TRILOGY

Transcatheter Heart Valve

Version: March 2026

2026 Reimbursement Guide

Inpatient hospital rates effective October 1, 2025
Physician rates effective January 1, 2026

Trilogy® Transcatheter Heart Valve System

The only TAVR system with FDA Premarket Approval for the treatment of native aortic regurgitation, as described in the Instructions for Use

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The information in this document is provided for educational purposes only and is not intended to be coding or billing advice. This coding information is based upon publicly available information and is current as of April 1, 2026 and subject to change without notice. JenaValve Technology, Inc. cannot guarantee that any product or service billed with the codes listed will be covered or, if covered, the listed payment amount will be paid by any payer. It is the responsibility of the provider to select appropriate codes for each patient and to submit appropriate codes, charges, and modifiers for services rendered. Providers should contact insurers to verify correct coding procedures prior to submitting claims related to the use of JenaValve products. In all cases, providers must bill according to the rules, policies and procedures of individual payers. The medical record should document that the product or procedure was medically necessary and furnished or performed as reported. Clinical need, not reimbursement amount, should always drive clinical decision making. If you have any questions about appropriate billing for products or services, please consult your local payer.

The information contained in this guide is provided to assist providers in understanding the reimbursement process. It is intended to assist providers in obtaining accurate and appropriate reimbursement for the healthcare services provided. It is not intended to increase or maximize reimbursement by any payer. It is strongly recommended that providers consult with their payer organizations with regard to local reimbursement policies. The information contained herein is provided for information purposes only and represents no statement, promise, or guarantee by JenaValve Technology, Inc. concerning levels of reimbursement, payment, or charge. Similarly, all CPT codes are supplied for information purposes only and represent no statement, promise, or guarantee by JenaValve Technology, Inc. that these codes will be appropriate or that reimbursement will be made.

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Reimbursement Assistance

Contact the JenaValve Reimbursement Team:
reimbursement.usa@jenavalve.com

What is the JenaValve Trilogy System?

The JenaValve Trilogy Transcatheter Heart Valve System is a self-expandable bioprosthetic aortic valve designed for the treatment of patients with symptomatic aortic regurgitation. The Trilogy system features proprietary locator technology that enables secure anchoring to the native aortic valve leaflets — even in the absence of calcium — providing stable fixation and commissural alignment.

The Trilogy valve is delivered via transfemoral catheter-based approach and features integrated leaflet-clipping locators in a single frame design that clip onto the native leaflets, combined with radial expansion of the stent frame, enabling anatomical fixation without relying on calcification or radial force. This is a fundamental design difference from all existing TAVR devices and is critical for aortic regurgitation, where non-calcified annuli present challenges for standard TAVR systems. The valve is delivered via a transfemoral catheter-based approach using a single-actuation deployment mechanism with integrated controls for THV rotation to orient locators to native anatomy.

System Components

Trilogy® THV: A trileaflet porcine pericardial valve attached to a self-expandable, radiopaque nitinol stent with integrated locators in a single frame design that clip onto the native leaflets and a sealing ring that conforms to the left ventricular outflow tract. Available in three sizes (23mm, 25mm, 27mm) for annulus diameters 21–28.6mm. Large, open cell design enables future coronary access. MR Conditional at 1.5T and 3T.

Delivery Catheter: Transfemoral delivery system with a tapered tip, handle-controlled deflection, integrated controls for THV rotation (to orient locators to native anatomy), and single-actuation unified THV/locator deployment.

Introducer Sheath: 85cm pre-shaped, hydrophilically-coated 20Fr sheath; one size fits all valve sizes. Requires femoral access ≥7.0mm.

Loading Tools: Size-matched components for valve preparation. All components are single-use and individually sterile-packaged. Implant materials: nitinol (titanium/nickel alloy) and porcine pericardial tissue. Latex-free. Storage: 2–25°C (36–77°F).

Coverage

Medicare Coverage

Medicare covers TAVR for Aortic Regurgitation (AR) under reasonable and necessary criteria according to the FDA approved indication.

There is a new section in the Transcatheter Valve Therapy (TVT) registry for TAVR for AR, and all cases should be entered into this section of the TVT registry.

Coverage from Medicare Advantage

Medicare Advantage plans may use prior authorization/pre-certification in advance of the procedure. Consult your local Medicare Advantage plans to understand any specific steps that may need to be taken.

