperative cardiac arrest during cardiac surgery
I97.711	Intraoperative cardiac arrest during other surgery
I97.790	Other intraoperative cardiac functional disturbances during cardiac surgery
I97.791	Other intraoperative cardiac functional disturbances during other surgery
I97.88	Other intraoperative complications of the circulatory system, not elsewhere classified
I97.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified
R57.0	Cardiogenic shock

ICD Procedure Code	Description
5A0221D	Assistance with Cardiac Output using Impeller pump, Continuous

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Percutaneous Ventricular Assist Device				
N/A	N/A	A53986 Billing and Coding: Percutaneous Ventricular Assist Device	Part B MAC	Palmetto**
N/A	N/A	A53988 Billing and Coding: Percutaneous Ventricular Assist Device	Part A MAC	Palmetto**
N/A	N/A	A59657 Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices	Part A and B MAC	Noridian
		A59658 Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices		

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

Other(s)

CGS Medicare News and Publications: Coding for Impella® Heart Device, Dated July 18, 2014

Clinical Evidence

A Hayes assessment (2022) reported there was a low-quality body of evidence suggesting a potential benefit of the Impella percutaneous ventricular assist device (pVAD) for the reduction and/or prevention of major adverse effects in patients undergoing high-risk percutaneous coronary intervention (HRPCI). However, future well-designed comparative studies are needed to assess the benefits versus harms of Impella support during high-risk PCI, the duration of benefit, and the patient selection criteria. The 2025 update resulted in no change to the current Hayes rating.

Albulushi et al. (2024) conducted a systematic review to evaluate the comparative effectiveness and safety of temporary mechanical circulatory support (MCS) devices in patients with acute cardiogenic shock (CS), with a particular emphasis

on subgroup-specific analyses. Findings from the included studies were synthesized qualitatively. A meta-analysis was performed using a random-effects model when data were sufficient, comparing the effectiveness and safety of different MCS devices across subgroups. The review included 15 studies involving a total of 3,450 patients who received temporary mechanical circulatory support (MCS) for acute cardiogenic shock using veno-arterial extracorporeal membrane oxygenation (VA-ECMO), Impella device, or intra-aortic balloon pumps (IABP). Treatment with VA-ECMO, Impella, and IABP resulted in 30-day mortality reductions of 30% (p = 0.12), 22% (p = 0.15), and 13% (p = 0.18), respectively. VA-ECMO was associated with the highest complication rates, including bleeding (27%), major adverse events (30%), and thromboembolic events (11%). Impella showed lower rates in these categories – bleeding (12%), major adverse events (20%), and thromboembolic events (8%). IABP demonstrated the lowest overall risk, with bleeding at 15%, major adverse events at 18%, and thromboembolic events at 9%. All comparisons yielded non-significant p-values (p > 0.05). In a subgroup analysis of findings for those with myocardial infarction-related CS, patients treated with Impella experienced a 15% reduction in mortality, compared to a 25% reduction with other devices (p = 0.04). Age-based sub-group analysis showed that those under 65 years had a 20% improvement in survival with MCS use, while those 65 and older had a 10% benefit (p = 0.01), suggesting younger patients may demonstrate better outcomes. A limitation is the lack of comprehensive long-term outcome data, which hinders optimal device selection and clinical decision-making. There is lack of randomized controlled trials in specific patient subgroups, which highlights a gap in the current literature. The complexity and risk of advanced MCS platforms require careful patient selection to ensure benefits outweigh potential harms. Future research should aim to close data gaps through rigorous multicenter trials, refining MCS strategies, and enhancing patient outcomes.

