Edwards EVOQUE
Tricuspid Valve
Replacement System

# REVOLUTIONARY

is the first transcatheter tricuspid valve replacement system

## 2026 Physician & Facility Billing Guide

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# EVOQUE tricuspid valve replacement system

**Indication**

The EVOQUE tricuspid valve replacement system is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite being treated optimally with medical therapy for whom tricuspid valve replacement is deemed appropriate by a Heart Team.

# Physician Services

Physicians use Current Procedural Terminology (CPT) codes to bill for procedures and services. Category I CPT codes are assigned unique relative value units (RVUs), which are used to determine payment by the Centers for Medicare and Medicaid Services (CMS).

A Category III CPT code was created to describe transcatheter tricuspid valve replacement/implantation (TTVR/I). Category III CPT codes do not have assigned RVUs therefore no national payment rate is established, and payment is based on carrier discretion.

Implantation of the EVOQUE system requires several sequenced procedures. Like many technologies, the procedures required to use them depend on the patient's clinical anatomy and comorbidities.

Furthermore, physicians have surgical technique preferences. The following table details CPT coding options for services associated with the implantation of the EVOQUE valve.

**CPT Codes[1,2]**

| CPT Code | Description | CY2026 Medicare National Physician Payment[3] | CY2026 Facility RVUs[3] |
|---|---|---|---|
| 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 | Based on carrier discretion | RVUs are not assigned |
| 93355 | Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D | $193 | 5.75 |

*CY 2026 payment rates effective January 1, 2026, through December 31, 2026. Payment calculated using the 2026 Qualifying APM Conversion Factor of $33.5675.*

**Additional notes for physician billing (CMS Claims Processing Instructions)[4]**

Medicare will only pay TTVR physician claims for CPT 0646T when billed with the following:

- ICD-10-CM diagnosis codes I07.1, I07.2, I08.1, I08.2, I08.3, I36.1, I36.2, or Q22.8
- ICD-10-CM secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- Place of service 21 (inpatient hospital)
- Modifier -Q0 (zero) signifying CED participation (qualifying registry or qualified clinical study)
- National Clinical Trial (NCT) number **06833476**. The 8-digit NCT number preceded by the two alpha characters "CT" is placed in Field 19 of paper Form CMS-1500 and entered WITHOUT the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4)

**Medicare will return all other claims as not processable.**

### Coding Modifiers for 0646T[1,2]

| Modifier | Notes | Notes |
|---|---|---|
| 62 | Co-Surgeons | Two separate primary surgeons working together |
| 66 | Surgical Team | Supporting documentation must be submitted with the claim to establish medical necessity for a surgical team |
| 80 | Assistant Surgeon | For Physician use only |
| 81 | Minimum Assistant Surgeon | For Physician use only |
| 82 | Assistant Surgeon (when qualified resident surgeon not available) | For Physician use only: The unavailability of a qualified resident surgeon is a prerequisite for use of this modifier |
| AS | Assistant Surgeon (non-physician) | Assistant at surgery services provided by a physician's assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) |

### Procedure coding notes 0646T[1]

**Do NOT Report in conjunction with 0646T:**

- Diagnostic right heart catheterization procedures intrinsic to the valve repair procedure (*see below for further information)
- Temporary pacemaker insertion (33210, 33211)
- Imaging guidance with intracardiac echocardiography (ICE) (+93662)

**The following services are INCLUDED in 0646T:**

- Code 0646T includes vascular access, catheterization, deploying the valve, repositioning the valve delivery device as needed, temporary pacemaker insertion for rapid pacing, and access site closure by any method, when performed.
- Angiography (e.g., peripheral) , radiological supervision and interpretation, intraprocedural roadmapping (eg, contrast injections, fluoroscopy, intracardiac echocardiography) to guide the TTVR right atrial and/or right ventricular angiography (e.g., to assess tricuspid regurgitation for guidance of TTVR), and completion angiography.

**Additional coding notes:**

- Transesophageal echocardiography (93355) performed by a separate operator for guidance of the procedure may be separately reported.
- When transcatheter ventricular support is required in conjunction with TTVI, the procedure may be reported with the appropriate ventricular assist device (VAD) procedure code (33990, 33991, 33992, 33993) or balloon pump insertion code (33967, 33970, 33973).