Coverage from Private Payers

Private payer plans vary significantly in coverage and compliance requirements for TAVR with Trilogy.

1. Commercial payer policies are evolving and vary on several factors including
    a. Prior authorization requirements
    b. Co-surgeon requirements
    c. Covered disease
2. Commercial payers should be consulted in advance of the procedure to verify terms and conditions of coverage

Coding

ICD-10-CM Diagnosis Coding

The following ICD-10-CM diagnosis codes may be appropriate for when the Trilogy TAVR procedure is performed. It is the responsibility of the hospital and physician to determine the appropriate diagnosis code for each patient based on documentation in the medical record. Diagnosis code Z00.6 should be used to identify participation in the TVT Registry.

ICD-10-CM	Code Description
I35.1	Nonrheumatic aortic (valve) insufficiency
Z00.6	Encounter for exam for normal comparison and control in clinical research program

Hospital ICD-10-PCS Procedure Coding

The following ICD-10-PCS may be appropriate to report the Trilogy TAVR procedure on hospital inpatient claims. It is the responsibility of the hospital to determine the appropriate procedure code for each patient based on documentation in the medical record.

ICD-10-PCS Code	Description
02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach

Hospital Inpatient Payment

Cases reported with ICD-10-PCS code 02RF38Z typically are assigned to Medicare Severity Diagnosis Related Group (MS-DRG) 266/267: Endovascular Cardiac Valve Replacement and Supplement Procedures for hospital inpatient payment. The payment varies based on the presence (MS-DRG 266) or absence (MS-DRG 267) of Major Complications and Co-morbidities. Other MS-DRG assignment is possible based on other procedures performed during the same hospitalization. Hospital-specific payment varies.

Procedure	MS-DRG	FY2026 Medicare National Average Payment[1]
Trilogy TAVR for Aortic Regurgitation	266 – with MCCs	$44,595
	267 – without MCCs	$34,643

1. FY 2026 IPPS/LTCH PPS Final Rule CMS-1833-F. Shown are national average rates for a hospital (i) with a wage index less than or equal to 1, (ii) that submitted quality data, and (iii) that is a meaningful electronic health record (EHR) user. Rates do not reflect adjustments (e.g., teaching hospital, area wages) that could alter significantly the payment amount.

Inpatient Only Procedure

All TAVR procedures are designated by CMS as Inpatient Only Procedures. As such, these procedures are not assigned to an ambulatory payment classification (APC) for hospital outpatient payment or a Healthcare Common Procedure Coding System (HCPCS) C-Code for TAVR for AR.

Additional Requirements

Specific identifying information must be on each claim that is enrolled in the TVT Registry.

Additional Required Information	Description
POS code 21	Place of service (POS) code 21 (inpatient hospital)
Modifier 62	Two surgeons/co-surgeons
Modifier Q0	Signifies CED participation (qualifying registry or qualified clinical study)
NCT01737528	The TVT Registry National Clinical Trial Number (NCT) is required. For Form UB-04 paper claims, enter **NCT01737528** in the value amount, value code D4. For 837I electronic claims, enter **01737528** in Loop 2300 REF02 (REF01 = P4).
Condition Code 30	Identifies cases enrolled in the TVT Registry
Revenue Code 0278	Charges for Trilogy should be in Revenue Code 0278, Medical/Surgical Supplies and Devices: Other Implants

Hospital Claim Preparation Checklist

Below is a summary of the information used to process claims for TAVR procedures with the Trilogy System. It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and/or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

Codes / Modifiers / Other	When is it used?	Included?	N/A
DIAGNOSIS CODES			
I35.1, Nonrheumatic aortic (valve) insufficiency	Implant cases	☐	☐
Z00.6: Encounter for exam for normal comparison and control in clinical research program	All implant cases	☐	☐
Any applicable secondary diagnosis code	As documented	☐	☐
PROCEDURE CODE			
02RF38Z, Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach	All implant cases	☐	☐
CONDITION CODE			
30, Qualifying clinical trial	All implant cases	☐	☐
NCT NUMBER			
NCT01737528	All implant cases	☐	☐
PLACE OF SERVICE CODE			
21 (inpatient hospital)	All implant cases	☐	☐
MODIFIERS			
Modifier 62 (two surgeons/co-surgeons)	All implant cases	☐	☐
Modifier Q0 (qualifying registry or qualified clinical study)	All implant cases	☐	☐
VALUE CODE			
D4, Form Locators 39-41 of the paper claim or Loop 2300 of the 837I electronic claim	All implant cases	☐	☐
REVENUE CODE FOR CHARGES			
278: Medical/Surgical supplies and devices, other implants	All implant cases	☐	☐

Documentation

An accurate description of the patient's condition should always be included to clearly document the indication, the procedure performed, and any complications and comorbidities that are present during the admission. Common complications and comorbidities associated with native aortic regurgitation are provided in Appendix B.

