Coverage of any medical intervention discussed in a Prevea360 Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or summary plan description (SPD) and to applicable state and/or federal laws.

Mechanical Circulatory Support Devices MP9528

Covered Service: Yes

Prior Authorization Required: No

Additional Information: See Heart Transplantation (Adult and Pediatric) MP9613 and Heart/Lung Transplantation MP9612 for additional information.

The criteria in this policy do not apply to those devices which have been granted a humanitarian device exemption (HDE) by the FDA, which are considered medically necessary when all FDA-required criteria are met.

For a current list of HDE approved devices, refer to the FDA HDE database at: Listing of CDRH Humanitarian Device Exemptions | FDA

Prevea360 Health Plan Medical Policy:

1.0 Percutaneous Left Ventricular Assist Device (pVAD) (e.g. Impella) **does not** require prior authorization and is considered medically necessary for **ANY** of the following indications:

- 1.1 Bridge to recovery
- 1.2 Bridge to decision
- 1.3 Destination therapy
- 1.4 Providing short-term circulatory support in cardiogenic shock
- 1.5 As an adjunct to percutaneous coronary intervention (PCI)

2.0 All other indications not listed are considered **experimental and investigational,** and therefore are not medically necessary

3.0 Total artificial heart (TAH) **does not** require prior authorization and is considered medically necessary when used as a bridge to heart transplantation in members with biventricular heart failure who have failed optimal medical therapy, are at imminent risk of death, and are currently listed as a heart transplant candidate.

Coverage of any medical intervention discussed in a Prevea360 Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or summary plan description (SPD) and to applicable state and/or federal laws.

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Quality and Care Management Division	July 18, 2018
Revised:	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	July 20, 2022
	Medical Policy Committee/Health Services Division	April 19, 2023
	Medical Policy Committee/Health Services Division	February 21. 2024
Reviewed:	Medical Policy Committee/Health Services Division	July 15, 2020
	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	July 20, 2022
	Medical Policy Committee/Health Services Division	April 19, 2023
	Medical Policy Committee/Health Services Division	February 21, 2024

Published: 04/01/2024
Effective: 04/01/2024