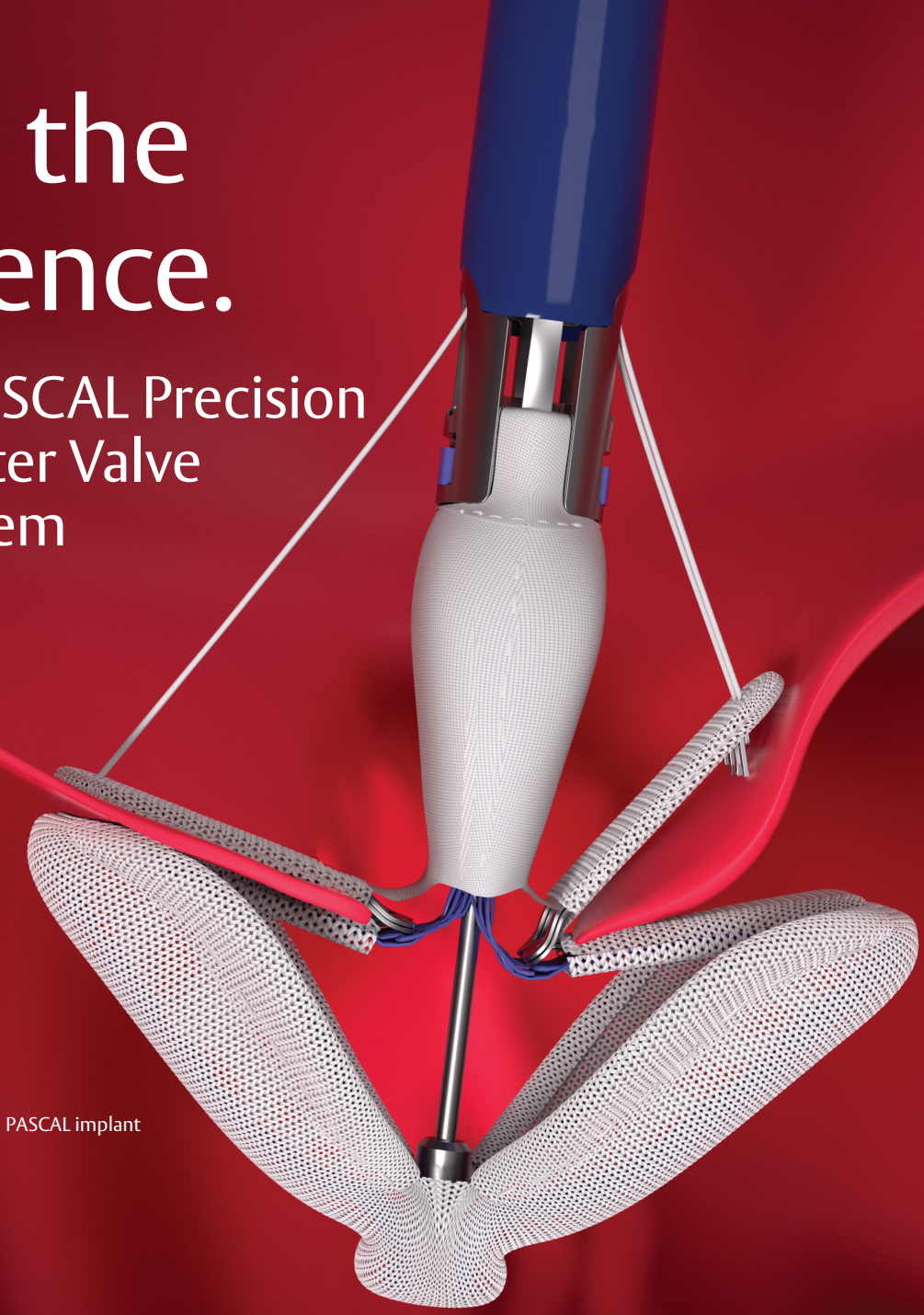
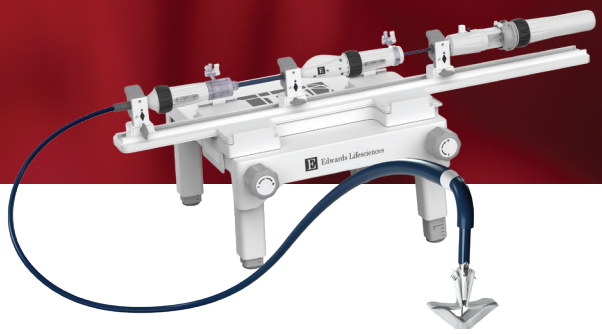
Grasp the difference.