Physician Procedure Note

- Indicate the medical necessity of the Trilogy TAVR procedure
- Establish the risk profile of the patient (STS score, frailty assessment)
- Provide pertinent case history and condition prior to the procedure
- Describe the hemodynamic status of the patient
- Document echocardiographic assessment and severity of aortic regurgitation
- Document heart team evaluation and rationale for TAVR approach
- Document presence of complications or comorbidities as appropriate
- Document implant procedure details and any complications

Clinical Documentation Guide

Thorough clinical documentation supports accurate MS-DRG assignment and appropriate reimbursement. For Trilogy TAVR patients, consider documenting the following elements:

Category	Documentation Elements
Clinical Indications	Severe symptomatic aortic regurgitation, echocardiographic severity grading, NYHA functional class, aortic root and annular anatomy
Clinical Profile	NYHA Class I–IV, STS risk score, ejection fraction, past medical history and physical exam
Other Comorbidities	Cardiac disease, diabetes, renal dysfunction, pulmonary disease, arrhythmia, MCC/CC
Valve Anatomy	Leaflet morphology, regurgitation mechanism and severity, annular dimensions, coronary height, CT aortography findings
Hemodynamic Profile	LV function, hemodynamic measurements, cardiac catheterization data
Heart Team Evaluation	Multidisciplinary heart team assessment including cardiac surgeon and interventional cardiologist, surgical risk evaluation, rationale for TAVR approach

Physician CPT[1] Coding

The CPT codes listed in the following tables should be used to report the implant, imaging, and related services for the Trilogy TAVR procedure.

Note: For CY2026, Medicare payment varies depending upon whether the physician participates in specific quality programs. The National average rates provided assume the physician is a qualifying APM.

Trilogy TAVR Implant

CPT©	Description	Total RVUs[2]	Work RVUs	2026 Medicare Nat'l Payment[3]
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	32.31	21.91	$1,085
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	35.19	23.93	$1,182

Note: CPT codes 33361-33366 bundle the following services when performed to complete the TAVR procedure: percutaneous access, access sheath placement, balloon aortic valvuloplasty, valve delivery system advancement, valve repositioning, valve deployment, temporary pacemaker insertion for rapid pacing, arteriotomy closure, fluoroscopic guidance, contrast injections, and radiological supervision and interpretation. These services should NOT be reported separately.

Diagnostic cardiac catheterization codes (93451-93453, 93456-93461) and supravalvular aortography (93567) are NOT separately reportable when performed intraprocedurally during TAVR. They may only be reported if performed as a separate diagnostic procedure with distinct medical necessity documentation.

TAVR Add-On Codes for Cardiopulmonary Bypass Support

CPT	Description	Total RVUs	Work RVUs	2026 Medicare Nat'l Payment
+33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)	16.72	11.58	$561
+33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)	20.26	14.03	$680
+33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)	26.77	18.53	$899

1. *CPT© 2026 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use.*
2. *2026 Medicare Physician Fee Schedule, released November 2025*
3. *2026 payment calculated using adjusted 2026 conversion factor, assumes physician is a qualified Alternative Payment Model participant.*

Transesophageal Echocardiogram

CPT	Description	Total RVUs	Work RVUs	2026 Medicare Nat'l Payment
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	5.75	4.54	$193

Cerebral Embolic Protection Add-On Code

CPT	Description	Total RVUs	Work RVUs	2026 Medicare Nat'l Payment
+33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)	3.47	2.44	$116

Note: This add-on code may be reported if performed with TAVR/TAVI procedures

Radiology and Imaging

TAVR CPT codes include radiological supervision and interpretation in their description. This indicates to some payers that the imaging and radiology procedures are included in the primary procedure and are not eligible for separate payment.