***Diagnostic right heart catheterization and angiography:**

- Diagnostic right heart catheterization codes (93451, 93453, 93456, 93457, 93460, 93461, 93593, 93594, 93596, 93597) and right atrial/right ventricular angiography code (93566) should not be used with 0646T to report:
  1. Contrast injections, angiography, road mapping, and/or fluoroscopic guidance for the TTVI
  2. Right atrial and/or ventricular angiography to assess or confirm valve positioning and function
  3. Right heart catheterization for hemodynamic measurements before, during, and after TTVI for guidance of TTVI.
- Diagnostic right heart catheterization (93451, 93453, 93456, 93457, 93460, 93461, 93593, 93594, 93596, 93597) and right atrial/right ventricular angiography (93566) performed at the time of TTVI may be separately reportable if:
  1. No prior study is available, and a full diagnostic study is performed, or
  2. A prior study is available, but as documented in the medical record:
     a. There is inadequate visualization of the anatomy and/or pathology, or
     b. The patient's condition with respect to the clinical indication has changed since the prior study, or
     c. There is a clinical change during the procedure that requires new evaluation.
- **For same session/same day diagnostic cardiac catheterization services, report the appropriate diagnostic cardiac catheterization code(s) appended with modifier 59, indicating separate and distinct procedural service from TTVI.**

# Inpatient Hospital

Medicare inpatient hospital reimbursement is based upon the Medicare Severity Diagnostic Related Group (MS-DRG) classification system, which assigns MS-DRGs based on ICD-10-CM diagnoses and ICD-10-PCS procedure codes. This guide is limited to the reporting and billing of the surgical procedure.

All preoperative, postoperative, and follow-up services should be billed according to the service performed in conjunction with standard billing and coding guidelines.

The following details ICD-10-PCS coding and the applicable FY2026 MS-DRG assignment for implantation of the EVOQUE System. The code reported for the procedure must be supported by the medical record documentation.

### ICD-10-PCS Procedure Codes[2,5]

| ICD-10-PCS Procedure Code | Description |
|---|---|
| X2RJ3RA | Replacement of tricuspid valve with multi-plane flex technology bioprosthetic valve, percutaneous approach, new technology group 10 |

*Note: This procedure code should be used to report all EVOQUE valve cases. Do NOT report 02RJ38Z.*

### Medicare Severity Diagnostic Related Groups (MS-DRG)[6]

| MS-DRG | Description | FY2026 Relative Weight | FY2026 Medicare National Unadjusted Base Payment | FY2026 Geometric Mean LOS |
|---|---|---|---|---|
| 266 | Endovascular cardiac valve replacement and supplement procedures with MCC | 6.1284 | $44,595 | 2.5 |
| 267 | Endovascular cardiac valve replacement and supplement procedures without MCC | 4.7608 | $34,643 | 1.3 |

*FY2026 payment rates effective October 1, 2025, through September 30, 2026*

***New Technology Add-on Payment (NTAP)[6]***

*Effective October 1, 2024 and continuing through FY 2026, ICD-10-PCS code X2RJ3RA will reflect cases eligible for NTAP payment for EVOQUE valve procedures. The NTAP calculation will be triggered ONLY if the ICD-10-PCS code **X2RJ3RA** is reported on the claim.*

**Additional notes for inpatient hospital billing (CMS Claims Processing Instructions)[4]**

Medicare will only pay TTVR inpatient hospital claims for ICD-10-PCS code X2RJ3RA when billed with the following:

- Inpatient hospitals must bill for TTVR on type of bill (TOB) 11X
- ICD-10-CM diagnosis codes I07.1, I07.2, I08.1, I08.2, I08.3, I36.1, I36.2, or Q22.8
- ICD-10-CM secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- National Clinical Trial (NCT) number **06833476**. For Form CMS-1450 paper claims, enter the 8-digit NCT number in Field Locators 39-41 (use value code D4). For 8371i electronic claims, enter the 8-digit NCT number in Loop 2300 REF02 (REF01 = P4)
- Value code D4
- Condition code 30

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

**Medicare will return all other claims as not processable.**

# Diagnosis Codes

### ICD-10-CM Diagnosis Codes[4,5]

For Medicare claims processing under the TTVR NCD, claims must include one of the following principal diagnosis codes and Z00.6 as a secondary diagnosis code.

| Principal ICD-10-CM Diagnosis Code | Description |
|---|---|
| I07.1 | Rheumatic tricuspid insufficiency |
| I07.2 | Rheumatic tricuspid stenosis and insufficiency |
| I08.1 | Rheumatic disorders of both mitral and tricuspid valves |
| I08.2 | Rheumatic disorders of both aortic and tricuspid valves |
| I08.3 | Combined rheumatic disorders of mitral, aortic and tricuspid valves |
| I36.1 | Nonrheumatic tricuspid (valve) insufficiency |
| I36.2 | Nonrheumatic tricuspid (valve) stenosis with insufficiency |
| Q22.8 | Other congenital malformations of tricuspid valve |

| Secondary ICD-10-CM Diagnosis Code | Description |
|---|---|
| Z00.6 | Encounter for examination for normal comparison and control in clinical research program |

