PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY

<table>
<thead>
<tr>
<th>PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY</th>
<th>Cardiac: Percutaneous Aortic Valve Replacement for Aortic Stenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date: 7/1/2018</td>
<td>Section: SUR</td>
</tr>
<tr>
<td>7/1/18</td>
<td>Technology Assessment Committee Approved Date: 2/12</td>
</tr>
<tr>
<td>Medical Officer Date</td>
<td>Medical Policy Committee Approved Date: 1/13; 6/13; 2/14; 9/15; 4/16; 5/17; 6/18</td>
</tr>
</tbody>
</table>

See Policy CPT CODE section below for any prior authorization requirements

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

I. Percutaneous aortic valve replacement for the treatment of aortic stenosis may be considered medical necessary and covered when all of the following criteria are met:

   A. Clinical documentation indicates patient has symptomatic aortic stenosis and is at high risk for an open procedure; and
   B. Documented senile degenerative aortic valve stenosis with any of the following echocardiography derived criteria:
      1. Mean gradient >40 mm Hg; or
      2. Jet velocity > 4.0 m/s; or
      3. Aortic valve area (AVA) of < 0.8 cm² or AVA index < 0.5 cm²/m²; and
   C. Symptomatic due to aortic valve stenosis as demonstrated by NYHA Functional Class ≥ II; and
   D. The subject, after formal consults by a cardiologist and a cardiovascular surgeon agreed that medical factors precluding operation, based on a conclusion that the probability of death or serious, irreversible morbidity exceeded the probability of meaningful improvement. Specifically, the probability of death or serious, irreversible morbidity exceeded 50%. The surgeons’ consult notes should specify medical or anatomic factors leading to that conclusion; and
   E. Documented formal palliative care consultation; and
   F. Documented mental status testing [such as the Saint Louis University Mental Status (SLUMS)
exam or other validated test] to evaluate for dementia. Dementia screening must be completed prior to the Formal Palliative Care consult so that results are available for inclusion in the consultation.

II. Percutaneous aortic valve replacement for the treatment of aortic stenosis is considered experimental/investigational and is not covered when criterion I. above is not met, including, but not limited to when the following condition are present:

A. Bicuspid or non-calcified aortic valve
B. Acute myocardial infarction
C. Substantial coronary artery disease requiring revascularization
D. Left ventricular ejection fraction of less than 20%
E. Diameter of the aortic annulus of less than 18 mm or more than 25 mm
F. Severe (>3+) mitral or aortic regurgitation
G. Transient ischemic attack or stroke within the previous 6 months
H. Life expectancy <12 months due to non-cardiac conditions

CPT CODES

<table>
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<tr>
<td><strong>No Prior Authorization Required</strong></td>
<td>Cardiac: Percutaneous Aortic Valve Replacement for Aortic Stenosis</td>
</tr>
<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
</tr>
<tr>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
</tr>
<tr>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
</tr>
<tr>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
</tr>
<tr>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)</td>
</tr>
<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)</td>
</tr>
<tr>
<td>33367</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>33368</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)</td>
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DESCRIPTION

Transcatheter heart valve replacement is a newer, minimally invasive procedure which is an emerging alternative to conventional open-heart surgery. A catheter inserted using a transfemoral (TF) or transapical (TA) approach allows the introduction of an expandable prosthetic heart valve which is then delivered to the diseased native valve.

REVIEW OF EVIDENCE

A review was conducted of the ECRI, Hayes and PubMed databases. One-year and two-year outcomes from the PARTNER trial were supplied by the medical director of the Providence Valve Center. Short-term (two years or less) results show improved 12-month survival, substantial and sustained improvement in symptoms, functional status, and quality of life, and reduced hospitalization for aortic stenosis or its treatment, for patients with severe aortic stenosis. The coverage criteria noted above are primarily based upon the inclusion/exclusion criteria outlined in the PARTNER clinical trial.

INSTRUCTIONS FOR USE

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES
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6. Hayes: Medical Technology Directory; Publication Date: September 10, 2015 Transcatheter Surgical Valve Implantation (TAVI) Versus Surgical Aortic Valve Replacement (SAVR) for Aortic Stenosis