Edwards PASCAL Precision Transcatheter Valve Repair System



PASCAL implant



PASCAL Precision System

2024 Physician and Facility Billing Guide

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PASCAL Precision System

Indication

The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

Physician Billing Codes

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). Category I CPT codes have been implemented for transcatheter edge-to-edge repair (TEER) procedures for mitral regurgitation.

CPT Codes[1,2]

Potential CPT Code	Description	CY2024 Medicare National Physician Payment*[3]	CY2024 Facility RVUs[3]
Transcatheter edge-to-edge repair			
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,759	52.84
+33419	Additional prosthesis(es) during same session (List separately in addition to code for primary procedure)**	$412	12.38
Transesophageal echocardiography			
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (e.g., 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.

** Report a maximum number of one unit for add-on code 33419 if two or more devices are inserted. (+) indicates add-on code. List add-on code separately in

Additional notes for physician billing:

Medicare will only pay TEER physician claims for CPT codes 33418 – 33419 when billed with the following: [4]

- Place of service (POS) code 21 (inpatient hospital)
- Modifier -Q0 (zero) signifying CED participation (qualifying registry or qualified clinical study)
- ICD-10-CM secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- Clinical Trial (CT) number (e.g. the CT number for the TVT Registry is 02245763)

Medicare will return all other claims as not processable.

Additional notes for physician billing continued:

- TEER may be a two-physician (interventional cardiologist and cardiac surgeon) procedure. When performed as a joint IC and CS procedure, each co-surgeon reports the same procedure code with the -62 modifier and payment for each physician is 62.5% of the established payment.
- Code 33418 has a 90-day global period.
- Angiography, radiological supervision, and interpretation performed to guide the valve repair procedure (eg, guiding device placement and documenting completion of the intervention) are included in these codes.
- Diagnostic right and left heart catheterization [93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93593, 93594, 93595, 93596, 93597, 93598] should not be used with 33418, 33419 to report:
  1. Contrast injections, angiography, road-mapping, and/or fluoroscopic guidance for the valve repair procedure,
  2. Left ventricular angiography to assess mitral regurgitation for guidance of the procedure, or
  3. Right and left heart catheterization for hemodynamic measurements before, during, and after the valve repair procedure for guidance of valve repair.
- Diagnostic right and left heart catheterization codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93593, 93594, 93595, 93596, 93597, 93598) and diagnostic coronary angiography codes (93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93563, 93564) may be reported with 33418, 33419, representing separate and distinct services from valve repair, 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.

Coding Modifiers

Modifier	Details
-Q0	Use -Q0 modifier for physician claims for cases enrolled in the TVT Registry. This modifier is to be used to indicate investigational clinical service provided in an approved clinical research study.
-59	Use -59 modifier for qualified circumstances when diagnostic cardiac catheterization occurs on the same session/same day as a TEER procedure.
-62	Use -62 modifier for physician claims where two surgeons work together as primary surgeons performing distinct part(s) of a procedure. Supporting documentation is required to establish the medical necessity of two surgeons for the procedure.
-80/-82	Use -80/-82 modifier for physician claims where surgical assistant services are provided. Modifier -82 is to be used only when qualified resident surgeon is not available.

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. The TEER procedure for mitral valve is designated by CMS as an inpatient only procedure.

Medicare Severity Diagnostic Related Groups (MS-DRG)

MS-DRG	Description	FY2024 Relative Weight[5]	FY2024 Medicare National Unadjusted Base Payment[5]	FY2024 Geometric Mean LOS[5]
Endovascular Cardiac Valve Replacement and Supplement Procedures				
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

*FY 2024 payment rates effective October 1, 2023, to September 30, 2024

ICD-10-PCS Procedure Codes[2,6]

Potential ICD-10-PCS Procedure Code	Description
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach

Additional notes for inpatient hospital billing:

Medicare will only pay for claims for ICD-10-PCS code 02UG3JZ when billed with the following: [4]

- ICD-10-CM secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- Clinical Trial (CT) number (e.g., the CT number for the TVT Registry Mitral Module is 02245763). For Form CMS-1450 paper claims, enter 02245763 in the value amount, value code D4. For 8371i electronic claims, enter 02245763 in Loop 2300 REF02 (REF01 = P4)
- Condition code 30
- Revenue code 278 (medical/surgical supplies and devices: other implants)