CPT	Description	Total RVUs	Work RVUs	2026 Medicare Nat'l Payment
33206	Insertion of permanent pacemaker, transvenous electrode(s); atrial	12.04	6.96	$404
33207	Insertion of permanent pacemaker, transvenous electrode(s); ventricular	12.64	7.61	$424
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	13.65	8.31	$458

Vascular Access and Closure

CPT	Description	Total RVUs	Work RVUs	2026 Medicare Nat'l Payment
34713	Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, where performed, unilateral	3.30	2.44	$111
34714	Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral	7.34	5.12	$246
34716	Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral	10.13	7.01	$340
35371	Thromboendarterectomy, including patch graft, if performed; common femoral	22.15	14.93	$744

Additional Physician Coding Guidance

Two-Surgeon Requirement

The NCD for Transcatheter Aortic Valve Replacement (TAVR), Publication Number 100.3 Section 20.32, requires two physicians — an interventional cardiologist and a cardiothoracic surgeon — to jointly participate in the intraoperative aspects of TAVR. Modifier 62 (Two Surgeons) must be reported with all TAVR CPT codes.

Modifier	Description
Q0	Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.
62	Two Surgeons — Required for all TAVR procedures
22	Increased Procedural Services — For unusually complex Trilogy cases (e.g., severe tortuosity, prolonged procedure)
80	Assistant Surgeon — For non-teaching community hospitals without surgery residents
82	Assistant Surgeon (when qualified resident unavailable) — For teaching hospitals with surgery residents
59	Distinct Procedural Service — When separately reportable procedures (e.g., PCI) are performed during the same session

Multiple Procedure Payment Reduction (MPPR) on the Professional Component may apply.

Physician Claim Preparation Checklist

This checklist is a summary of the information used to process claims for TAVR procedures with the Trilogy System. It is always the responsibility of the hospital and the physician to determine accurate coding for each patient and for the patient's procedure. All claims should be coded appropriately and supported with documentation in the patient's medical record.

Codes / Modifiers / Other	When it is used?	Included?	N/A
DIAGNOSIS CODE			
I35.1: Nonrheumatic aortic (valve) insufficiency	Select one	☐	☐
Z00.6: Encounter for exam for normal comparison and control in clinical research program	All implant cases	☐	☐
Any applicable secondary diagnosis codes	As documented	☐	☐
CPT CODE			
33361: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	Select one for all implant cases	☐	☐
33362: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach		☐	☐
Other CPT codes for additional services performed	As documented	☐	☐
CPT CODE MODIFIERS			
- Q0: Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All implant cases	☐	☐
- 62: When two surgeons work together as primary surgeons performing distinct part(s) of a procedure.	When appropriate	☐	☐
- 22: Increased Procedural Services for unusually complex Trilogy cases (e.g., severe tortuosity, prolonged procedure)	When appropriate	☐	☐
- 80: Assistant Surgeon — For non-teaching community hospitals without surgery residents	When surgical assistant services are used during the procedure	☐	☐
- 82: Assistant Surgeon (qualified resident unavailable) — For teaching hospitals with surgery residents		☐	☐
- 59: Distinct Procedural Service — When separately reportable procedures (e.g., PCI) are performed during the same session	When appropriate	☐	☐
NCT NUMBER			
01737528 (NCT is not included on professional claims)	All implant cases	☐	☐

JenaValve Healthcare Economic & Reimbursement Support

JenaValve Reimbursement Team

Email: reimbursement.usa@jenavalve.com

Overview of Available Assistance

- Program review: Recommendations to develop strategies for billing and coding accuracy
- Coding education: Provide up-to-date education to hospital and professional coding teams
- Pre-submission redacted claim review: Ensures all processes are in place prior to submitting first 3 claims
- Documentation education: Provide education on best practices for establishing medical necessity documentation
- Payer strategy & support: Solutions offered for payer-specific questions

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Disclaimer

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Important Safety Information

Indications for use: The Trilogy® Transcatheter Heart Valve System is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The Trilogy Transcatheter Heart Valve System is contraindicated in patients who cannot tolerate an anticoagulation/ antiplatelet regimen, have known hypersensitivity to nitinol alloy (nickel and titanium) or contrast agents that cannot be managed with premedication, or who have active bacterial endocarditis or other active infection.

