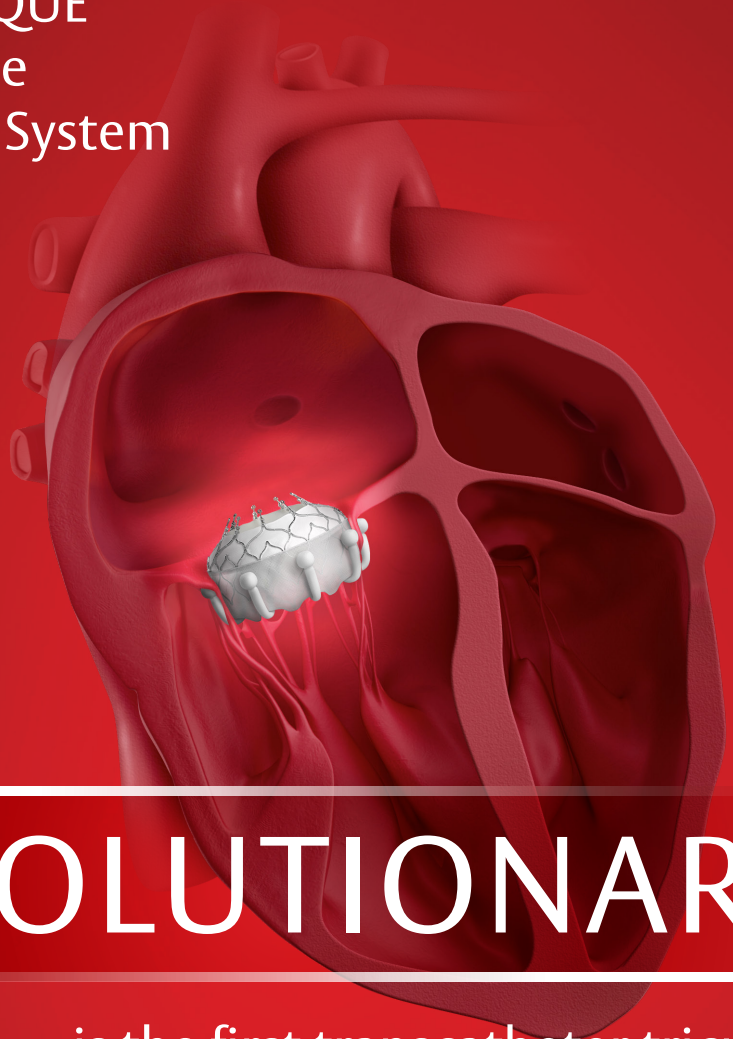
Edwards EVOQUE Tricuspid Valve Replacement System



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2025 NTAP & TTVR NCD Information

2025 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.

Edwards EVOQUE Tricuspid Valve Replacement System

Billing Guide Executive Summary

The 2025 Physician and Facility Billing Guide is intended to provide an overview of the coding and billing requirements for transcatheter tricuspid valve replacement (TTVR). Accurate medical coding ensures claims are processed timely and correctly. Coverage, reimbursement and health economics information provided by Edwards Lifesciences is gathered from third-party sources and presented for illustrative purposes only. For more detailed information, please see the the comprehensive billing guide in the following pages.

Physician Services

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 Current Procedural Terminology (CPT) coding options for services associated with implantation of the EVOQUE valve.

See pages 5-6 for additional references and information regarding physician coding and current national Medicare physician payment rates.[3]

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

Inpatient Hospital

The following details ICD-10-PCS coding and the applicable FY2025 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] and Medicare Severity Diagnostic Related Groups (MS-DRG)

Potential ICD-10-PCS Procedure Code	ICD-10-PCS Description	MS-DRG	MS-DRG Description
X2RJ3RA	**Replacement of tricuspid valve with multi-plane flex technology, bioprosthetic valve, percutaneous approach, new technology group 10**	266	Endovascular cardiac valve replacement and supplement procedures with MCC
		267	Endovascular cardiac valve replacement and supplement procedures without MCC

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

Medicare Severity Diagnostic Related Group (MS-DRG) based on ICD-10-CM diagnoses and ICD-10-PCS procedure codes page 7.

New Technology Add-on Payment (NTAP)

Effective October 1, 2024, new ICD-10-PCS code X2RJ3RA will reflect cases eligible for NTAP payment for EVOQUE valve cases. NTAP will be issued ONLY if the new code, X2RJ3RA (Replacement of tricuspid valve with multi-plane flex technology, bioprosthetic valve, percutaneous approach, new technology group 10) is reported on the claim.

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.

