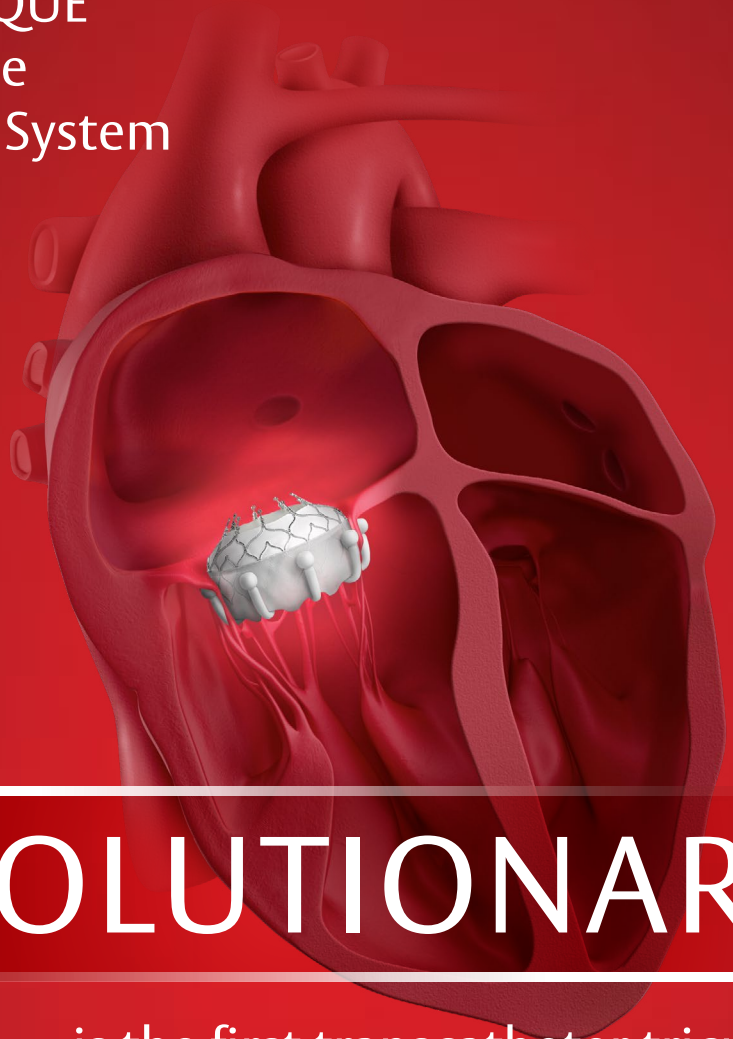
Edwards EVOQUE Tricuspid Valve Replacement System



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2024 Physician and 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. In most cases, 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 new 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 implantation of the EVOQUE valve.

CPT Codes[1,2]

CPT Code	Description	CY2024 Medicare National Physician Payment*[3]	CY2024 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	$219	6.58

** Medicare National Physician Payment amounts for claims with dates of service March 9 through December 31, 2024.*

Coding Modifiers[1,2]

Modifier	Notes
62	Co-Surgeons
66*	Surgical Team
80	Assistant Surgeon
81	Minimum Assistant Surgeon
82	Assistant Surgeon (when qualified resident surgeon not available) (The unavailability of a qualified resident surgeon is a prerequisite for use of this modifier)
AS	Assistant at surgery services provided by a physician's assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS)

Modifiers 80, 81 and 82 are for Physician use only.

**Supporting documentation must be submitted with the claim to establish medical necessity for a surgical team.*

Procedure coding notes 0646T

0646T – Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed

Do NOT Report 0646T in conjunction with:	
33210, 33211	For temporary pacemaker insertion
93451, 93453, 93456, 93457, 93460, 93461, 93503, 93566, 93593, 93594, 93596, 93597	For diagnostic right heart catheterization procedures intrinsic to the valve repair procedure
93662	For imaging guidance with intracardiac echocardiography

The following services are INCLUDED in 0646T:

Code 0646T includes vascular access, catheterization, repositioning the valve delivery device as needed, deploying the valve, temporary pacemaker insertion for rapid pacing (33210), and access site closure by any method, when performed.

