Transcatheter Aortic Valve Replacement (TAVR)

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr, go to “Comunicados a Proveedores”, and click “Cartas Circulares”.

Medical Policy: MP-SU-01-13
Original Effective Date: August 15, 2013
Revised: June 13, 2016
Next Revision: June, 2017

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Aortic valve replacement is the mainstay of treatment of symptomatic aortic stenosis (AS). In properly selected patients, this surgical procedure offers substantial improvements in symptoms and life expectancy (UpToDate®, 2016).

Transcatheter Aortic Valve Replacement (TAVR), also known as Transcatheter Aortic Valve Implantation (TAVI), is a new technology used in the treatment of Aortic Stenosis (AS). A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve (CMS NCD 20.32, 2013).

Transcatheter Aortic Valve Replacement (TAVR) has been developed for the treatment of patients with severe symptomatic Aortic Stenosis (AS), who have an unacceptably high estimated surgical risk, or in whom TAVR is preferred due to technical issues with surgery, e.g., a porcelain aorta or prior significant mediastinal radiation, prior pericardectomy with dense adhesions, or prior sterna infection with complex reconstruction, or a patent left internal mammary graft lying beneath the sternum (as identified by Computed Tomography Angiography). Thus, accurate estimation of the risk of surgical aortic valve replacement performed by an experienced cardiothoracic surgeon and multidisciplinary valve team is vital to appropriate evaluation of potential candidates for this procedure. Risk calculators are available to estimate the risk of valvular surgery (UpToDate®, 2016).

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.
INDICATIONS

I. **Medical Card System, Inc. (MCS)** will consider medically necessary the use of Transcatheter Aortic Valve Replacement (TAVR/TAVI), for the Commercial LOB, for the treatment of severe Aortic Stenosis (AS)*, as an alternative to surgical Aortic Valve Replacement (AVR), when the patient meets Criteria A, and Criteria B:

A. Patient **Must** be at high risk, or greater (i.e., prohibitive), for open surgical therapy. This is evidenced by Any of the following:

1. Operative risk, as defined by the Society of Thoracic Surgeons (STS)**, must have an STS PROM (i.e., Predicted Risk of Mortality) Score of 8% to 15%; or

2. Anatomic factors that increase surgical risk are present; or

3. Patient has Significant Frailty**.

B. After complying with Criteria A, the patient must have One (i.e., Any) of the indications set forth below:

1. Patient is symptomatic with severe Aortic Stenosis (AS) (stage D1) with All of the following:
   a. Decreased systolic opening of a calcified or congenitally stenotic aortic valve; and
   b. An aortic velocity 4.0 m/second or greater, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg or higher; and
   c. Symptoms of Heart Failure (HF), syncope, exertional dyspnea, angina, or pre-syncope by history or on exercise testing.

2. Patient is asymptomatic with severe AS (stage C2) and has a Left Ventricular Ejection Fraction (LVEF) less than 50%, with a decreased systolic opening of a calcified aortic valve, with an aortic velocity 4.0 m/second or greater, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg or higher.

3. Patient has severe AS (stage C or D) when undergoing cardiac surgery for other indications, when there is decreased systolic opening of a calcified aortic valve, and an aortic velocity of 4.0 m/second or greater, or Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg or higher.

4. Patient is asymptomatic with very severe AS (stage C1) with All of the following:
   a. Decreased systolic opening of a calcified valve; and
   b. An aortic velocity 5.0 m/second or greater, or Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 60 mmHg or higher.

5. Patient is apparently asymptomatic with severe AS (stage C1) with All of the following:
   a. A calcified aortic valve; and
Clinical Medical Policy Department  
Clinical Affairs Division

b. An aortic velocity of 4.0 m/second to 4.9 m/second, or Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg to 59 mmHg; and

c. An exercise test demonstrating decreased exercise tolerance, or a fall in systolic Blood Pressure (BP).

6. Patient is symptomatic with low-flow/low-gradient severe AS with a reduced Left Ventricular Ejection Fraction (LVEF) (stage D2) with All of the following:

a. A calcified aortic valve with reduced systolic opening; and

b. A resting valve area of 1.0 cm$^2$ or less; and

c. An aortic velocity less than 4.0 m/second, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of less than 40 mmHg; and

d. LVEF less than 50%; and

e. A low-dose dobutamine stress study that shows an aortic velocity of 4.0 m/second or greater, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg or higher, with a valve area of 1.0 cm$^2$ or less, at Any dobutamine dose.