Medicare will return all other claims as not processable

ICD-10-CM Diagnosis Codes[6]

Potential ICD-10-CM Diagnosis Code	Description
I34.0	Non-rheumatic mitral (valve) insufficiency
I34.1	Non-rheumatic mitral (valve) prolapse
Z00.6	Encounter for exam for normal comparison and control in clinical research program

Documentation of Complications and Comorbidities

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 in M-TEER procedures (ICD-10-PCS 02UG3JZ Supplement mitral valve with synthetic substitute, percutaneous approach) identified in the FY 2024 MedPAR Final Rule.[8]

The table is not intended to be an exhaustive list of all potential complications and comorbidities (CCs) or major complications or comorbidities (MCCs).

Top 25 Reported MCCs *(Alphabetical)*

ICD-10-CM Diagnosis Codes	Short Description
A419	Sepsis, unspecified organism
E43	Unspecified severe protein-calorie malnutrition
G928	Other toxic encephalopathy
G9341	Metabolic encephalopathy
I214	Non-ST elevation (NSTEMI) myocardial infarction
I21A1	Myocardial infarction type 2
I330	Acute and subacute infective endocarditis
I469	Cardiac arrest, cause unspecified
I5023	Acute on chronic systolic (congestive) heart failure
I5031	Acute diastolic (congestive) heart failure
I5033	Acute on chronic diastolic (congestive) heart failure
I5043	Acute on chronic combined systolic and diastolic hrt fail
I511	Rupture of chordae tendineae, not elsewhere classified
J189	Pneumonia, unspecified organism
J690	Pneumonitis due to inhalation of food and vomit
J9601	Acute respiratory failure with hypoxia
J9602	Acute respiratory failure with hypercapnia
J9621	Acute and chronic respiratory failure with hypoxia
J9622	Acute and chronic respiratory failure with hypercapnia
K7200	Acute and subacute hepatic failure without coma
N170	Acute kidney failure with tubular necrosis
N186	End stage renal disease
R570	Cardiogenic shock
R578	Other shock
R6521	Severe sepsis with septic shock

Top 25 Reported CCs *(Alphabetical)*

ICD-10-CM Diagnosis Codes	Short Description
D62	Acute posthemorrhagic anemia
E871	Hypo-osmolality and hyponatremia
I130	Hyp hrt & chr kdny dis w hrt fail and stg 1-4/ unsp chr kdny
I132	Hyp hrt & chr kdny dis w hrt fail and w stg 5 chr kdny/ESRD
I25810	Atherosclerosis of CABG w/o angina pectoris
I420	Dilated cardiomyopathy
I428	Other cardiomyopathies
I429	Cardiomyopathy, unspecified
I442	Atrioventricular block, complete
I4811	Longstanding persistent atrial fibrillation
I4819	Other persistent atrial fibrillation
I4820	Chronic atrial fibrillation, unspecified
I4821	Permanent atrial fibrillation
I4892	Unspecified atrial flutter
I5022	Chronic systolic (congestive) heart failure
I5032	Chronic diastolic (congestive) heart failure
I5042	Chronic combined systolic and diastolic hrt fail
I510	Cardiac septal defect, acquired
J9611	Chronic respiratory failure with hypoxia
J9811	Atelectasis
N179	Acute kidney failure, unspecified
N184	Chronic kidney disease, stage 4 (severe)
N390	Urinary tract infection, site not specified
Z681	Body mass index [BMI] 19.9 or less, adult
Z6841	Body mass index [BMI] 40.0-44.9, adult

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 edge-to-edge repair procedures to be inpatient only procedures, meaning the hospital will not receive payment from Medicare should it be performed in an outpatient setting.

Commercial Payer Billing

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

Edwards PASCAL Precision Transcatheter Valve Repair System

Indications: The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

Contraindications: The PASCAL Precision system is contraindicated in patients with the following conditions: patients who cannot tolerate procedural anticoagulation or post-procedural anti-platelet regimen; untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media; active endocarditis of the mitral valve; rheumatic etiology for mitral regurgitation; evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

Warnings: The devices are designed, intended, and distributed for single use only. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing. Devices should be handled using standard sterile technique to prevent infection. Do not expose any of the devices to any solutions, chemicals, etc., except for the sterile physiological and/or heparinized saline solution. Irreparable damage to the device, which may not be apparent under visual inspection, may result. Do not use any of the devices in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants. Do not use the devices if the expiration date has elapsed. Do not use if the packaging seal is broken or if the packaging is damaged for sterile devices. Do not use if any of the devices were dropped, damaged or mishandled in any way. Standard flushing and de-airing technique should be used during preparation and throughout procedure to prevent air embolism.

