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 policy and applicable state and/or federal laws.

Transcatheter Heart Valve Replacement and Repair Procedures MP9623

Covered Service: Yes

Prior Authorization Required: No

Additional Information: None

Prevea360 Health Plan Medical Policy:

Transcatheter Aortic Valve Replacement (TAVR)

1.0 TAVR using an FDA approved system (e.g., Edwards SAPIEN™ system; CoreValve® system; Abbott Portico™ with FlexNav™) according to FDA-approved indications **does not** require prior authorization and is considered medically necessary for members when **ALL** of the following criteria are met:

- 1.1 Member has severe symptomatic native aortic valve stenosis; **AND**
- 1.2 Member has been determined an appropriate surgical candidate for TAVR by a cardiac surgeon (this may include members determined to be inoperable for, or at high or greater risk for, open aortic valve replacement); **AND**
- 1.3 Member's existing co-morbidities, if present, will not preclude the expected benefit from correction of the aortic stenosis.

2.0 TAVR using the Core Valve® system according to FDA-approved indications **does not** require prior authorization and is considered medically necessary for members when **ALL** of the following criteria are met:

- 2.1 Member has a failed surgical bioprosthetic aortic valve (stenosed, insufficient, or combined); **AND**
- 2.2 Member is judged to be at high or greater risk for open aortic valve replacement by a cardiac surgeon; **AND**
- 2.3 Member's existing co-morbidities, if present, will not preclude the expected benefit from correction of the failed bioprosthetic valve.

3.0 TAVR using any other system and/or for any treatment indication not listed in (1.0 or 2.0) are considered experimental and investigational, and therefore not medically necessary.

Percutaneous Pulmonary Valve Implantation (PPVI)

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 policy and applicable state and/or federal laws.

4.0 PPVI using an FDA approved system (e.g. Melody® transcatheter pulmonary valve and delivery system; Edwards SAPIEN XT valve; Harmony™ transcatheter pulmonary valve) according to FDA-approved indications **does not** require prior authorization and is considered medically necessary for members when **ALL** of the following criteria are met:

- 4.1 Member has a right ventricular outflow tract (RVOT) disorder; **AND**
- 4.2 Member has been determined an appropriate surgical candidate (e.g. moderate or greater pulmonary regurgitation) by a cardiac surgeon; **AND**
- 4.3 Member's existing co-morbidities, if present, will not preclude the expected benefit from correction of the RVOT.

5.0 PPVI using any other system and/or for any treatment indications not listed in (4.0) is considered experimental and investigational, and therefore not medically necessary.

Transcatheter Mitral Valve Leaflet Repair

6.0 Transcatheter mitral valve leaflet repair using an FDA approved device (e.g., MitraClip®) used according to the FDA-approved indications **does not** require prior authorization and is considered medically necessary for members when **ALL** of the following criteria are met:

- 6.1 Procedure is intended to be used for percutaneous reduction of significant degenerative (e.g., primary) and functional (e.g. secondary) mitral regurgitation; **AND**
- 6.2 Member has been determined an appropriate surgical candidate (e.g., moderate-to-severe or severe mitral valve regurgitation) by a cardiac surgeon; **AND**
- 6.3 Member's existing co-morbidities, if present, will not preclude the expected benefit from correction of the mitral regurgitation.

7.0 Transcatheter mitral valve leaflet repair using any other system and/or for any treatment indication not listed in (6.0) is considered experimental and investigational, and therefore not medically necessary.

	Committee/Source	**Date(s)**
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