Warnings General: The Trilogy® THV is only to be used with the Trilogy® INT, Trilogy® DC and Trilogy® LT. Use of other devices may damage the THV and/or result in patient injury. This procedure should only be performed by physicians experienced in transcatheter aortic valve replacement (TAVR) procedures and trained in the use of the Trilogy® Transcatheter Heart Valve System, and where emergency cardiac surgery (surgical aortic valve replacement) may be promptly performed. Only physicians who have successfully completed the JenaValve Professional Education training program are authorized to use the Trilogy Heart Valve System. The procedure must be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Ensure the guidewire is in proper location in the ventricle throughout the procedure to mitigate risk of ventricular wall perforation. Improper management of the guidewire, allowing it to move forward into the left ventricle, may lead to ventricular injury requiring intervention. Systemic anticoagulation with heparin should be administered and adjusted as needed throughout the procedure per hospital and physician preference. Activated clotting time (ACT) > 250 seconds is recommended to be maintained prior to Introducer Sheath insertion through completion of the procedure. Failure to maintain proper ACT levels may lead to patient harm or death. If heparin is contraindicated, an alternative anticoagulant should be considered and administered as per institutional policy. The THV must be sized appropriately to fit the patient's anatomy. Proper device sizing is the responsibility of the treating physician. Refer to the THV sizing chart in the instructions for use. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed under the potential adverse events section. DO NOT bend or kink the Introducer Sheath. Doing so may damage the Delivery Catheter and the THV during or after the loading process. DO NOT mix the sizes of the THV, Delivery Catheter, or Loading Tools. Use of mixed size configurations of THV, Delivery Catheter, and Loading Tools may result in implantation difficulties such as premature/ failure to release the THV from the Delivery Catheter, THV damage, or patient injury requiring intervention. DO NOT use the Trilogy® THV System components if: the Use-By date has elapsed; the packaging or any of its components are not sterile or have been unintentionally opened before use; or the product has been dropped, damaged, or mishandled. DO NOT use the Trilogy® INT with any pre-implant balloon valvuloplasty catheter. Trilogy THV: DO NOT use the THV if: the serial number tag is missing or does not match the container label; the container or seal is damaged, cracked, or leaking; the temperature indicator is out of range; or the THV is not fully covered in solution after opening the package. Incorrect sizing of the THV with the patient's native aortic valve may lead to paravalvular leak, migration, annular injury, embolization, and/or unsuccessful implant. Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism.

Precautions General: DO NOT expose the THV to solutions other than the storage, sterile rinse, and sterile chilling solutions. DO NOT add any other substance or drug to the THV storage, sterile rinse, or sterile chilling solutions. Always keep the THV tissue moist with rinsing or immersion. Long-term clinical durability has not been established for the Trilogy transcatheter heart valve. Engineering testing has demonstrated an in vitro valve durability equivalent to 3.5 years, which did not meet the 5 years recommended by the relevant international standard. Regular medical follow-up including assessment of valve function is advised. The safety and effectiveness of the THV has not been evaluated in the following patient populations: patients with percutaneous Ventricular Assist Devices (pVAD) or Left Ventricular Assist Devices (LVAD); pediatric patients; or patients who are pregnant/ or breastfeeding. The safety and effectiveness of the THV has not been evaluated in patient populations presenting with the following: blood dyscrasias as defined: leukopenia (WBC < 3000/mm^3), thrombocytopenia (platelets < 90,000/µl) or anemia (Men: Hgb < 8.1 g/dl; Women: Hgb < 7.4 g/dl); congenital/functional unicuspid, bicuspid or quadricuspid native aortic valve morphology; previous prosthetic aortic valve (bioprosthesis or mechanical) implant; echocardiographic evidence of current left heart thrombus; hypertrophic cardiomyopathy with or without obstruction; severe pulmonary hypertension (systolic PA pressure > 80 mmHg) or severe RV dysfunction as assessed clinically and by echo; very severely reduced left ventricular ejection fraction (LVEF < 25%); significant disease of ascending aorta, including ascending aortic aneurysm (defined as maximal luminal diameter of 50 mm or greater) or significant protruding or ulcerated atheroma; aortic annular diameter of less than 21 mm or more than 28.6 mm (assessed by multidetector computed tomography (MDCT) measurement); access vessel characteristics that would preclude safe placement of the JenaValve 20Fr introducer sheath, such as severe obstructive calcification, severe tortuosity, or vessel diameter <7mm; or severe renal insufficiency (GFR<30 mL/min) or renal disease requiring replacement therapy (i.e., dialysis).