7. Patient is symptomatic with low-flow/low-gradient severe AS (stage D3) with a Left Ventricular Ejection Fraction (LVEF) of 50% or greater, a calcified aortic valve with significantly reduced leaflet motion, and a valve area of 1.0 cm$^2$ or less, Only if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms and data recorded when the patient is normotensive (systolic BP <140 mmHg) indicate All of the following:

a. An aortic velocity of less than 4.0 m/second, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of less than 40 mmHg; and

b. A stroke volume index less than 35 mL/m$^2$; and

c. An indexed valve area of 0.6 cm$^2$/m$^2$ or less.

8. Patient is asymptomatic with severe AS (stage C1), with an aortic velocity of 4.0 m/second or greater, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) of 40 mmHg or higher, if the patient is at low surgical risk, and serial testing shows an increase in aortic velocity of 0.3 m/second or greater, per year.

9. TAVR is may also be considered medically reasonable and necessary for patients with moderate AS (stage B) with an aortic velocity between 3.0 m/second and 3.9 m/second, or a Mean Pressure Gradient ($\Delta P_{\text{mean}}$) between 20 mmHg and 39 mmHg, who are undergoing cardiac surgery for other indications.

*Note:* For further details on the stages of Aortic Stenosis (AS), according to the American Heart Association (AHA) & the American College of Cardiology (ACC), please refer to Appendix A, at the end of this medical policy.
**Note**: The Society of Thoracic Surgeons (STS)’s Risk Calculator, which includes the Predicted Risk of Mortality (i.e., PROM) Score, allows a user to calculate a patient’s Risk of Mortality and Morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity (STS, 2014). To access the STS Risk Calculator, please refer to: Online STS Risk Calculator.

***Note***: Significant Frailty is defined, as per the American Heart Association & the American College of Cardiology (AHA/ACC, 2014), as a moderate-to-severe degree of frailty, in which the patient is unable to perform two or more (≥ 2) of the following Daily Life Activities (DLA): Feeding, Bathing, Dressing, Transferring, Toiletting, Urinary incontinence, and/or Ambulation. Significant frailty may also include, as per the American Association for Thoracic Surgery (AATS, 2013), the presence of Any of the following criteria:

a. Slowness; or  
b. Weakness; or  
c. Exhaustion; or  
d. Wasting & malnutrition; or  
e. Poor endurance & inactivity; or  
f. Loss of independence; or  
g. 5 m walking time or Grip strength, which may be variable with respect to age and gender without validated scientific thresholds; or  
h. BMI < 20 kg/m2 and/or weight loss 5 kg/year; or  
i. Serum albumin < 3.5 g/dL; or  
j. Cognitive impairment or dementia.

II. Medical Card System, Inc., (MCS) will consider medically necessary the use of Transcatheter Aortic Valve Replacement (TAVR), for the Classicare Line of Business (LOB), for the treatment of symptomatic aortic valve stenosis, under the medical criteria established by the:

- Medicare National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) [20.32]. Please refer to aforementioned NCD for further details.

Note4: In order to validate that the patient is properly enrolled in a CMS approved Clinical Trial, please refer to: Centers for Medicare & Medicaid (CMS) Coverage with Evidence Development – List of All Approved Studies.

Note5: In order to validate which hospitals are within the Participant Directory of the National Cardiovascular Data Registry® (NCDR), in association with the Society of Thoracic Surgeons (STS) & the
LIMITATIONS

1. TAVR is **Not medically covered** for patients in whom existing co-morbidities would preclude the expected benefit from correction of the Aortic Stenosis (Aortic Stenosis).

2. TAVR **Must** be done using a U.S. Food & Drug Administration (FDA) approved device (i.e., Edwards SAPIEN, Edwards SAPIEN XT, and/or Medtronic’s CoreValve).

3. For patients in whom TAVR is being considered, a Heart Valve Team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in Ventricular Heart Disease (VHD), cardiac imaging, interventional cardiology, cardiac anesthesia, and cardiac surgery should collaborate to provide optimal patient care.

CONTRAINDICATIONS

1. The Transcatheter Heart Valve (THV) & delivery systems are contraindicated in patients who exhibit **Any** of the following conditions:

   a. Patient cannot tolerate an anticoagulation/antiplatelet regimen; or
   
   b. Presence of active bacterial endocarditis or other active infections; or
   
   c. Known hypersensitivity to Nitinol (Titanium or Nickel); or
   
   d. Known hypersensitivity to contrast media, which cannot be adequately pre-medicated; or
   
   e. Preexisting mechanical heart valve in aortic position.