Top ICD-10 diagnosis codes reflecting MCC and CC diagnosis codes from transcatheter tricuspid valve replacement and surgical tricuspid valve procedures can be found on pages 9-10.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS) provides coverage for TTVR for tricuspid regurgitation under a National Coverage Determination (NCD) with Coverage with Evidence Development (CED). The NCD (CAG-00467N) is effective March 19, 2025. This NCD applies to Medicare beneficiaries enrolled in either traditional Medicare or Medicare Advantage. See page 11 for additional details.

Please reach out to the Edwards reimbursement hotline with any questions: **reimbursementsupport@edwards.com or 1 (888) 352-0901.**

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or 1 (888) 352-0901

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). 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 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	CY2025 Medicare National Physician Payment[3]	CY2025 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	$213	6.60

CY 2025 payment rates effective January 1, 2025, through December 31, 2025

Coding Modifiers for 0646T[1,2]

Modifier	Use	Notes
62	Co-Surgeons	If two surgeons (each in a different specialty) are required to perform a specific procedure, each surgeon bills for the procedure with a modifier "-62." Co-surgery also refers to surgical procedures involving two surgeons performing the parts of the procedure simultaneously, i.e., heart transplant or bilateral knee replacements
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 at surgery services provided by a physician's assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS)	

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 (ICE)

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 FY2025 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	FY2025 Relative Weight[4]	FY2025 Medicare National Unadjusted Base Payment[4]	FY2025 Geometric Mean LOS[4]
266	Endovascular cardiac valve replacement and supplement procedures with MCC	5.9908	$42,754	2.6
267	Endovascular cardiac valve replacement and supplement procedures without MCC	4.7047	$33,575	1.3

FY2025 payment rates effective October 1, 2024, through September 30, 2025

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

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

New Technology Add-on Payment (NTAP)

Effective October 1, 2024, new ICD-10-PCS code X2RJ3RA will reflect cases eligible for NTAP payment for EVOQUE valve cases. NTAP will be issued ONLY if the new code, X2RJ3RA (Replacement of tricuspid valve with multi-plane flex technology, bioprosthetic valve, percutaneous approach, new technology group 10) is reported on the claim.

Primary tricuspid valve diagnosis codes

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

Other potential concomitant valvular disease diagnosis codes[5]

Potential ICD-10-CM Diagnosis Code	Description
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
I08.8	Other rheumatic multiple valve diseases
I08.9	Rheumatic multiple valve disease, unspecified
For concomitant nonrheumatic valvular diseases, diagnosis codes are reported for each valve (eg, I36.1 with I35.1, Nonrheumatic aortic (valve) 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 identified the top ICD-10 diagnosis codes reflecting MCC and CC diagnosis codes from transcatheter tricuspid valve replacement (TTVR) and tricuspid valve surgery (TVS) procedures as reported in the MEDPAR data for FY 2023.[6]

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	Short Description	Procedure
I50.33	Acute on chronic diastolic (congestive) heart failure	TTVR / TVS
J96.01	Acute respiratory failure with hypoxia	TVS
R57.0	Cardiogenic shock	TVS
I50.43	Acute on chronic combined systolic and diastolic hrt fail	TTVR / TVS
N17.0	Acute kidney failure with tubular necrosis	TVS
I50.23	Acute on chronic systolic (congestive) heart failure	TTVR / TVS
R57.8	Other shock	TVS
N18.6	End stage renal disease	TVS
J95.1	Acute pulmonary insufficiency following thoracic surgery	TVS
E43	Unspecified severe protein-calorie malnutrition	TVS
J96.02	Acute respiratory failure with hypercapnia	TVS
I33.0	Acute and subacute infective endocarditis	TVS
J18.9	Pneumonia, unspecified organism	TVS
A41.9	Sepsis, unspecified organism	TVS
J69.0	Pneumonitis due to inhalation of food and vomit	TVS
R65.21	Severe sepsis with septic shock	TVS
J98.59	Other diseases of mediastinum, not elsewhere classified	TVS
R57.1	Hypovolemic shock	TVS
G92.8	Other toxic encephalopathy	TVS
J95.821	Acute postprocedural respiratory failure	TVS

