Centers for Medicare and Medicaid Services

National Coverage of Transcatheter Valve Technologies

December 2015

National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32)

- Effective date 5/1/2012
- Covered indications are coverage with evidence development (CED)
  - FDA approved indications
  - Non-FDA approved indications in a clinical study
  - TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

FDA approved indications

- 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. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

FDA approved indications

3. 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.

TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

- On-site heart valve surgery program,
- Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
- Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
- Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
- Appropriate volume requirements per the applicable qualifications below.

FDA approved indications

3, continued

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

- Qualifications to begin a TAVR program for hospitals without TAVR experience:
- The hospital program must have the following:
  - ≥ 50 total AVRs in the previous year prior to TAVR, including . 10 high-risk patients, and;
  - ≥ 2 physicians with cardiac surgery privileges, and;
  - ≥ 1000 catheterizations per year, including . 400 percutaneous coronary interventions (PCIs) per year.

FDA approved indications

3, continued

Qualifications to begin a TAVR program for heart teams without TAVR experience:

- The heart team must include:
  - Cardiovascular surgeon with:
    - ≥ 100 career AVRs including 10 high-risk patients; or,
    - ≥ 25 AVRs in one year; or,
    - ≥ 50 AVRs in 2 years; and
      which include at least 20 AVRs in the last year prior to TAVR initiation; and,
  - Interventional cardiologist with:
    - i. Professional experience with 100 structural heart disease procedures lifetime; or,
    - ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and,
  - Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and,
  - Device-specific training as required by the manufacturer.

FDA approved indications

3, continued

Qualifications for hospital programs with TAVR experience:

– The hospital program must maintain the following:

- ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and,
- ≥ 2 physicians with cardiac surgery privileges; and,
- ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

FDA approved indications

3, continued

Qualifications for heart teams with TAVR experience:

– The heart team must include:

- cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:
  - ≥ 20 TAVR procedures in the prior year, or,
  - ≥ 40 TAVR procedures in the prior 2 years; and,
- Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

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FDA approved indications

4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

5. The heart team and hospital are 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. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

- Stroke;
- All cause mortality;
- Transient Ischemic Attacks (TIAs);
- Major vascular events;
- Acute kidney injury;
- Repeat aortic valve procedures;
- Quality of Life (QoL).

FDA approved indications

5, continued.

- The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):
  - When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
  - How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
  - What is the long term (5 year) durability of the device?
  - What are the long term (5 year) outcomes and adverse events?
  - How do the demographics of registry patients compare to the pivotal studies?

Not expressly listed as an FDA indication

TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following.

1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:
    - What is the incidence of stroke?
    - What is the rate of all cause mortality?
    - What is the incidence of transient ischemic attacks (TIAs)?
    - What is the incidence of major vascular events?
    - What is the incidence of acute kidney injury?
    - What is the incidence of repeat aortic valve procedures?

Not expressly listed as an FDA indication

3. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56. In particular, the informed consent includes a straightforward explanation of the reported increased risks of stroke and vascular complications that have been published for TAVR.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed as Medicare coverage requirements.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Not expressly listed as an FDA indication

- 4. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

National Coverage Determination (NCD) for Transcatheter Mitral Valve Repair (TMVR) (20.33)

- Effective date 8/7/2014
- Covered indications are coverage with evidence development (CED)
  - FDA approved indications
  - Non-FDA approved indications in a RCT
  - TMVR is non-covered for the treatment of MR when not furnished under CED . TMVR used for the treatment of any non-MR indications are non-covered.

FDA approved indication

Treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication and when all of the following conditions are met:

- 1. The procedure is furnished with a complete TMVR system that has received FDA premarket approval (PMA) for that system's FDA-approved indication.
- 2. Both a cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient face-to-face and evaluated the patient's suitability for mitral valve surgery and determination of prohibitive risk; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

FDA approved indication

3. The patient (pre-operatively and post-operatively) 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.

- TMVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
- a. On-site active valvular heart disease surgical program with >2 hospital-based cardiothoracic surgeons experienced in valvular surgery;
- b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering catheterization laboratory-quality imaging,
- c. Non-invasive imaging expertise including transthoracic/transesophageal/3D echocardiography, vascular studies, and cardiac CT studies;
- d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
- e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;
- f. Adequate outpatient clinical care facilities
- g. Appropriate volume requirements per the applicable qualifications below.

FDA approved indication

4. The heart team's interventional cardiologist or a cardiothoracic surgeon must perform the TMVR. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TMVR 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 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient-, practitioner-, and facility-level variables that predict each of these outcomes:

- All-cause mortality;
- Stroke;
- Repeat mitral valve surgery or other mitral procedures;
- Worsening MR;
- Transient ischemic events (TIAs);
- Major vascular events;
- Renal complications;
- Functional capacity;
- Quality of Life (QoL).

FDA approved indication

5, continued

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
- What is the long-term (.5 year) durability of the device?
- What are the long-term (.5 year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Not expressly listed as an FDA-approved indication

TMVR for MR uses that are not expressly listed as an FDA-approved indication when performed within an FDA-approved randomized controlled trial that fulfills all of the following:

1. TMVR must be performed by an interventional cardiologist or a cardiac surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

2. As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up:

- What is the rate of all-cause mortality in the group randomized to TMVR compared to the patients randomized to control (surgical repair, optimal medical therapy, or other specified control group)?
- What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?
- .What is the rate of severe MR in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?

Not expressly listed as an FDA-approved indication

3. The randomized controlled trial must address all of the following questions at one year post- procedure:

- What is the incidence of stroke?
- What is the incidence of TIAs?
- What is the incidence of major vascular events?
- What is the incidence of renal complications?
- What is the incidence of worsening MR?
- What is the patient's post-TMVR QoL?
- What is the patient's post-TMVR functional capacity?

Not expressly listed as an FDA-approved indication

- The CMS-approved clinical trials and registries must adhere to the following standards of scientific integrity and relevance to the Medicare population:
- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.
- h. The research study has a written protocol that clearly addresses, or incorporates by reference; the standards listed as Medicare coverage requirements.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

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