Karami et al. (2021) conducted a 5-year follow-up of the IMPRESS randomized controlled trial (RCT) to assess differences in clinical outcomes and functional status between patients with cardiogenic shock (CS) supported by percutaneous mechanical circulatory support (pMCS) and intra-aortic balloon pumping (IABP). Between June 2012 and September 2015, patients (n = 48) with severe CS complicating acute ST-segment elevation myocardial infarction undergoing revascularization were randomized into two groups, either pMCS by Impella CP (n = 24) or IABP (n = 24). All-cause mortality, functional status, and occurrence of major adverse cardiac and cerebrovascular events (MACCE) were determined for the 5-year assessment. Five-year mortality was 50% (n = 12/24) in pMCS patients and 63% (n = 15/24) in IABP patients. MACCE occurred in12/24 (50%) of the pMCS patients vs. 19/24 (79%) of the IABP patients. All survivors except for one were in New York Heart Association Class I/II [pMCS n = 10 (91%) and IABP n = 7(100%)], and none of the patients had residual angina. There were no differences in left ventricular ejection fraction between the groups. The authors concluded that for patients with severe CS after acute myocardial infarction (AMI), there were no differences in all-cause mortality and functional status between treatment with pMCS or IABP. Limitations include lack of blinding in the original study and small sample size.

Iannaccone et al. (2020) conducted a meta-analysis to evaluate the safety and efficacy of Impella in patients with cardiogenic shock (CS). Seventeen observational retrospective studies for a total of 3,933 patients with CS and impella positioning were included in the review. Median age was 61.9 years. Cardiogenic shock was mainly related to acute coronary syndrome (ACS): 79.6%. Thirty-day mortality was 47.8%. Based on meta regression analysis, the Impella 5.0 and the Impella CP devices were related to a higher survival rate, whereas the Impella 2.5 was not. Furthermore, a correlation with reduced mortality was found when Impella was initiated in CS not complicated by cardiac arrest, and before revascularization. The vascular complication and major bleeding rate were 7.4% and 15.2% respectively, and were associated with older age and comorbidities, while the implantation of an Impella CP/2.5 L was associated with fewer complications. The authors concluded that the use of an Impella CP, initiation of Impella before PCI, and in those without cardiac arrest was associated with better outcomes. The authors note the 30-day mortality of CS was high despite the use of Impella, and ongoing RCTs to determine the role of mechanical circulatory support (MCS) in the management of CS are needed. Limitations include the retrospective nature of the studies.

Rios et al. (2018) conducted a meta-analysis and Trial Sequential Analysis (TSA) to determine the benefit and harm of IABP compared with pVAD used during high-risk risk percutaneous coronary intervention (PCI) or cardiogenic shock (CS) based on short and long-term patient outcomes. Five randomized controlled trials (RCTs) and one nonrandomized study that compared pVAD (TandemHeart or Impella) with IABP were included in the review. Based on the RCTs, the authors found no difference in short-term (six months) or long-term (12 months) all-cause mortality. The use of pVAD seemed associated with more adverse events (acute kidney injury, limb ischemia, infection, major bleeding, and vascular injury) compared with IABP, but this was not supported by TSA. According to the authors, no difference was found in short or long-term mortality when IABP or pVAD was used for high-risk PCI or CS. Additionally, pVAD was associated with more adverse events compared to IABP. Limitations noted include all the RCTs in the study were at high risk of bias, and instead of comparing Impella and TandemHeart individually against IABP, they were placed in one category. The authors state that future high-quality RCTs are needed.

Thiele et al. (2017) performed a collaborative meta-analysis of randomized trials to investigate the efficacy and safety of active percutaneous mechanical circulatory support (pMCS) devices compared to either no support or IABP in CS. Studies considered for inclusion had to compare active pMCS versus control in patients with CS predominantly complicated by AMI reporting at least short-term all-cause mortality assessed at 30 days. Four randomized trials, two using the TandemHeart device and two using the Impella device, for a total of 148 participants (MCS n = 77, control n = 71) were included in the review. All four trials used IABP as the control. Risk ratios (RR) and 95% confidence intervals (95% CI) were calculated to analyze the primary endpoint of 30-day mortality and device-related complications including bleeding and leg ischemia. Mean differences (MD) were calculated for mean arterial pressure (MAP), cardiac index (CI), pulmonary capillary wedge pressure (PCWP), and arterial lactate. There was no difference in 30-day mortality for active MCS compared with control. Active MCS significantly increased MAP and decreased arterial lactate at comparable CI and PCWP. No significant difference was observed in the incidence of leg ischemia, whereas the rate of bleeding was significantly increased in MCS compared to IABP. The authors determined that active pMCS had an initial beneficial effect on MAP and arterial lactate but did not improve mortality in comparison to control in patients with CS complicating AMI. The authors state the use of active pMCS should be restricted to select patients. Limitations include small study sizes and the use of two different MCS.