Top 20 Reported CCs

ICD 10-CM Diagnosis Codes	Short Description	Procedure
D62	Acute posthemorrhagic anemia	TTVR / TVS
N17.9	Acute kidney failure, unspecified	TTVR / TVS
I13.0	Hyp hrt & chr kdny dis w hrt fail and stg 1-4/unsp chr kdny	TTVR / TVS
J89.11	Atelectasis	TVS
I44.2	Atrioventricular block, complete	TTVR / TVS
E87.1	Hypo-osmolality and hyponatremia	TTVR / TVS
I50.32	Chronic diastolic (congestive) heart failure	TTVR / TVS
I48.92	Unspecified atrial flutter	TTVR / TVS
D68.9	Coagulation defect, unspecified	TVS
E87.20	Acidosis, unspecified	TVS
I48.21	Permanent atrial fibrillation	TTVR / TVS
I48.19	Other persistent atrial fibrillation	TTVR / TVS
I47.20	Ventricular tachycardia, unspecified	TTVR / TVS
J90	Pleural effusion, not elsewhere classified	TVS
R18.8	Other ascites	TTVR / TVS
I42.8	Other cardiomyopathies	TTVR / TVS
I48.20	Chronic atrial fibrillation, unspecified	TTVR / TVS
I50.22	Chronic systolic (congestive) heart failure	TTVR / TVS
Q21.12	Patent foramen ovale	TVS
E44.0	Moderate protein-calorie malnutrition	TVS

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS) provides coverage for TTVR for tricuspid regurgitation under a National Coverage Determination (NCD) with Coverage with Evidence Development (CED).[7] The NCD is effective March 19, 2025. This NCD applies to Medicare beneficiaries enrolled in either traditional Medicare or Medicare Advantage.

TTVR Medicare Coverage Criteria

The procedure is covered for Medicare beneficiaries when furnished according to an FDA market-authorized indication, and all of the following conditions are met:

1. **Patient Criteria:** Despite optimal medical therapy (OMT), patients must have symptomatic tricuspid regurgitation (TR) with tricuspid valve replacement being considered as appropriate by a heart team.

2. **Physician Criteria (Heart Teams):** The patient (preoperatively and postoperatively) is under the care of a heart team, which includes, at minimum, a cardiac surgeon, interventional cardiologist, cardiologist with training and experience in heart failure management, electrophysiologist, multi-modality imaging specialists, and an interventional echocardiographer.

   All of the specialists listed above must have experience in the care and treatment of tricuspid regurgitation.

3. **CED Criteria:** All TTVR items and services are furnished in the context of a CMS-approved CED study. To meet CED requirements under the TTVR NCD for coverage of the EVOQUE system, patient data must be reported to the STS/ACC Transcatheter Valve Therapy (TVT) Registry.

   Edwards Lifesciences designed the CMS-approved STRONG under CED ("TTVR in Patients with Severe TR Ongoing Evidence Generation (STRONG) under CED") to meet coverage requirements under CED. This is a retrospective, non-randomized cohort study measuring 2-year effectiveness of the EVOQUE system in the real-world.

Coding and Billing Considerations

NCD specific coding information will be made available when CMS publishes TTVR NCD claims processing instructions. Please check with your coding department on appropriate coding requirements. **The following codes may apply to TTVR claims covered under this NCD.**

	Physician Claims	Facility Claims
Procedure	**CPT 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[1] **Modifier –Q0:** Investigational clinical service provided in a clinical research study that is in an approved clinical research study[3]	**ICD-10-PCS X2RJ3RA:** Replacement of tricuspid valve with multi-plane flex technology bioprosthetic valve, percutaneous approach, new technology group 10[5]
Dianosis	**Applicable primary diagnosis code** (e.g., I07.1, I07.2, I36.1, or I36.2)[5]	
	Secondary Diagnosis Z00.6: Encounter for examination for normal comparison and control in clinical research program[8]	
Condition Code	N/A	**Condition Code 30:** Qualified Clinical Trial[8]
NCT	**CT06833476** (STRONG under CED)[8]	**NCT06833476 reported with Value Code D4** (STRONG under CED)[8]

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 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 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.

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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. CY2025 Physician Fee Schedule (MPFS) Final Rule [CMS-1807-F]. Payments are effective January 1, 2025, through December 31, 2025.

4. Centers for Medicare & Medicaid Services. FY2025 Inpatient Prospective Payment System (IPPS) Final Rule, Correction Notice with Interim Final Action [CMS-1808-CN, CMS-1808-IFC]. Payments are effective October 1, 2024, through September 30, 2025.

5. International Classification of Diseases, 10th Revision, Clinical Modification 2025 ICD-10-CM and PCS Expert for hospitals.

6. Analysis of TTVR – ICD 10 PCS 02RJ38Z and 02RJ08Z FY2023 MEDPAR data.

7. Transcatheter Tricuspid Valve Replacement National Coverage Determination Final Decision Memo, CAG-00467N.

8. Centers for Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Publication 100-04, Transmittal 2955, Change Request 8401.

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