As with any implanted medical device, there is a potential for an adverse immunological response. Serious adverse events, sometimes leading to surgical intervention and/or death, may be associated with the use of this system ("Potential Adverse Events"). A full explanation of the benefits and risks should be given to each prospective patient before use. Careful and continuous medical follow-up is advised so that implant-related complications can be diagnosed and properly managed. Anticoagulation therapy must be determined by the physician per institutional guidelines.

Precautions: Prior to use, patient selection should be performed by a heart team to assess patient risk and anatomical suitability. After use, short-term anticoagulation therapy may be necessary after valve repair with the PASCAL Precision system. Prescribe anticoagulation and other medical therapy per institutional guidelines.

Potential Adverse Events: Below is a list of the potential adverse effects (e.g., complications) associated with the use of the PASCAL Precision system: death; abnormal lab values; allergic reaction to anesthetic, contrast, heparin, Nitinol; anemia or decreased hemoglobin (may require transfusion); aneurysm or pseudoaneurysm; angina or chest pain; anaphylactic shock; arrhythmias - atrial (i.e. atrial fibrillation, Supraventricular tachycardia); arrhythmias - ventricular (i.e. ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; atrial septal injury requiring intervention; bleeding; cardiac arrest; cardiac 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 permanent pacemaker; deep vein thrombosis (DVT); deterioration of native valve (e.g. leaflet tearing, retraction, thickening); dislodgement of previously deployed implant; dyspnea; edema; electrolyte imbalance; emboli/embolization including air, particulate, calcific material, or thrombus; endocarditis; esophageal irritation; esophageal perforation or stricture; exercise intolerance or weakness; failure to retrieve any PASCAL Precision system components; fever; gastrointestinal bleeding or infarct; heart failure; hematoma; hemodynamic compromise; hemolysis; hemorrhage requiring transfusion or intervention; hypertension; hypotension; implant deterioration (wear, tear, fracture, or other); implant embolization; implant malposition or failure to deliver to intended site; implant migration; implant thrombosis; infection; inflammation; LVOT obstruction; mesenteric ischemia; multi-system organ failure; myocardial infarction; native valve injury; native valve stenosis; nausea and/or vomiting; need for open surgery (conversion, emergent or nonemergent reoperation, explant), nerve injury neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-neurological

thromboembolic events; pain; papillary muscle damage; paralysis; PASCAL Precision system component(s) embolization; peripheral ischemia; permanent disability; pleural effusion; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; renal failure; renal insufficiency; respiratory compromise, respiratory failure, atelectasis, pneumonia - may require prolonged ventilation; retroperitoneal bleed; septal damage or perforation; septicemia, sepsis; skin burn, injury or tissue changes due to exposure to ionizing radiation; single leaflet device attachment (SLDA); stroke; syncope; transient ischemic attack (TIA); urinary tract infection and/or bleeding; valvular regurgitation; vascular injury or trauma, including dissection or occlusion; vessel spasm; ventricular wall damage or perforation; worsening native valve regurgitation / valvular insufficiency; worsening of heart failure; wound dehiscence, delayed or incomplete healing.

CAUTION: Federal (United States) law restricts these devices to s ale by or on the order of a physician. See instructions for use for full prescribing information.

Important - Please Note: This information is provided as a general educational resource and is not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any individual patient needs or circumstances. Coverage, reimbursement and health economics information provided by Edwards is gathered from third-party sources and presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and Edwards makes no representation or warranty regarding this information or its completeness, accuracy, or timeliness. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently; service providers are responsible for all decisions relating to coding and reimbursement submissions.

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References

1. Current Procedure Terminology (CPT) copyright 2023, 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' transcatheter edge-to-edge repair 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. Medicare Claims Processing Manual; Chapter 32 Billing Requirements for Special Services. Section 340
5. Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation. Available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf
6. Centers for Medicare & Medicaid Services. FY2024 Inpatient Prospective Payment System (IPPS) Final Rule Correction Notice. Payments are effective October 1, 2023, through September 30, 2024.
7. International Classification of Diseases, 10th Revision, Clinical Modification 2024 ICD-10-CM and PCS Expert for hospitals.
8. Analysis of FY 2022 MEDPAR data issued with FY 2024 Final Inpatient Prospective Payment

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