O'Neill et al. (2012) conducted a multicenter RCT designed to compare outcomes between the IABP versus the Impella 2.5 pVAD in patients who required hemodynamic support during high-risk PCI. Symptomatic individuals (n = 452) with complex 3-vessel disease or unprotected left main CAD and severely depressed left ventricular function were randomly assigned to IABP (n = 226) or Impella 2.5 (n = 226) support during nonemergent high-risk PCI. A 30-day incidence of major adverse events was the primary end point, and a 90-day follow-up was required. Impella 2.5 provided superior hemodynamic support in comparison with IABP, with maximal decrease in cardiac power output from baseline. The primary end point (30-day major adverse events) was not statistically different between groups: 35.1% for Impella 2.5 versus 40.1% for IABP, in the intent-to-treat population and 34.3% versus 42.2% in the per protocol population. At 90 days, a strong trend toward decreased major adverse events was observed in Impella 2.5–supported patients in comparison with IABP: 40.6% versus 49.3% in the intent-to-treat population and 40.0% versus 51.0% in the per protocol population, respectively. The authors concluded Impella 2.5 did not result in a better outcome of the primary end point at 30 days; however, it did show a strong trend to superior outcome at 90 days in the total cohort and a significant improvement in the per protocol analysis at 90 days. Study limitations include that due to the data safety monitoring board (DSMB) determination of futility this trial was terminated on the assumption from the first 50% (327) of patients enrolled. Only 69% (452) of the planned enrollment occurred.

Cheng et al. (2009) performed a meta-analysis of three controlled trials which compared the safety and efficacy of percutaneous left ventricular assist devices (LVADs) with IABP aimed to evaluate potential benefits of percutaneous LVAD on 30-day survival and hemodynamics. One trial used the Impella device, and two trials evaluated the TandemHeart. Weighted MDs were calculated for CI, MAP, and pulmonary capillary wedge pressure (PCWP). After device implantation, percutaneous LVAD patients had higher CI, higher MAP, and lower PCWP compared with IABP patients. Similar 30-day mortality was observed using percutaneous LVAD compared with IABP. No significant difference was observed in incidence of leg ischemia in percutaneous LVAD patients compared with IABP patients. Bleeding was significantly more observed in TandemHeart patients compared with patients treated with IABP. The authors concluded that the use of percutaneous LVAD provided a superior hemodynamic support when compared to IABP, although this did not result into a reduced 30-day mortality rate. Additionally, the higher invasive nature of the LVAD led to a higher rate of adverse events. The authors recommend future, large RCTs that are designed to evaluate clinical outcomes and adverse effects. Limitations include small sample sizes of the studies and the limited number of studies included.

Dixon et al. (2009) conducted a prospective, multicenter study for individuals undergoing high-risk PCI with minimally invasive circulatory support employing the Impella 2.5 system to determine the safety and efficacy of the Impella 2.5 system. Twenty patients undergoing high-risk nonemergent PCI at seven centers between July 2006 and April 17, 2007, were enrolled in the study. Inclusion criteria comprised patients with a left ventricular ejection fraction of ≤ 35% who required PCI on either an unprotected left main coronary artery or the last patent coronary conduit. Incidence of major adverse cardiac events at 30 days was the primary safety end point and freedom from hemodynamic compromise during PCI was the primary efficacy end point which was defined as a decrease in MAP below 60 mm Hg for > 10 minutes. The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 ±0.6 h (range: 0.4 to 2.5 h). Mean pump flow during PCI was 2.2 ±0.3 l/min. At 30 days, the incidence of major adverse cardiac events was 20% (two patients had a periprocedural myocardial infarction; two patients died at days 12 and 14). There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia. Two patients (10%) developed mild, transient hemolysis without clinical sequelae. None of the patients developed hemodynamic compromise during PCI. The authors concluded that during high-risk PCI, the Impella 2.5 system was easy to implant, safe, and provided exceptional hemodynamic support. Limitations include small study size and lack of control group. The authors note that a future RCT is planned to compare the efficacy of Impella 2.5 device versus conventional IABP counterpulsation during high-risk PCI.