Prior to Use: Removal of the Delivery Catheter and Introducer Sheath from the respective packaging should be performed carefully to prevent damage or kinking. The Trilogy® THV System is designed for single patient use only. Do not reuse, reprocess or resterilize any component of this product. Reusing, reprocessing or resterilizing this product may compromise its initial integrity which could result in patient injury, illness, or death. The THV and the glutaraldehyde storage solutions are STERILE. The exterior of the THV container is NONSTERILE and must NOT be placed in the sterile field. Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors and use adequate ventilation. If skin contact occurs, immediately flush the affected area with water. In the event of eye contact, flush with water and seek immediate medical attention.

During Use: Adequate rinsing of the THV with sterile cold saline prior to use as described in the instructions for use is mandatory before implantation. No other solutions, drugs, or chemicals (including antibiotics) should be added to the storage or rinsing solutions, as irreparable damage to the THV Leaflets, which may not be apparent under visual inspection, may occur. The use of this device requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively (e.g., patients with Stage 4 or 5 chronic kidney disease). Care should be taken to limit the amount of contrast media used during the procedure. Introducer Sheath and Delivery Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the Introducer Sheath or Delivery Catheter when resistance is encountered. Vessel or device damage may occur. Care should be taken in areas of stenosis, intravascular thrombosis, or in calcified and/or tortuous vessels. Pre-dilatation of the native aortic annulus using balloon aortic valvuloplasty (BAV) is performed at physician discretion. Ensure guidewire access and

positioning is maintained at all times. Do not remove the guidewire while the Delivery Catheter and Introducer Sheath are inserted in the patient. Inaccurate placement, inadequate Locator to Leaflet fixation and/or incomplete sealing of the THV within the annulus may result in increased risk of paravalvular leakage, migration, or inadvertent coronary occlusion. Incorrect deployment or migration of the THV may require intervention. Once deployment has occurred, repositioning of the THV (e.g., using a snare) is not recommended. Repositioning of a deployed THV may cause patient injury and/or require emergent surgery. DO NOT attempt to retrieve or recapture the prosthetic aortic valve if the sealing ring has been deployed. If the sealing ring has been deployed, the THV must be released from the catheter before the catheter can be withdrawn with the Introducer Sheath. Take care during manipulation of catheters, wires, and sheaths within the aorta. Excessive manipulation may dislodge fragments of atheroma or calcification which can cause embolization. Clinical long-term durability for the Trilogy® THV has not been established. Regular medical follow-up is advised to evaluate THV performance as per standard of care for similar bio-prosthetic valves. Post-procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk of prosthetic valve infection or endocarditis. Post-procedure, administer anticoagulation and/or antiplatelet therapy per physician judgment.

Potential Adverse Events
Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. Death; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; anemia; angina; aortic root distortion; atelectasis; arrhythmia; arteriovenous (AV) fistula; blood loss requiring transfusion; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium or valvular structures that may require intervention; cardiac arrest; cardiac failure; cardiogenic shock; chest pain/discomfort; conduction system injury; coronary flow obstruction/transvalvular flow disturbance; deep vein thrombosis; device acute migration or malposition; device dysfunction (regurgitation and/or stenosis); device embolization; device thrombosis; dislodgement of previously implanted devices (i.e., pacing lead); dyspnea; electrolyte imbalance; embolic event: air, calcific material, thrombus, device fragments; endocarditis; exercise intolerance or weakness; fever; hematoma or ecchymosis; hemolysis/hemolytic anemia; hypertension or hypotension; infection including incisional site infection, septicemia and endocarditis; inflammation; mechanical failure of delivery system, and/or accessories; myocardial infarction; pain; pericardial effusion/cardiac tamponade; pleural effusion; pneumothorax; pulmonary edema; radiation injury; renal insufficiency or renal failure; reoperation; respiratory insufficiency or respiratory failure; stroke/transient ischemic attack; syncope; systemic or peripheral ischemia; systemic or peripheral nerve injury.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. Implantation of the transcatheter heart valve should be performed only by physicians who have received JenaValve Technology Inc. training. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. For more information please refer to https://eifu.jenavalve.com.

