Transcatheter Aortic Valve Repair (TAVR)

National Coverage Determination (NCD) Background

- May 1, 2012: Effective date for initial NCD for Transcatheter Aortic Valve Replacement (TAVR) (20.32).
- June 21, 2019: Decision Memo for TAVR (CAG-00430R) published making updates to May 2012 NCD.

Indications and Limitations of Coverage

Note, the following indications and limitations of coverage are from the updated June 21, 2019 Decision Memo. The Centers for Medicare & Medicaid Services (CMS) will cover Transcatheter Aortic Valve Replacement (TAVR) for the **treatment of symptomatic aortic valve stenosis** through Coverage with Evidence Development (CED).

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when **all of the following conditions are met:**

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
2. The **patient (preoperatively and postoperatively) is under the care of a heart team**: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. **The heart team includes the following**:
    a. **Cardiac surgeon and an interventional cardiologist** experienced in the care and treatment of aortic stenosis who have:
        i. **independently examined the patient face-to-face**, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
        ii. documented and made available to the other heart team members the rationale for their clinical judgment.
    b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) **must jointly participate in the intra-operative technical aspects of TAVR.**
4. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
    a. On-site heart valve surgery and interventional cardiology programs,
    b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
    c. Appropriate volume requirements per the applicable qualifications below:

There are two sets of qualifications; the first for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

For **Hospitals without TAVR Experience**, the hospital must have the following:

d. ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation, and;
e. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
f. ≥ 2 physicians with cardiac surgery privileges, and;
g. ≥ 1 physician with interventional cardiology privileges, and;
h. ≥ 300 percutaneous coronary interventions (PCIs) per year.

To **begin a TAVR program** for **heart teams without TAVR experience,** the heart team must include:

i. Cardiovascular surgeon with:
    i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and,
j. Interventional cardiologist with:
    i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and,
    ii. Device-specific training as required by the manufacturer.

For **hospital programs with TAVR experience, t**he hospital program must maintain the following:

k. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or,
l. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and,
m. ≥ 2 physicians with cardiac surgery privileges; and,
n. ≥ 1 physician with interventional cardiology privileges, and
o. ≥300 percutaneous coronary interventions (PCIs) per year; and

5. The heart team and hospital participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56.
6. The registry shall collect all data necessary and have a written executable analysis plan in place to address questions outlined in the Decision Memo

B. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all elements listed in this section of the NCD.

The TAVR Decision Memos, Registry Approvals and Clinical Study Approvals are posted on the CMS CED website at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html.

NCD 20.32 Nationally Non-Covered Indications **TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.**

Shared Decision Making for TAVR Procedure

A Shared Decision Making encounter is not a requirement in the NCD. However, CMS did note in the June 2019 Final Decision Memo that *"we strongly encourage standardized decision aids or tools [the National Quality Forum (NQF) has published standards for decision aids (www.qualityforum.org/Projects/c-d/Decision_Aids/Final_Report.aspx)] to facilitate the decision making process between a patient and physician and will be monitoring this space closely."*

A Decision Aid is available on the American College of Cardiology's CardioSmart website at https://www.cardiosmart.org/SDM/Decision-Aids/Find-Decision-Aids/Aortic-Stenosis.

Hospital Inpatient Only Procedure

The TAVR procedure is on the Medicare "Inpatient-Only" Procedure (IPO) List and is not an approved procedure in the outpatient hospital setting for Medicare beneficiaries. The Medicare IPO list defines services that support an inpatient admission and Part A payment as appropriate, regardless of the expected length of stay. CMS has directed MACs to approve these cases so long as other requirements (i.e., NCD indications and limitations of coverage) are met.

ICD-10 Procedure and Diagnosis Codes, Claims Requirements and MS-DRG Assignment for TAVR

This procedure is covered under Coverage with Evidence Development (CED). This means the claims must include a secondary diagnosis code, condition code, and value code related to the clinical trial/registry.

- **ICD-10 Procedure Code(s) (one of the following):**
  - 02RF37Z (Replacement of Aortic Valve with Autologous Tissue Substitute, Percutaneous Approach),
  - 02RF38Z (Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach),
  - 02RF3JZ (Replacement of Aortic Valve with Synthetic Substitute, Percutaneous Approach),
  - 02RF3KZ (Replacement of Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Approach),
  - 02RF37H (Replacement of Aortic Valve with Autologous Tissue Substitute, Transapical, Percutaneous Approach),
  - 02RF38H (Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach),
  - 02RF3JH (Replacement of Aortic Valve with Synthetic Substitute, Transapical, Percutaneous Approach), and
  - 02RF3KH (Replacement of Aortic Valve with Nonautologous Tissue Substitute, Transapical, Percutaneous Approach)
- **Covered Primary ICD-10 Diagnosis Code (One of the following):**
  - I35.0 Non-rheumatic aortic (valve) stenosis
  - T82.222A (Displacement of biological heart valve graft, initial encounter)
    - Code for when a previously placed valve was malpositioned or became displaced
  - T82.857A (Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter)
    - Code for when the previously placed valve developed stenosis prematurely

    - T82.223A (Leakage of biological heart valve graft, initial encounter)
        - Code for when the previously placed valve developed regurgitation prematurely
    - Z45.09 (Encounter for adjustment and management of other cardiac device)
- Secondary Diagnosis code – Z00.6 – Encounter for examination for normal comparison and control in clinical research program.
- Condition Code 30 – Qualified Clinical Trial
- Value Code D4 and corresponding 8-digit clinical trial number (Clinical trial and/or registry numbers can be found on the Medicare's CED website.
- MS-DRG Assignment:
    - 266: Endovascular Cardiac Valve Replacement with MCC, or
    - 267: Endovascular Cardiac Valve Replacement without MCC

How to Avoid Denials for Inpatient Transcatheter Aortic Valve Replacement (TAVR) Services

In August 2019, Palmetto GBA, the Medicare Administrative Contractor (MAC) for Jurisdiction J (AL, GA, and TN) posted an article on their website regarding CERT denials of inpatient claims for TAVR procedures. The following two key reasons for denials were included in the article:

- Missing documentation to support the need for the TAVR procedure. Reminder, CMS covers this procedure when the patient has symptomatic aortic stenosis.
- The submitted medical records were missing evidence that two cardiac surgeons had independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery. Both surgeons must document the rationale for their clinical judgment and that the rationale was available to the heart team.

  Note: The requirement has changed from two cardiac surgeons independently examining the patient to a cardiac surgeon and an interventional cardiologist with the release of the June 2019 Decision Memo.

New-Technology Add-On Payment for FY 2020

Sentinel® Cerebral Protection System is an embolic protection device used to capture and remove thrombus and debris during a TAVR procedure. For FY 2020 (effective October 1, 2019), this system will continue to be considered a new technology available for an add-on payment (maximum amount $1,820).

Steps to follow if your hospital is using this device:

- Ensure there is documentation in the medical record indicating the system was used, and
- Educate your Coding staff to look for this documentation so they can code the new technology code (X2A5312: Cerebral Embolic Filtration, dual filter in innominate artery and left common carotid artery percutaneous approach).

Disclaimer: This material was compiled to share information. MMP is not offering legal advice. This material was current at the time it was compiled. Every reasonable effort has been taken to ensure the information is accurate and useful.

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