Angiography (eg, peripheral), radiological supervision and interpretation, intraprocedural roadmapping (eg, contrast injections, fluoroscopy, intracardiac echocardiography) to guide the transcatheter tricuspid valve implantation/replacement (TTVI), right atrial and/or right ventricular angiography (eg, to assess tricuspid regurgitation for guidance of TTVI), and completion angiography are included in 0646T.

Additional coding notes:

Transesophageal echocardiography (TEE)

Transesophageal echcardiology (93355) performed by a separate operator for guidance of the procedure may be separately reported.

Ventricular assist devices (VAD)

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 FY2024 MS-DRG assignment for implantation of the EVOQUE System. The code reported for the procedure must be supported by the medical record documentation.

Medicare Severity Diagnostic Related Groups (MS-DRG)

MS-DRG	Description	FY2024 Relative Weight[4]	FY2024 Medicare National Unadjusted Base Payment[4]	FY2024 Geometric Mean LOS[4]
266	Endovascular cardiac valve replacement and supplement procedures with MCC	6.2461	$43,733	2.7
267	Endovascular cardiac valve replacement and supplement procedures without MCC	4.8802	$34,169	1.3

FY2024 payment rates effective October 1, 2023- September 30, 2024

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

Potential ICD-10-PCS Procedure Code	Description
02RJ38Z	Replace tricuspid valve with zooplastic tissue, percutaneous approach

ICD-10-CM Diagnosis Codes[5]

Potential ICD-10-CM Diagnosis Code	Description
I07.1	Rheumatic tricuspid insufficiency
I07.2	Rheumatic tricuspid stenosis and insufficiency
I36.1	Nonrheumatic tricuspid (valve) insufficiency
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency

Revenue code

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

Major Complication and Comorbidity Classification (MCC) Complication and Comorbidity Classification (CC)

All primary and secondary diagnoses pertinent to the admission must be clearly identified in the hospital documentation (history & physician examination notes, progress notes, and hospital summary) to facilitate accurate coding and billing.

The following list identifies the top MCC and CC diagnosis codes used for surgical tricuspid valve replacement procedures (STVR) – ICD 10 PCS 02RJ08Z as reported in the MEDPAR data for FY 2022[1].

As the EVOQUE system is the first transcatheter tricuspid valve on the market, the top ICD-10 CM diagnosis codes reflecting MCC and CC diagnosis codes from surgical tricuspid replacement procedures are listed as a reference only. This list is not meant to be directive or all-inclusive and your documentation should reflect the patients' comorbidities and history.

Top 20 Reported MCCs

ICD 10-CM Diagnosis Codes	Classification	Short Description
R570	**MCC**	Cardiogenic shock
J9601	**MCC**	Acute respiratory failure with hypoxia
I5033	**MCC**	Acute on chronic diastolic (congestive) heart failure
N170	**MCC**	Acute kidney failure with tubular necrosis
N186	**MCC**	End stage renal disease
R6521	**MCC**	Severe sepsis with septic shock
I5043	**MCC**	Acute on chronic combined systolic and diastolic heart failure
I330	**MCC**	Acute and subacute infective endocarditis
I5023	**MCC**	Acute on chronic systolic (congestive) heart failure
E43	**MCC**	Unspecified severe protein-calorie malnutrition
J951	**MCC**	Acute pulmonary insufficiency following thoracic surgery
A419	**MCC**	Sepsis, unspecified organism
G9341	**MCC**	Metabolic encephalopathy
J189	**MCC**	Pneumonia, unspecified organism
G928	**MCC**	Other toxic encephalopathy
I2690	**MCC**	Septic pulmonary embolism without acute cor pulmonale
K7200	**MCC**	Acute and subacute hepatic failure without coma
R578	**MCC**	Other shock
J95821	**MCC**	Acute postprocedural respiratory failure
I5021	**MCC**	Acute systolic (congestive) heart failure