Appendix A: Cardiac Cath Lab ICD-10 PCS Procedure Codes

The accurate documentation of procedures performed is essential to appropriate MS-DRG assignment and reimbursement. The following ICD-10-PCS codes may be applicable when other procedures are performed in conjunction with Trilogy TAVR.

Cardiac Catheterization / Hemodynamic Assessment

ICD-10-PCS	Code Description
4A023N7	Measurement of Cardiac Sampling and Pressure, Left Heart, Percutaneous Approach
4A023N6	Measurement of Cardiac Sampling and Pressure, Right Heart, Percutaneous Approach
4A023N8	Measurement of Cardiac Sampling and Pressure, Bilateral, Percutaneous Approach

Angiography / Imaging

ICD-10-PCS	Code Description
B2111ZZ	Fluoroscopy of Multiple Coronary Arteries using Low Osmolar Contrast
B2101ZZ	Fluoroscopy of Single Coronary Artery using Low Osmolar Contrast
B2151ZZ	Fluoroscopy of Left Heart using Low Osmolar Contrast
B3101ZZ	Fluoroscopy of Thoracic Aorta using Low Osmolar Contrast

Balloon Aortic Valvuloplasty (if performed pre-TAVR)

ICD-10-PCS	Code Description
027F3ZZ	Dilation of Aortic Valve, Percutaneous Approach

Permanent Pacemaker Insertion (Post-TAVR Complication)

ICD-10-PCS	Code Description
0JH604Z	Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach
0JH606Z	Insertion of Pacemaker, Dual Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach
02HK3JZ	Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Approach
02H63JZ	Insertion of Pacemaker Lead into Right Atrium, Percutaneous Approach

Note: Temporary pacemaker insertion for rapid pacing during TAVR is bundled into the primary TAVR procedure code and is not separately reportable.

Any additional procedures performed may or may not change the MS-DRG assignment for the admission.

Appendix B: MCC Common Diagnosis Codes with Trilogy TAVR

The accurate documentation of MCCs is required to document the patient's condition. All patients should have MCCs documented in the medical record when clinically present. The presence of MCC-level diagnoses can significantly affect DRG assignment and reimbursement levels.

The following MCCs were identified in the 2024 MedPar data as appearing on claims for patients receiving TAVR for AR.

Major Complication or Comorbidity (MCC)

ICD-10-CM Code	Description
I50.21	Acute systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
J96.01	Acute respiratory failure with hypoxia
J96.21	Acute and Chronic respiratory failure with hypoxia
J95.821	Acute postprocedural respiratory failure
N17.0	Acute kidney failure with tubular necrosis
T81.12XA	Postprocedural septic shock, initial encounter
R57.0	Cardiogenic shock
I46.9	Cardiac arrest, cause unspecified
I33.0	Acute and subacute infective endocarditis
I21.4	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.9	Acute myocardial infarction, unspecified
I63.9	Cerebral infarction, unspecified