CODING INFORMATION

CPT® Codes for **Both** the Commercial & Classicare Lines of Business (LOB) (List May Not be All Inclusive)

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<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</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>--------</td>
<td>--------------------------------------------------------------------------------------------------------</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 (e.g., median sternotomy, mediastinotomy)</td>
</tr>
<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., 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) (Use 33367 in conjunction with CPT Codes 33361, 33362, 33363, 33364, 33365, 33366, 33418, 33477)</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) (Use 33368 in conjunction with CPT Codes 33361, 33362, 33363, 33364, 33365, 33366 33418, 33477) (Do not report 33368 in conjunction with 33367, 33369)</td>
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<tr>
<td>+33369</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure) (Use 33369 in conjunction with CPT Codes 33361, 33362, 33363, 33364, 33365, 33366, 33418, 33477) (Do not report 33369 in conjunction with 33367, 33368)</td>
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MODIFIERS (List may not be all inclusive)

<table>
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<tr>
<th>MODIFIERS</th>
<th>DESCRIPTION</th>
</tr>
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<tbody>
<tr>
<td>QO</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study [For Classicare (Advantage) use Only]</td>
</tr>
<tr>
<td>62</td>
<td>Two surgeons: When 2 surgeons work together as primary surgeons performing distinct part (s) of a procedure, each surgeon should report his/her distinct operative work by adding modifier -62 to the procedure code and any associated add-on code (s) for that procedure as long as both surgeons continue to work together as primary surgeons. Each surgeon should report the co-surgery once using the same procedure code. If additional procedure (s) including add-on procedure [s] are performed during the same surgical session, separate code(s) may also be reported with modifier -62 added. <strong>Note:</strong> If a co-surgeon acts as an assistant in the performance of additional procedure(s), other than those reported with modifier -62, during the same surgical session, those services may be reported using separate procedure code (s) with modifier -80 or modifier -82 added, as appropriate.</td>
</tr>
</tbody>
</table>

Note: The use of modifier – Q0 is exclusively for the Classicare (Advantage) LOB.
Note: American Medical Association (AMA)’s CPT® Manual 2016 states that TAVR/TAVI requires two physician operators and all components of the procedure are reported using modifier – 62.

Note: Professional Claims for the Classicare (Advantage) only must include the 8-digit ClinicalTrials.gov Identifier Number (Medicare CPM, 2015).

ICD-10 Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD-10-Codes</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>I06.0</td>
<td>Rheumatic aortic stenosis</td>
</tr>
<tr>
<td>I08.0</td>
<td>Rheumatic disorders of both mitral and aortic valves</td>
</tr>
<tr>
<td>I35.0</td>
<td>Nonrheumatic aortic (valve) stenosis</td>
</tr>
<tr>
<td>I35.1</td>
<td>Nonrheumatic aortic (valve) insufficiency</td>
</tr>
<tr>
<td>I35.2</td>
<td>Nonrheumatic aortic (valve) stenosis with insufficiency</td>
</tr>
<tr>
<td>I35.8</td>
<td>Other nonrheumatic aortic valve disorders</td>
</tr>
<tr>
<td>I35.9</td>
<td>Nonrheumatic aortic valve disorder, unspecified</td>
</tr>
<tr>
<td>Q23.0</td>
<td>Congenital stenosis of aortic valve</td>
</tr>
<tr>
<td>Q23.1</td>
<td>Congenital Insufficiency of aortic valve</td>
</tr>
<tr>
<td>T82.01x+</td>
<td>Breakdown (Mechanical) of heart valve prosthesis</td>
</tr>
<tr>
<td>T82.03x+</td>
<td>Leakage of heart valve prosthesis</td>
</tr>
<tr>
<td>T82.857+</td>
<td>Stenosis of cardiac prosthetic devices, implants and grafts</td>
</tr>
<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
</tr>
<tr>
<td>Z45.09</td>
<td>Encounter for adjustment and management of other cardiac device</td>
</tr>
</tbody>
</table>

