



Transcatheter Heart Valve Procedures

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

The heart has four valves (aortic, pulmonary, mitral, and tricuspid), which direct blood flow to the lungs and aorta. Defective valves (e.g., diseased or congenital defects) can result in stenosis (when the valve opening narrows and cannot open all the way) or leakage of blood around the valve (also referred to as regurgitation). Conventional treatment of heart valve disorders includes surgical repair or replacement, which require open-heart surgery using cardiopulmonary bypass. Transcatheter (percutaneous or catheter-based) valve procedures use a catheter to access the heart and heart valves without the need for open-heart surgery and cardiopulmonary bypass. During the procedure, a compressed artificial heart valve or bioprosthetic valve is implanted.

Procedures include, but may not be limited to, the following examples (Note, not all are addressed by this Medicare Advantage medical policy):

- Transcatheter aortic valve replacement (TAVR) or implantation (TAVI)
- Transcatheter mitral valve replacement or implantation (TMVR)
- Transcatheter mitral valve repair / Mitral valve transcatheter edge-to-edge repair (TEER)
- Transcatheter pulmonary valve replacement (TPVR);
- Transcatheter edge-to-edge repair for tricuspid valve regurgitation (T-TEER)
- Transcatheter tricuspid valve replacement (TTVR);
- Valve-in-Valve (ViV) replacement within a failed bioprosthesis;
- Transcatheter mitral valve annuloplasty reconstruction (TMVAR); and,
- Transcatheter tricuspid valve annuloplasty reconstruction (TTVAR)
- Transcatheter caval valve implantation (CAVI).

MEDICARE ADVANTAGE POLICY CRITERIA

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) OR IMPLANTATION (TAVI)		
General	33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369, 33999	Transcatheter Aortic Valve Replacement (TAVR) (20.32)
<i>Example:</i> Edwards' Sapien Transcatheter Heart Valve (THV)		
For the treatment of symptomatic aortic valve stenosis	NCD 20.32, A	Reminder: The heart team and hospital must be participating in a prospective, national, audited registry. Medicare-approved TAVR/TAVI registries and studies can be found on the Coverage with Evidence Development web page. Medicare CED also requires each patient be entered into a qualified national registry or participate in a qualifying clinical study. ^[2,3]
For uses not expressly listed as FDA-approved indications	NCD 20.32, B	"For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies. The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS." ^[2,3] Again, Medicare-approved studies are posted on the CMS website Coverage with Evidence Development .
Repeat aortic valve replacement procedures		Paravalvular leaks and paravalvular regurgitation (PVR) are known complications of TAVR, and can lead to the need for a repeat aortic valve procedure. ^[4,5] The durability of TAVR valves has been established at 5-year follow up but the long-term durability remains unknown, so the Medicare NCD 20.32 requires registries to track various outcomes, including repeat aortic procedures as they collect data regarding the long-term safety and efficacy of TAVR procedures. The health plan will consider repeat TAVR procedures to be medically necessary for paravalvular regurgitation (PVR) or leaks when the National Clinical Trial (NCT) number of the registry is included, in order to meet the NCD registry requirement for tracking repeat valve procedures.

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
MITRAL VALVE TRANSCATHETER EDGE-TO-EDGE REPAIR (TEER, previously known as TRANSCATHETER MITRAL VALVE REPAIR)		
General <i>Example:</i> Abbott Vascular's MitraClip®	33418, 33419, 0345T	According to a Decision Memo (CAG-00438R), CMS replaced the term Transcatheter Mitral Valve Repair with Mitral Valve Transcatheter Edge-to-Edge Repair (TEER) . The NCD 20.33 is applicable to TEER for the treatment of functional mitral regurgitation (MR) and degenerative MR. Note: Mitral valve <u>repair</u> is a different procedure from mitral valve <u>replacement</u> . Mitral valve replacement is addressed further in the policy.
For the treatment of mitral regurgitation (MR)	NCD 20.33, A.	Reminder: Criteria for coverage listed in NCD 20.33, A. state the heart team and hospital are participating in a prospective, national, audited registry. Medicare-approved registries and studies can be found on the Coverage with Evidence Development web page. Medicare CED also requires each patient be entered into a qualified national registry or participate in a qualifying clinical study. ^[6]
For uses not expressly listed as FDA-approved indications	Mitral valve TEERs are covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the Criteria listed in NCD 20.33, B.	
Repeat mitral valve surgery	Complications of TEER can lead to the need for a repeat mitral valve procedure. Durability of the device is also not known beyond five years ^[8] , so the Medicare NCD 20.33 requires registries to track various outcomes, including repeat mitral surgery as they collect data regarding the long-term safety and efficacy of TEER procedures. The health plan will consider repeat TEER procedures to be medically necessary when the National Clinical Trial (NCT) number of the registry is included, in order to meet the NCD registry requirement for tracking repeat valve procedures.	
TRANSCATHETER MITRAL VALVE REPLACEMENT (TMVR)		

