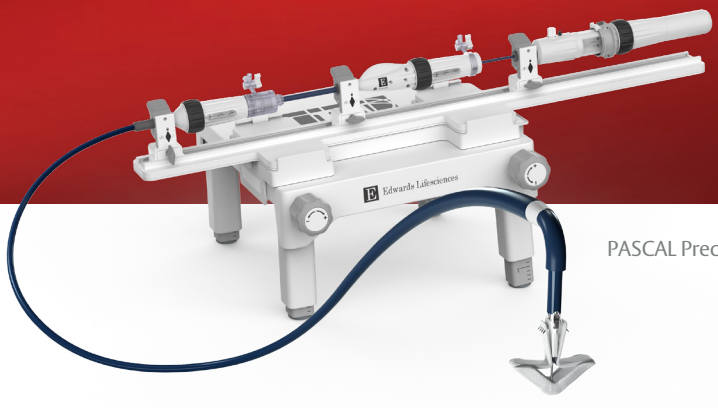
PASCAL Precision System

Transcatheter Valve Repair System for Degenerative Mitral Regurgitation

PASCAL Implant



PASCAL Precision System

2023 Physician and Facility Billing Guide

Edwards Reimbursement Hotline:
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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	CY2023 Medicare National Physician Payment[3]	CY2023 Facility RVUs[3]
Transcatheter edge-to-edge repair			
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,780	52.53
+33419	Additional prosthesis(es) during same session (List separately in addition to code for primary procedure)*	$419	12.35
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	$223	6.57

* 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 addition to code for primary procedure.

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	FY2023 Relative Weight[5]	FY2023 Medicare National Unadjusted Base Payment[5]	FY2023 Geometric Mean LOS[5]
Endovascular Cardiac Valve Replacement and Supplement Procedures				
266	Endovascular cardiac valve replacement and supplement procedures with MCC	6.6007	$45,278	2.8
267	Endovascular cardiac valve replacement and supplement procedures without MCC	5.1606	$35,399	1.4

*FY2023 payment rates effective October 1, 2022 to September 30, 2023

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

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.

Edwards Reusable Accessories

Indications: The Edwards reusable platform, reusable plate, and reusable cradle are reusable, non-sterile accessories indicated for use with compatible Edwards transcatheter cardiac therapies. The reusable platform and reusable plate are non-patient contacting and are intended to aid the positioning and stabilization of delivery systems during intra-cardiac procedures.

Contraindications: There are no specific contraindications for these accessories.

Warnings: There are no warnings specific to these accessories.

Precautions: The reusable platform, reusable plate, and reusable cradle are NON-STERILE; introduction of the reusable platform, reusable plate, and reusable cradle into the sterile field may result in infection. Prior to use, cleaning must be performed according to the Edwards Reusable Accessories Instructions for Use. Do not use metallic brushes, scrub pads, or other abrasive cleaning aids when cleaning the devices. They can cause permanent device damage.

Potential Adverse Events: There are no known potential adverse events specific to the Edwards reusable platform, reusable plate, or reusable cradle.

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

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