REFERENCES


## POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 15, 2013</td>
<td>Origination of Policy</td>
<td>To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.</td>
</tr>
<tr>
<td>February 21, 2014</td>
<td>Revised</td>
<td>References updated: New references were added, numbers: 1, 4-5, 7-11, 13-14, 16-19, 21-22, 24-32, &amp; 34.</td>
</tr>
</tbody>
</table>
| October 20, 2014 | Revised | To the Description Section:  
  - Added the respective citations: (CMS NCD 20.32, 2013) & (UpToDate®, 2014).  
  - Deleted: I. Medical Card System, Inc., (MCS) considers transcatheter aortic valve replacement (TAVR) performed via a transfemoral delivery approach using a U.S. Food and Drug Administration (FDA) approved device (i.e., Edwards SAPIEN Transcatheter Heart Valve), medically necessary in patients with severe symptomatic native aortic valve stenosis who have been determined by a Cardiovascular surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.  
  - Deleted: Previous Note1: The hospital in which transcatheter aortic valve replacement (TAVR) is performed must participate in a prospective, national, audited registry that follows the patient for at least 1 year but tracks outcomes for 5 years.  
  - Deleted: II. Medical Card System, Inc., (MCS) considers transcatheter aortic valve replacement (TAVR) using a U.S. Food and Drug Administration (FDA) approved device (i.e., Edwards SAPIEN Transcatheter Heart Valve), medically necessary when performed via a transapical or transfemoral delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction > 20% who have been examined by a heart team including an experienced Cardiovascular surgeon and (a cardiologist or an Interventional cardiologist) and found to be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons operative risk score ≥ 8% or are judged by the heart team to be at a ≥ 15% risk of mortality for surgical aortic valve replacement.  
  - Deleted: Previous Note2: The ACC/AHA guidelines define severe Aortic Stenosis (AS) as: A valve area of < 1.0 cm²; a mean gradient > 40 mm Hg; or An aortic jet velocity > 4.0 m/sec.  
  - Deleted: Medical Card System, Inc., (MCS) allows coverage of transcatheter aortic valve replacement (TAVR) for medical uses that are not expressly listed as an FDA approved indications when performed within a clinical study and/or under Coverage with Evidence Development (CED) with certain conditions and the following criteria's: For professional claims processed on or
after July 1, 2013, Medical Card System, Inc. and Medicare expects that those numeric, (8-digit clinical trial (CT) registry numbers will be preceded by the alpha characters of “CT” in the paper form CMS-1500 claims or entered similarly in the electronic Form 837P. In the professional claim that have codes (0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365, and 0318T); those codes must have the CT registry number, Q0 modifier, and a secondary diagnosis code V70.7.