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
General	0483T, 0484T	<p>Note: Mitral valve replacement is a different procedure from mitral valve repair. Mitral valve repair is addressed above in the policy.</p> <p>For devices not approved by the FDA: According to the Medicare Benefit Policy Manual, Chapter 14, while U.S. Food and Drug Administration (FDA) approval does not automatically <i>guarantee</i> coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, mitral valve replacement using a non-FDA-approved device is considered not medically reasonable or necessary unless the service is provided through a Medicare-approved IDE study per §1862(a)(1)(A).</p> <p>For FDA-approved devices: Medicare coverage guidance is not available for transcatheter mitral valve replacement. Therefore, the health plan's medical policy is applicable.</p> <p>Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders, Surgery, Policy No. 221 (see REGULATORY STATUS below)</p>
TRANSCATHETER TRICUSPID VALVE REPAIR (T-TEER) and IMPLANTATION/REPLACEMENT (TTVR)		
General	0569T, 0570T, 0646T	CMS covers T-TEER and TTVR for the treatment of symptomatic tricuspid regurgitation under Coverage with Evidence Development (CED) . Coverage for T-TEER and TTVR is available when furnished
Example:		

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
<i>TriClip™ (Abbott), Evoque™ (Edwards)</i>		according to Food and Drug Administration (FDA) market-authorized indications and when criteria are met. Not all devices have received FDA approval for this purpose.
<i>For the treatment of severe symptomatic tricuspid regurgitation (TR)</i>		Decision Memo CAG-00468N is applicable to Transcatheter Tricuspid Valve Repair (T-TEER). Decision Memo CAG-00467N is applicable to Transcatheter Tricuspid Valve Replacement (TTVR).
<i>For devices or uses not expressly listed as FDA-approved indications</i>		For devices not approved by the FDA: According to the Medicare Benefit Policy Manual, Chapter 14, while FDA approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, T-TEER and TTVR using a non-FDA-approved device is considered not medically reasonable or necessary unless the service is provided through a Medicare-approved IDE study per Medicare under §1862(a)(1)(A). (To confirm participation in a Medicare-approved IDE study, the NCT number must be provided.)
AORTIC AND MITRAL VALVE-IN-VALVE PROCEDURES		
<i>General</i>	33361	A valve-in-valve procedure is the transcatheter heart valve implantation within an existing bioprosthetic valve that has failed or degenerated over time.
	33362	
	33363	
	33364	
	33365	Not all devices have received FDA approval for this purpose. Even if part of a Medicare-approved IDE study (see table in “Regulatory Status”
	33366	

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
	33999	<p>section below), all TAVR and TMVR devices are subject to the above CED requirements, clinical criteria, and study participation, outlined in NCDs 20.32 and 20.33above. This is a Medicare requirement, until the scientific evidence demonstrating established safety and efficacy is available.</p> <ul style="list-style-type: none"> • TAVR devices used in a valve-in-valve procedure: NCD 20.32, B • TMVR devices used in a valve-in-valve procedure: NCD 20.33, B
TRANSAPICAL MITRAL VALVE REPAIR AND TRANSCATHETER MITRAL VALVE ANNULOPLASTY RECONSTRUCTION (TMVAR)		
General	0543T, 0544T	<p>For devices not approved by the FDA: According to the Medicare Benefit Policy Manual, Chapter 14, while FDA approval does not automatically <i>guarantee</i> coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, transapical mitral valve repair and transcatheter mitral valve annuloplasty reconstruction (TMVAR) using a non-FDA-approved device is considered not medically reasonable or necessary unless the service is provided through a Medicare-approved IDE study per Medicare under §1862(a)(1)(A).</p> <p>For FDA-approved devices: <i>Medicare coverage guidance is not available for transapical mitral valve repair and transcatheter mitral valve</i></p>

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
		<p><i>annuloplasty reconstruction (TMVAR). Therefore, the health plan's medical policy is applicable.</i></p> <p>Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders, Surgery, Policy No. 221 (see REGULATORY STATUS below)</p>
TRANSCATHETER TRICUSPID VALVE ANNULOPLASTY RECONSTRUCTION (TTVAR)		
General	0545T	<p>For devices not approved by the FDA: According to the Medicare Benefit Policy Manual, Chapter 14, while FDA approval does not automatically <i>guarantee</i> coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, TTVAR using a non-FDA-approved device is considered not medically reasonable or necessary unless the service is provided through a Medicare-approved IDE study per Medicare under §1862(a)(1)(A).</p> <p>For FDA-approved devices: <i>Medicare coverage guidance is not available for transcatheter tricuspid valve annuloplasty reconstruction (TTVAR). Therefore, the health plan's medical policy is applicable.</i></p> <p>Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders, Surgery, Policy No. 221 (see REGULATORY STATUS below)</p>
CAVAL VALVE IMPLANTATION (CAVI)		