### Revenue Code

| Revenue Code | Description |
|---|---|
| 278 | Medical/surgical supplies and devices; other implants |

# Medicare Coverage

Effective March 19, 2025 , the Centers for Medicare and Medicaid Services (CMS) covers TTVR/I for treating symptomatic TR under CED according to the coverage criteria outlined in the Medicare National Coverage Determination (NCD) Manual, Chapter 1, section 20.37.

The complete NCD may be found at the following link: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=314. Please see the TTVR NCD Checklist for additional information.

# Outpatient Hospital

Hospitals use CPT codes when billing for procedures in the outpatient setting. Medicare pays for many procedures performed in the outpatient hospital setting under a prospective payment system. However, Medicare does not reimburse for outpatient services they do not believe may be safely done in the outpatient hospital setting for their patient population.

CMS has designated transcatheter heart valve procedures to be inpatient-only procedures, meaning the hospital will not receive payment from Medicare should it be performed in an outpatient setting. HCPCS C-Codes are only used for Medicare hospital outpatient claims, therefore a HCPCS C-Code does not exist for Edwards Transcatheter Valve Systems.

# Commercial Payer

Each non-Medicare payer has its own methodology for paying providers. Check with the patient's payer medical policy and your payer contracts to determine potential payments and if the procedure will be covered. The best way to determine if the procedure will be covered is to submit a preauthorization/pre-determination request to the patient's payer prior to scheduling the surgery.

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# Important Safety Information

**Edwards EVOQUE Tricuspid Valve Replacement System**

**Indications:** The EVOQUE tricuspid valve replacement system is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite being treated optimally with medical therapy for whom tricuspid valve replacement is deemed appropriate by a Heart Team.

**Contraindications:** The EVOQUE valve is contraindicated in patients who cannot tolerate an anticoagulation/ antiplatelet regimen, who have active bacterial endocarditis or other active infections, or who have untreatable hypersensitivity to nitinol alloys (nickel and titanium).

**Warnings:** The EVOQUE valve, delivery system, loading system, dilator kit, are designed, intended, and distributed as STERILE and for single use only. The positioning accessories are available in single use, nonsterile, disposable as well as reusable configurations, please refer to the device information and ensure the device is used as intended. Do not resterilize or reuse any of the single use devices. There are no data to support the sterility, nonpyrogenicity, or functionality of the single use devices after reprocessing. Ensure the correct valve size is selected. Implantation of the improper size (i.e., undersizing or oversizing) may lead to paravalvular leak (PVL), migration, embolization, and/ or annular damage. Patients with previously-implanted devices (e.g., IVC filter) should be carefully assessed prior to insertion of the delivery system to avoid potential damage to vasculature or a previously-implanted device. Patients with pre-existing cardiac leads should be carefully assessed prior to implantation to avoid potential adverse interaction between devices. Care should be taken when implanting cardiac leads after EVOQUE valve implantation to avoid potential adverse interaction between the devices. Patients implanted with the EVOQUE valve should be maintained on anticoagulant/ antiplatelet therapy as determined by their physicians in accordance with current guidelines, to minimize the risk of valve thrombosis or thromboembolic events. There are no data to support device safety and performance if the patient has: echocardiographic evidence of severe right ventricular dysfunction; pulmonary arterial systolic pressure (PASP) > 70 mmHg by echo Doppler; a trans-tricuspid pacemaker or defibrillator lead that has been implanted in the RV within the last 3 months; or dependency on a transtricuspid pacemaker without alternative pacing options.