- Deleted: Previous Note3: As part of (CED); Center of Medicare and Medicaid Services (CMS) identified below the Medicare approved registry and Medicare approved clinical trials which have been reviewed and determined to meet the requirements of coverage. To see the register go to the following URL: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257.
- Deleted: Title of Note 4 and moved its content to the Classicare (Advantage) Indications Section.
- Reconstructed Indications Section and Dived medical coverage between the Commercial LOB first (Part I), and then the Classicare (Advantage) LOB (Part II).
- To new part I added: Medical Card System, Inc., (MCS) will consider medically necessary the use of Transcatheter Aortic Valve Replacement (TAVR/TAVI), for the Commercial LOB, for the treatment of severe Aortic Stenosis (AS)*, as an alternative to surgical Aortic Valve Replacement (AVR), when the patient meets Criteria A, and Criteria B.
  - To new part I added: Sub-part A: Patient Must be at high risk, or greater (i.e., prohibitive), for open surgical therapy. This is evidenced by Any of the following:
    1. Operative risk, as defined by the Society of Thoracic Surgeons (STS)**, must have an STS PROM (i.e., Predicted Risk of Mortality) Score of 8% to 15%; or
    2. Anatomic factors that increase surgical risk are present; or
    3. Patient has Significant Frailty***.
  - To new part I added: Sub-part B: After complying with Criteria A, the patient must have One (i.e., Any) of the indications set forth below:
    1. Patient is symptomatic with severe Aortic Stenosis (AS) (stage D1) with All of the following: a. Decreased systolic opening of a calcified or congenitally stenotic aortic valve; and b. An aortic velocity 4.0 m/second or greater, or a Mean Pressure Gradient (ΔPmean) of 40 mmHg or higher; and c. Symptoms of Heart Failure (HF), syncope, exertional dyspnea, angina, or pre-syncope by history or on exercise testing.
    2. Patient is asymptomatic with severe AS (stage C2) and has a Left Ventricular Ejection Fraction (LVEF) less than 50%, with a decreased systolic opening of a calcified aortic valve, with an aortic velocity 4.0 m/second or greater, or a Mean Pressure Gradient (ΔPmean) of 40 mmHg or higher.
    3. Patient has severe AS (stage C or D) when undergoing cardiac surgery for other indications, when there is decreased systolic opening of a calcified aortic valve, and an aortic velocity of 4.0 m/second or greater, or a Mean Pressure Gradient (ΔPmean) of 40 mmHg or higher.
    4. Patient is asymptomatic with very severe AS (stage C1) with All of the following: a. Decreased systolic opening of a calcified valve; and b. An aortic velocity 5.0 m/second or greater, or Mean Pressure Gradient (ΔPmean) of 60 mmHg or higher.
    5. Patient is apparently asymptomatic with severe AS (stage C1) with All of the following: a. A calcified aortic valve; and b. An aortic velocity of 4.0 m/second to 4.9 m/second, or Mean Pressure Gradient (ΔPmean) of 40 mmHg to 59 mmHg; and c.
|   | An exercise test demonstrating decreased exercise tolerance, or a fall in systolic Blood Pressure (BP).  
|   | 6. Patient is symptomatic with low-flow/low-gradient severe AS with a reduced Left Ventricular Ejection Fraction (LVEF) (stages D2) with All of the following: a. A calcified aortic valve with reduced systolic opening; and b. A resting valve area of 1.0 cm² or less; and c. An aortic velocity less than 4.0 m/second, or a Mean Pressure Gradient (Δ Pmean) of less than 40 mmHg; and d. LVEF less than 50%; and e. A low-dose dobutamine stress study shows an aortic velocity of 4.0 m/second or greater, or a Mean Pressure Gradient (Δ Pmean) of 40 mmHg or higher, with a valve area of 1.0 cm² or less, at Any dobutamine dose.  
|   | 7. Patient is symptomatic with low-flow/low-gradient severe AS (stage D3) with a Left Ventricular Ejection Fraction (LVEF) of 50% or greater, a calcified aortic valve with significantly reduced leaflet motion, and a valve area of 1.0 cm² or less, Only if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms and data recorded when the patient is normotensive (systolic BP <140 mmHg) indicate All of the following: a. An aortic velocity of less than 4.0 m/second, or a Mean Pressure Gradient (Δ Pmean) of less than 40 mmHg; and b. A stroke volume index less than 35 mL/m²; and c. An indexed valve area of 0.6 cm²/m² or less.  
|   | 8. Patient is asymptomatic with severe AS (stage C1), with an aortic velocity of 4.0 m/second or greater, or a Mean Pressure Gradient (Δ Pmean) of 40 mmHg or higher, if the patient is at low surgical risk, and serial testing shows an increase in aortic velocity of 0.3 m/second or greater, per year.  
|   | 9. TAVR is may also be considered medically reasonable and necessary for patients with moderate AS (stage B) with an aortic velocity between 3.0 m/second and 3.9 m/second, or a Mean Pressure Gradient (Δ Pmean) between 20 mmHg and 39 mmHg, who are undergoing cardiac surgery for other indications.  
|   | - Added New *Note 1: For further details on the stages of Aortic Stenosis (AS), according to the American Heart Association (AHA) & the American College of Cardiology (ACC), please refer to Appendix A, at the end of this medical policy.  
|   | - Added New **Note 2: The Society of Thoracic Surgeons (STS)’s Risk Calculator, which includes the Predicted Risk of Mortality (i.e., PROM) Score, allows a user to calculate a patient’s risk of mortality and morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity (STS, 2014). To access the STS Risk Calculator, please refer to: Online STS Risk Calculator.  
|   | - Added New ***Note 3: Significant Frailty is defined, as per the American Heart Association & the American College of Cardiology (AHA/ACC, 2014), as a moderate-to-severe degree of frailty, in which the patient is unable to perform two or more (≥ 2) of the following Daily Life Activities (DLA): Feeding, Bathing, Dressing, Transferring, Toileting, Urinary incontinence, and/or Ambulation. Significant frailty may also include, as per the American Association for Thoracic Surgery (AATS, 2013), the presence of Any of the following criteria: a. Slowness; or b. Weakness; or c. Exhaustion; or d. Wasting & malnutrition; or e. Poor endurance & inactivity; or f. Loss of independence; or g. g. 5 m walking time or Grip strength, which may be variable with respect to age and gender without validated scientific thresholds; or h. BMI<20 kg/m² and/or weight loss 5 kg/year; or i. Serum albumin<3.5 g/dL; or j. Cognitive impairment or dementia.  
|   | - Added New ****Note 4: In the context of this medical policy, TAVR refers to Transcatheter Aortic Valve Replacement, which is a treatment option for severe AS that involves the implantation of an artificial valve through a small incision in the femoral artery, with the aim of improving blood flow and reducing symptoms.
To new part II added: Medical Card System, Inc. (MCS) will consider medically necessary the use of Transcatheter Aortic Valve Replacement (TAVR), for the Classicare Line of Business (LOB), for the treatment of symptomatic aortic valve stenosis, under the medical criteria established by the: Medicare National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32). Please refer to aforementioned NCD for further details.