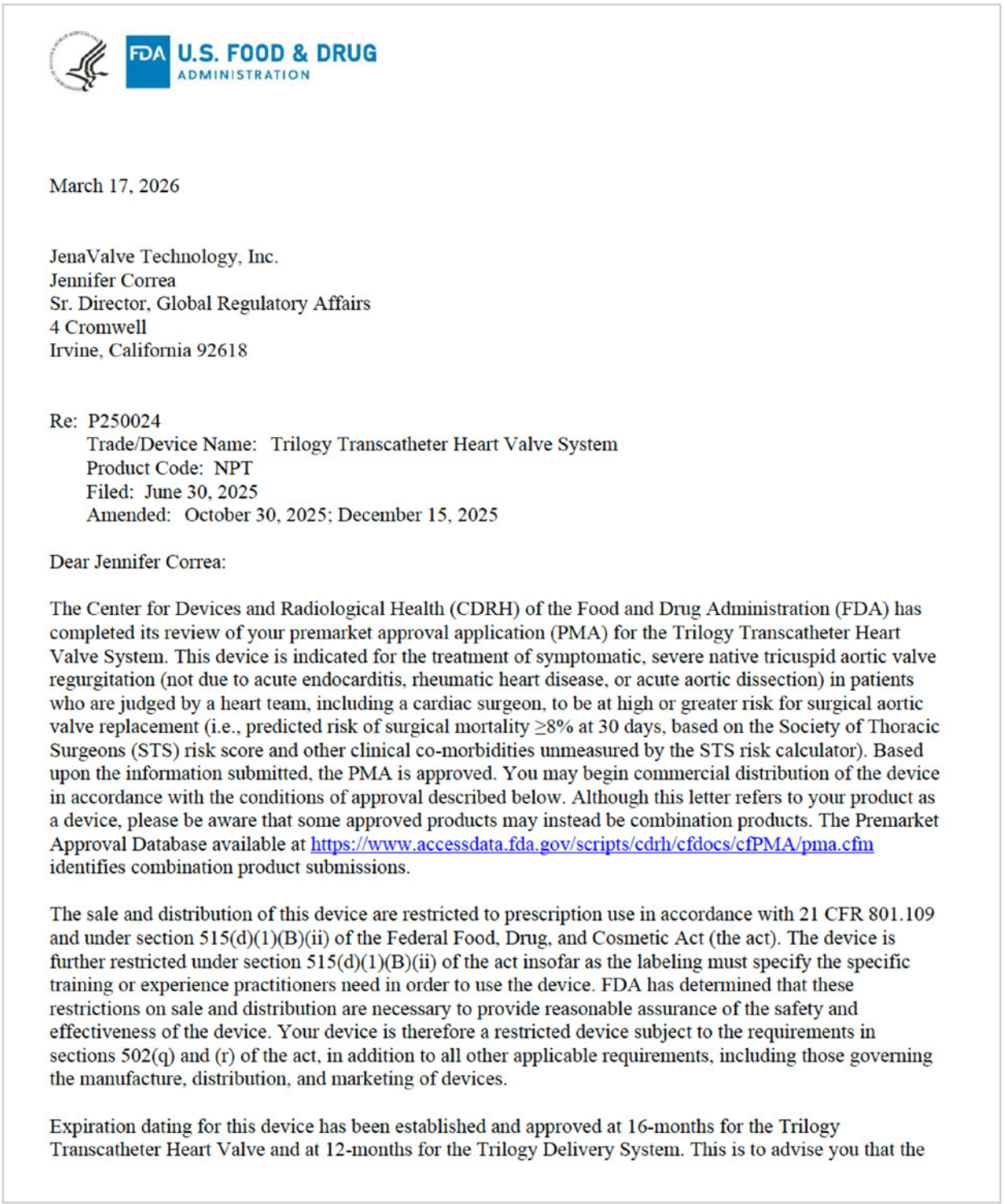
Coding and Documentation Tips

Always use the most specific ICD-10-CM code available. Document the clinical significance of each major comorbidity or complication, including its treatment during the hospitalization and status at discharge.

Thorough documentation of all clinically present MCCs supports future data analysis to achieve appropriate MS-DRG clinical and cost alignment.

Appendix C: Indications for Use

Per the March 17, 2026 FDA decision: "This device is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality ≥8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator)."



U.S. FOOD & DRUG ADMINISTRATION

March 17, 2026

JenaValve Technology, Inc.
Jennifer Correa
Sr. Director, Global Regulatory Affairs
4 Cromwell
Irvine, California 92618

Re: P250024
Trade/Device Name: Trilogy Transcatheter Heart Valve System
Product Code: NPT
Filed: June 30, 2025
Amended: October 30, 2025; December 15, 2025

Dear Jennifer Correa:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Trilogy Transcatheter Heart Valve System. This device is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality ≥8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator). Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 16-months for the Trilogy Transcatheter Heart Valve and at 12-months for the Trilogy Delivery System. This is to advise you that the

Appendix D: Sources

1. Hospital Inpatient Prospective Payment-Final Rule FY 2026 Home Page CMS-1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page
2. 2026 ICD-10-PCS Procedure Coding System and Index: https://www.cms.gov/files/document/2026-official-icd-10-pcs-coding-guidelines.pdf
3. 2026 ICD-10-CM: https://www.cms.gov/files/document/fy-2026-icd-10-cm-coding-guidelines.pdf
4. CMS MLN Matters MM8401 Mandatory Reporting of 8-Digit Clinical Trial Number on Claims: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM8401.pdf
5. 2025 American Medical Association. https://www.ama-assn.org/
6. Physician Prospective Payment Final rule with comment period and final CY 2026 Payment Rates. CMS-1832-F: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f
7. National Correct Coding Initiative Edits: https://www.cms.gov/medicare/coding-billing/ncci-medicare

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