**Precautions:** Prior to use, the patient's eligibility depends on the anatomic conditions based on CT scan. It is advised that a multi-disciplinary heart team be of the opinion that EVOQUE valve implantation is preferable to alternative percutaneous device solutions, including minimally-invasive open heart surgery. It is advised that a multi-disciplinary heart team takes into consideration the severity of disease and the chances of reversibility of right heart failure based on a complete hemodynamic assessment. The EVOQUE valve is to be used only with the EVOQUE delivery system and EVOQUE loading system. The procedure should be conducted under appropriate imaging modalities, such as transesophageal echocardiography (TEE), fluoroscopy, and/ or intracardiac echocardiography (ICE). Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. Conduction disturbances may occur before, during, or following implantation of the EVOQUE valve, which may require continuous ECG monitoring before hospital discharge. The risk of conduction disturbances may increase with the 56mm valve size. If a patient has confirmed or suspected conduction disturbances, consider patient monitoring and/or electrophysiology evaluation. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Long-term durability has not been established for the EVOQUE valve. Regular medical follow-up is advised to evaluate EVOQUE valve performance. Implantation of the EVOQUE valve should be postponed in patients with (1) a history of myocardial infarction within one month (30 days) of planned intervention, (2) pulmonary emboli within 3 months (90 days) of planned intervention, (3) cerebrovascular accident (stroke or TIA) within 3 months (90 days) of planned intervention, (4) active upper GI bleeding within 3 months (90 days) prior to procedure requiring transfusion.

**Potential Adverse Events:** Potential adverse events related to standard cardiac catheterization, use of anesthesia, the EVOQUE valve, and the implantation procedure include: death; abnormal lab values; allergic reaction to anesthesia, contrast media, anti-coagulation medication, or device materials; anaphylactic shock; anemia or decreased hemoglobin (Hgb), may require transfusion; aneurysm or pseudoaneurysm; angina or chest pain; arrhythmia – atrial (i.e., atrial fibrillation, supraventricular tachycardia); arrhythmias – ventricular (i.e., ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; bleeding; cardiac arrest; cardiac (heart) failure; cardiac injury, including perforation; cardiac tamponade / pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury, which may require implantation of a pacemaker (temporary or permanent); conversion to open heart surgery; coronary

artery occlusion; damage to or interference with function of pacemaker or implantable cardioverter defibrillator (ICD); edema; electrolyte imbalance; embolization including air, particulate, calcific material, or thrombus; emergent cardiac surgery; endocarditis; esophageal irritation; esophageal perforation or stricture; EVOQUE system component(s) embolization; failure to retrieve any EVOQUE system components; fever; gastrointestinal bleeding; hematoma; hemodynamic compromise; hemolysis / hemolytic anemia; hemorrhage requiring transfusion/surgery; hypertension; hypotension; inflammation; injury to the tricuspid apparatus including chordal damage, rupture, papillary muscle damage; local and systemic infection; mesenteric ischemia or bowel infarction; multi-system organ failure; myocardial infarction; nausea and/or vomiting; nerve injury; neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-emergent reoperation; pain; pannus formation; paralysis; percutaneous valve intervention; peripheral ischemia; permanent disability; pleural effusion; pneumonia; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; rehospitalization; renal failure; respiratory failure, atelectasis – may require prolonged intubation; retroperitoneal bleed; right ventricular outflow tract (RVOT) obstruction; septicemia, sepsis; skin burn, injury, or tissue changes due to exposure to ionizing radiation; stroke; structural deterioration (wear, fracture, calcification, leaflet tear, leaflet thickening, stenosis of implanted device, or new leaflet motion disorder); thromboembolism; transient ischemic attack (TIA); valve dislodgement/embolization; valve endocarditis; valve explant; valve leaflet entrapment; valve malposition; valve migration; valve paravalvular leak (PVL); valve regurgitation (new or worsening tricuspid, aortic, mitral, pulmonary); valve thrombosis; vascular injury or trauma, including dissection or occlusion; vessel spasm ; wound dehiscence, delayed or incomplete healing.

**CAUTION: US law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.**

# References


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2. Not all codes provided are applicable for the clinical scenarios in which Edwards Lifesciences' technologies are used. The provider is responsible for selecting the most appropriate code(s) for the patient's clinical presentation. When diagnostic services are performed, it may be appropriate to add applicable codes according to the service provided following the correct coding guidelines. Services that are considered a component of another procedure may not always be coded and billed separately.
3. Centers for Medicare & Medicaid Services. CY2026 Physician Fee Schedule (MPFS) Final Rule, [CMS-1832-F]. Payments are effective January 1, 2026, through December 31, 2026.
4. Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual; Chapter 32 Billing Requirements for Special Services, Transcatheter Tricuspid Valve Replacement.
5. International Classification of Diseases, 10th Revision, Clinical Modification 2026 ICD-10-CM and PCS Expert for hospitals volume 1, 2 and 3.
6. Centers for Medicare & Medicaid Services. FY2026 Inpatient Prospective Payment System (IPPS) Final Rule [CMS-1833-F]. Payments are effective October 1, 2025, through September 30, 2026.

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