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)/ Society for Cardiovascular Angiography & Interventions (SCAI)

Lawton et al. (2022) developed an American College of Cardiology (ACC), American Heart Association (AHA), and the Society for Cardiovascular Angiography & Interventions (SCAI) guideline which provides evidence-based recommendations for managing individuals with coronary artery disease (CAD) who are being considered for coronary revascularization. The guideline states that in selected high-risk patients, elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable to prevent hemodynamic compromise during percutaneous coronary intervention (PCI). (Strength of recommendation: 2B -- weak, level of evidence: BR – moderate, randomized).

American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA)

Heidenreich et al. (2022) developed a guideline to update and address the management of heart failure in a collaborative effort by the American Heart Association (AHA), the American College of Cardiology (ACC), and the Heart Failure Society of America (HFSA). In patients with advanced heart failure with reduced ejection fraction (HFrEF) and hemodynamic compromise and shock, temporary mechanical circulatory support (MCS), including percutaneous and extracorporeal ventricular assist devices, are reasonable as a “bridge to recovery” or “bridge to decision”. (Strength of recommendation: 2A -- moderate, quality of evidence: BR – moderate, nonrandomized).

International Society for Heart and Lung Transplantation (ISHLT)/Heart Failure Society of America (HFSA)

Bernhardt et al. (2023) developed a guideline for the management of patients requiring acute mechanical circulatory support in a collaborative effort by the International Society for Heart and Lung Transplantation (ISHLT) and Heart Failure Society of America (HFSA). The guideline notes indications vary for acute MCS in those with cardiogenic shock (CS) due to heterogeneity in etiology and severity of presentation and may also vary by the expected end points of the support such as recovery, bridge to decision, and length of support. The recommendations are as follows (not all-inclusive):

- Acute MCS should be initiated as soon as possible in patients with CS who fail to stabilize or continue to deteriorate despite initial interventions. (Class of recommendation: I -- strong, level of evidence: B -- moderate quality).
- The use of acute MCS should be considered in patients with multiorgan failure to allow successful optimization of clinical status and neurologic assessment before placement of durable MCS or organ transplantation. (Class of recommendation: II -- moderate, level of evidence: C -- randomized or nonrandomized observational or registry studies with limitations of design or execution, or consensus of expert opinion).
- Patients supported with acute MCS for CS should be monitored for signs of improved end organ function and early weaning/discontinuation of MCS. (Class of recommendation: II -- moderate, level of evidence: B -- moderate quality).

The National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) (2016) developed a Medtech innovation briefing on the use of Impella 2.5 to temporarily support the circulatory system during elective and urgent high-risk PCI. The briefing noted Impella 2.5 to be of benefit in patients with CS following myocardial infarction or used as a ‘bridge’ to more invasive methods.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A variety of products have received FDA Premarket Approval (PMA) or marketing clearance through the 510(k) Premarket Notification process. Refer to the following websites for more information, and search by product name in the device section: For PMA devices, refer to Premarket Approval (PMA) (fda.gov). For 510(k) devices, refer to 510(k) Premarket Notification (fda.gov).

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Policy History/Revision Information

Date	Summary of Changes
10/01/2025	**Centers for Medicare and Medicaid Services (CMS) Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version MMP240.15

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their

independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.