Top 20 Reported CCs

ICD 10-CM Diagnosis Codes	Classification	Description
D62	**CC**	Acute posthemorrhagic anemia
N179	**CC**	Acute kidney failure, unspecified
I442	**CC**	Atrioventricular block, complete
I130	**CC**	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
J9811	**CC**	Atelectasis
E871	**CC**	Hypo-osmolality and hyponatremia
D689	**CC**	Coagulation defect, unspecified
I5032	**CC**	Chronic diastolic (congestive) heart failure
I4892	**CC**	Unspecified atrial flutter
E870	**CC**	Hyperosmolality and hypernatremia
J90	**CC**	Pleural effusion, not elsewhere classified
I4821	**CC**	Permanent atrial fibrillation
I4819	**CC**	Other persistent atrial fibrillation
I4820	**CC**	Chronic atrial fibrillation, unspecified
I428	**CC**	Other cardiomyopathies
R188	**CC**	Other ascites
I5022	**CC**	Chronic systolic (congestive) heart failure
N390	**CC**	Urinary tract infection, site not specified
I132	**CC**	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
E440	**CC**	Moderate protein-calorie malnutrition

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. Edwards recommends checking 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.

Important Safety Information

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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 for patients with any of the following conditions: active endocarditis or other active infection requiring antibiotic therapy (oral or intravenous); untreatable hypersensitivity or contraindication to any of the following: all antiplatelets, all anticoagulants, nitinol alloys (nickel and titanium), bovine tissue, glutaraldehyde, contrast media, or transesophageal echocardiography; tricuspid valve anatomy that precludes proper device deployment and functionality based on CT and echocardiographic evaluation. Note: Patient must be able to tolerate at least one antiplatelet medication AND one anticoagulant medication.

Warnings: The EVOQUE valve, delivery system, loading system, dilator kit, and stabilizer are designed, intended, and distributed for STERILE single use only. The base and plate are provided nonsterile for single use only. Do not resterilize or reuse any of the devices. There are no data to support the sterility, nonpyrogenicity, or functionality of the devices after reprocessing. Ensure proper sterile techniques are utilized during the preparation, transfer, and use of the devices. Do not use the valve if the tamper evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. The EVOQUE valve must remain hydrated at all times. The valve cannot be exposed to solutions, antibiotics, or chemicals other than its shipping storage solution and sterile physiologic saline solution. This will help prevent leaflet damage that may impact valve functionality. Keep the EVOQUE valve hydrated with normal saline until ready for implantation. 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 trans-tricuspid 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 9850TDS delivery system and 9850LS 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. 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.

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References

1. Current Procedure Terminology (CPT) 2023 copyright 2022, American Medical Association (AMA). All rights reserved. CPT is a registered trademark of the AMA. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Applicable FARS/DFARS restrictions apply to government use.

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. CY2024 Physician Fee Schedule (MPFS) Final Rule, Correction and Correcting Amendment [CMS-1784-F2-CN]. Payments are effective March 9, 2024, through December 31, 2024.

4. Centers for Medicare & Medicaid Services. FY2024 Inpatient Prospective Payment System (IPPS) Final Rule. Payments are effective October 1, 2023, through September 30, 2024.

5. International Classification of Diseases, 10th Revision, Clinical Modification 2024 ICD-10-CM and PCS Expert for hospitals.

As a member of the Advanced Medical Technology Association ("AdvaMed"), Edwards strictly adheres to the requirements of the AdvaMed Code of Ethics on Interactions with Health Care Professionals. If required by law (e.g., US Sunshine Law), Edwards will disclose the value of this educational item, and Edwards also may publish such information on its website or other public manner in order to provide the public with full disclosure of its financial arrangements with health care professionals.

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