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National Coverage Determination 20.37: Transcatheter Tricuspid Valve Replacement

Related CR Release Date: July 31, 2025	**MLN Matters Number:** MM14149
Effective Date: March 19, 2025	**Related Change Request (CR) Number:** CR 14149
Implementation Date: January 5, 2026	**Related CR Transmittal Number:** R13343CP & R13343NCD

Affected Providers

- Physicians
- Hospitals

Action Needed

Make sure your billing staff knows about national coverage of transcatheter tricuspid valve replacement (TTVR):

- Criteria
- Coverage with evidence development (CED) study criteria
- Claims processing requirements

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Key Updates

Nationally Covered Indications

TTVR treats tricuspid regurgitation (TR). Effective March 19, 2025, CMS covers TTVR for treating symptomatic TR under CED according to the coverage criteria we outline in the Medicare National Coverage Determination (NCD) Manual, Chapter 1, section 20.37.

Patient Criteria

Patients must have symptomatic TR despite optimal medical therapy, and their heart team must consider tricuspid valve replacement as an appropriate treatment.

Physician Criteria

The patient is under the care of a heart team (preoperatively and postoperatively), which includes, at a minimum:

- Cardiac surgeon
- Interventional cardiologist
- Cardiologist with training and experience in heart failure management
- Electrophysiologist
- Multi-modality imaging specialist
- Interventional echocardiographer

All the specialists above must have experience caring for and treating TR.

CED Study Criteria

The heart team must provide TTVR items and services in the context of a CMS-approved CED study. Study protocols must:

- Include only those patients who meet the patient criteria in NCD 20.37
- Provide items and services only through practitioners who meet the physician criteria in NCD 20.37
- Include:
  - Primary outcomes of all-cause mortality, hospitalizations, or a composite of these through a minimum of 24 months. For composite outcome measures, physiological, patient-reported, and other relevant health outcomes should be co-directional (all outcomes comprising the composite outcome should demonstrate movement in the same direction). A practitioner on the heart team must individually report each component of a composite outcome.
  - An active comparator.
  - A care management plan that includes the experience and role of each member of the heart team described in NCD 20.37.
  - A design sufficient for subgroup analyses by:
    - Age
    - Sex
    - Race and ethnicity
    - Practitioner- and facility-level variables that predict the primary outcome of the study
    - Left ventricular ejection fraction (by guideline-defined subgroups)
    - Previous tricuspid surgery or intervention
    - Severe aortic or mitral stenosis or regurgitation
    - Patients with chronic kidney disease
    - Patients with indwelling cardiac implantable electronic devices

CMS-approved CED studies must adhere to the scientific standards (criteria 1–17) identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in section VI of our CED guidance document and CR 14149.

Note: Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that we determine meet all the criteria and standards identified.

Other Uses of TTVR

- We don't cover TTVR for patients outside of a CMS-approved study
- Nothing in this NCD would preclude coverage of TTVR through NCD 310.1 (Clinical Trial Policy) or through the investigational device exemption policy

Claims Processing Requirements

Bill the following procedure codes for TTVR:

- ICD-10-PCS code X2RJ3RA — Replacement of Tricuspid Valve with Multi-plane Flex Technology Bioprosthetic Valve, Percutaneous Approach, New Technology Group 10
- ICD-10-PCS code 02RJ38Z — Replacement of Tricuspid Valve with Zooplastic Tissue, Percutaneous Approach
- CPT code 0646T — Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed

Submit claims for TTVR with 1 of these ICD-10-CM diagnosis codes as principal diagnosis code — I07.1, I07.2, I08.1, I08.2, I08.3, I36.1, I36.2, or Q22.8 — **and** Z00.6 as other diagnosis code.

Professional Claims

We cover claims for TTVR in a clinical research study when billed with:

- HCPCS code 0646T
- The 8-digit clinical trial identifier number
- Modifier Q0 — Investigational clinical service provided in a clinical research study that's in an approved clinical research study
- Appropriate ICD-10-CM principal diagnosis code and ICD-10-CM diagnosis code Z00.6 as other diagnosis code

Institutional Claims

Inpatient hospitals must bill for TTVR on type of bill (TOB) 11X. We cover claims for TTVR when billed with:

- ICD-10-PCS code X2RJ3RA or 02RJ38Z
- Condition code 30 — Qualified clinical trial
- Value code D4 — Clinical trial number (8-digit number)

If you provide TTVR to a Medicare Advantage (MA) plan patient, you must also report condition code 04. MA organizations are responsible for payment.

Your Medicare Administrative Contractor (MAC) will return any TTVR claims you submitted with the wrong TOB; claims without the appropriate ICD-10 diagnosis code, condition code, or value code; or claims not including the clinical trial number. If you perform other procedures at the same time as TTVR, we'll apply our current payment guidelines to those services.

Note: Your MAC won't search their files for TTVR claims processed with dates of service from March 19, 2025 – January 5, 2026; however, they'll adjust any claims that you bring to their attention.

More Information

We issued CR 14149 to your MAC as the official instruction for this change. The CR is in 2 transmittals:

- R13343CP adds section 413 to the Medicare Claims Processing Manual, Chapter 32
- R13343NCD adds section 20.37 to the Medicare NCD Manual, Chapter 1, Part 1

For more information, find your MAC's website.

Document History

Date of Change	Description
August 1, 2025	Initial article released.