Added new Note 4: In order to validate that the patient is properly enrolled in a CMS approved Clinical Trial, please refer to: Centers for Medicare & Medicaid (CMS) Coverage with Evidence Development – List of All Approved Studies.

Added new Note 5: In order to validate which hospitals are within the Participant Directory of the National Cardiovascular Data Registry® (NCDR), in association with the Society of Thoracic Surgeons (STS) & the American College of Cardiology (ACC), for Transcatheter Valve Therapy (TVT), please refer to: STS/ACC TVT Registry™.

To the Limitations Section:
- Separated from the Contraindications Section.
- Deleted: For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies. The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS.
- Revised and modified #1 as to read: TAVR is Not medically covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the Aortic Stenosis (Aortic Stenosis).
- Added New Limitation #2: TAVR Must be done using a U.S. Food & Drug Administration (FDA) approved device (i.e., Edwards SAPIEN, Edwards SAPIEN XT, and/or Medtronic’s CoreValve).
- Added New Limitation #3: For patients in whom TAVR is being considered, a Heart Valve Team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in Ventricular Heart Disease (VHD), cardiac imaging, interventional cardiology, cardiac anesthesia, and cardiac surgery should collaborate to provide optimal patient care.

To the Contraindications Section:
- Added: 1. The Transcatheter Heart Valve (THV) & delivery systems are contraindicated in patients who exhibit Any of the following conditions: a. Patient cannot tolerate an anticoagulation/antiplatelet regimen; or b. Presence of active bacterial endocarditis or other active infections; or c. Known hypersensitivity to Nitinol (Titanium or Nickel); or d. Known hypersensitivity to contrast media, which cannot be adequately pre-medicated; or e. Preexisting mechanical heart valve in aortic position.

To the Coding Information:
- Clear distinction was made for Lines of Business (LOB): Commercial & Classicare (Advantage).
- Deleted CPT Codes: 0256T, 0257T, 0258T, 0259T, & 0318T.
- Added New CPT Code: 33366.
- Restructured Modifiers Section, and revised & modified descriptions for modifiers: Q0 & -62.
- Deleted: MODIFIERS 62: As stipulated in the NCD Manual and the CMS "Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N)" the NCD requires an interventional cardiologist and a cardiothoracic surgeon to
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Notes</th>
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<tbody>
<tr>
<td>December 9, 2014</td>
<td>Revised</td>
<td>The MCS Medical Advisory Committee (MAC) revised and approved 2014 changes done to medical policy on December 9, 2014.</td>
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</table>
| November 23, 2015   | Revised    | To the coding section:  
- Eliminate ICD-9 codes since they are no longer valid for diagnosis classification.  
- Add new section of ICD-10 codes which are the valid diagnosis classification since October 1, 2015. |
| June 13, 2016       | Revised    | To the Coding Section:  
- New ICD-10 codes I08.0, T82.01x+, T82.03x+, T82.857+ and 245.09 were added to the Policy.  
- ICD-10 code I08.8 was deleted from the Policy.  
To the References Section:  
- References # 12, 14, 15, 16, 17, and 18 were deleted from the Policy.  
- New Reference #20 was added to the Policy. |
### Appendix A: Stages of Aortic Stenosis (AS) (AHA/ACC, 2014)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Anatomy</th>
<th>Valve Hemodynamics</th>
<th>Hemodynamics Consequences</th>
<th>Symptoms</th>
</tr>
</thead>
</table>
| A     | At risk of AS | • Bicuspid aortic valve (or other congenital valve anomaly).  
• Aortic valve sclerosis. | • Aortic $V_{\text{max}} < 2 \text{ m/s.}$ | • None. | • None. |
| B     | Progressive AS | • Mild-to-moderate leaflet calcification of a bicuspid or trileaflet valve with some reduction in systolic motion;  
• Rheumatic valve changes with commissural fusion. | • Mild AS: Aortic $V_{\text{max}} = 2.0 – 2.9 \text{ m/s, or mean } \Delta P < 20 \text{mmHg.}$  
• Moderate AS: Aortic $V_{\text{max}} = 3.0 – 3.9 \text{ m/s, or mean } \Delta P = 20-39 \text{mmHg.}$ | • Early LV diastolic dysfunction may be present.  
• Normal LVEF. | • None. |
| C: Asymptomatic Severe AS | | | | |
| C1    | Asymptomatic Severe AS | • Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening. | • Aortic $V_{\text{max}} \geq 4 \text{ m/s, or mean } \Delta P \geq 40 \text{mmHg.}$  
• AVA typically is $\leq 1.0 \text{ cm}^2$ (or AVAi $\leq 0.6 \text{ cm}^2/m^2$).  
• Very severe AS is an aortic $V_{\text{max}} \geq 5 \text{ m/s, or mean } \Delta P \geq 60 \text{mmHg.}$ | • LV diastolic dysfunction.  
• Mild LV Hypertrophy.  
• Normal LVEF. | • None: Exercise testing is reasonable to confirm symptom status. |
| C2    | Asymptomatic severe AS with LV dysfunction | • Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening. | • Aortic $V_{\text{max}} \geq 4 \text{ m/s, or mean } \Delta P \geq 40 \text{mmHg.}$  
• AVA typically $\leq 1.0 \text{ cm}^2$ (or AVAi $\leq 0.6 \text{ cm}^2/m^2$). | • LVEF $<50\%$. | • None. |
| D: Symptomatic severe AS | | | | |
| D1    | Symptomatic severe high-gradient AS | • Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening. | • Aortic $V_{\text{max}} \geq 4 \text{ m/s, or mean } \Delta P \geq 40 \text{mmHg.}$  
• AVA typically $\leq 1.0 \text{ cm}^2$ (or AVAi $\leq 0.6 \text{ cm}^2/m^2$), but may be larger with | • LV diastolic dysfunction.  
• LV hypertrophy.  
• Pulmonary hypertension may be | • Exertional dyspnea or decreased exercise tolerance  
• Exertional |
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<tr>
<td><strong>D2</strong></td>
<td>Symptomatic severe low flow/low-gradient AS with reduced LVEF</td>
<td>• Severe leaflet calcification with severely reduced leaflet motion.</td>
<td>• AVA ≤ 1.0 cm² with resting Aortic $V_{\text{max}} &lt; 4$ m/s, or mean $\Delta P &lt; 40$mmHg.  • Dobutamine stress echocardiography shows AVA ≤ 1.0 cm² with $V_{\text{max}} ≥ 4$ m/s at any flow rate.</td>
<td>• LV diastolic dysfunction.  • LV hypertrophy.  • LVEF &lt;50%.  • HF.  • Angina.  • Syncope or pre-syncope.</td>
</tr>
<tr>
<td><strong>D3</strong></td>
<td>Symptomatic severe low-gradient AS with normal LVEF, or paradoxical low-flow severe AS</td>
<td>• Severe leaflet calcification with severely reduced leaflet motion.</td>
<td>• AVA ≤ 1.0 cm² with Aortic $V_{\text{max}} &lt; 4$ m/s, or mean $\Delta P &lt; 40$mmHg.  • Indexed AVA ≤ 0.6 cm²/m² and  • Stroke volume index &lt;35 mL/m².  • Measured when patient is normotensive (systolic BP &lt;140 mmHg)</td>
<td>• Increased LV relative wall thickness.  • Small LV with low stroke volume.  • Restrictive diastolic filling.  • LVEF ≥ 50%.  • HF.  • Angina.  • Syncope or pre-syncope.</td>
</tr>
</tbody>
</table>

AR indicates Aortic Regurgitation; AS= Aortic Stenosis; AVA= Aortic Valve Area; AVAi= Aortic Valve Area indexed to body surface area; BP= Blood Pressure; HF= Heart Failure; LV= Left Ventricular; LVEF= Left Ventricular Ejection Fraction; $\Delta P$= pressure gradient; and $V_{\text{max}}$= Maximum Aortic Velocity.