Procedure(s):	Code(s)	CMS Coverage Manuals and National Coverage Determinations (NCD)*
General	0805T, 0806T	<p>For devices not approved by the FDA: According to the Medicare Benefit Policy Manual, Chapter 14, while FDA approval does not automatically <i>guarantee</i> coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, caval valve implantation (CAVI) using a non-FDA-approved device is considered not medically reasonable or necessary unless the service is provided through a Medicare-approved IDE study per Medicare under §1862(a)(1)A.</p> <p>For FDA-approved devices: <i>Medicare coverage guidance is not available for caval valve implantation (CAVI). Therefore, the health plan's medical policy is applicable.</i></p> <p>Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders, Surgery, Policy No. 221 (see REGULATORY STATUS below)</p>

BACKGROUND

Aortic Valve Procedures

The aortic valve directs blood flow from the left ventricle into the aorta. When the aortic valve does not open properly due to stenosis (narrowing or obstruction of the aortic valve), the left ventricle must work harder to ensure enough blood is pumped through the narrowed opening to circulate to the rest of the body. Reduced blood flow can cause chest pain, shortness of breath, excess fluid retention and other symptoms, and if left untreated, can result in left ventricular hypertrophy and heart failure.

The gold standard for treating severe, symptomatic aortic stenosis is open-heart surgery with a prosthetic valve. However, due to various reasons (e.g., age, overall frailness, presence of other medical conditions), not all individuals may be candidates for open-heart surgery, making the surgery too risky. Transcatheter aortic valve replacement (TAVR) is a minimally invasive alternative to open-heart valve replacement. TAVR involves the percutaneous insertion of a bioprosthetic valve using a catheter in the orifice of the aortic valve. The procedure is done without removing the diseased native valve.

Mitral Valve Procedures

The mitral valve directs blood flow from the left atrium to the left ventricle. When the mitral valve does not close properly, this is known as mitral regurgitation (MR). MR may also be referred to as mitral incompetence or mitral insufficiency. MR can allow blood to flow backwards from the ventricle to the atrium and if left untreated, moderate to severe MR can lead to congestive heart failure. MR that cannot be managed conservatively may require surgical valve intervention, with repair of the mitral valve (MV) preferred over replacement, particularly in patients with preserved left ventricle function.

Transcatheter leaflet repair, percutaneous annuloplasty, artificial chordae tendineae and annulus reconstruction are minimally invasive approaches to repair damaged mitral valves.

- Transcatheter leaflet repair keeps the two valve leaflets more closely fitted together, thereby reducing regurgitation, using a clip instead of a suture to secure the leaflets.
- Percutaneous transcatheter annuloplasty attempts to replicate the functional effects of open surgical annuloplasty by reshaping the mitral annulus from within the coronary sinus. Techniques to repair the mitral annulus include those that target the annulus itself (direct annuloplasty) and those that tighten the mitral annulus via manipulation of the adjacent coronary sinus (indirect annuloplasty). Indirect annuloplasty devices include the Carillon® Mitral Contour System (Cardiac Dimension) and the Monarc™ device (Edwards Lifesciences).

- Various artificial chordae tendineae and annulus reconstruction devices are in the early stages of development.

Transcatheter mitral valve replacement (TMVR) is a minimally invasive alternative to open surgical valve replacement. TMVR involves the percutaneous insertion of a bioprosthetic valve. The procedure is done without removing the diseased native valve.

Tricuspid Valve Procedures

The tricuspid valve directs blood flow from the right atrium to the right ventricle. When the tricuspid valve does not close properly, this is known as tricuspid regurgitation (TR). TR may also be referred to as tricuspid incompetence or tricuspid insufficiency. TR allows blood to flow backwards from the ventricle to the atrium. The gold standard for treating tricuspid valve disease is surgical annuloplasty, but devices for transcatheter tricuspid valve repair, reconstruction and replacement are in the early stages of development.

Valve-in-Valve Procedures

A valve-in-valve procedure is the transcatheter heart valve implantation within an existing bioprosthetic valve that has failed or degenerated over time. Not all devices have received FDA approval for this purpose.

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For ALL transcatheter valve procedures, provide medical/clinical notes documenting the following:

- All clinical documentation pertinent to request, including:
 - Condition to be treated;
 - Documentation of two (2) specialists having examined the patient's suitability for valve replacement **and** the rationale for their judgment (the NCDs in this Medicare Advantage medical policy provide specific requirements regarding which specialists are to independently examine the patient – these NCD requirements will be used as appropriate for the request); and
 - Confirmation the patient is under the care of a heart team;
- The name of the device that will be used; and,
- The NCT number for the registry or study the member is enrolled in (enrollment is a requirement under various Medicare NCDs). This is also required for **repeat** TAVR, TAVI, and transcatheter mitral valve repair with mitral valve TEER procedures.

Note: Medicare requires the 8-digit identifier number to be included on claims for TAVR and mitral valve TEER.^[1,8] Registry and study numbers for NCDs with coverage with evidence development (CED) requirements can be found online at:

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development>

REGULATORY STATUS

The fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

Some devices are still investigational in nature and may only be eligible for coverage if the member is enrolled in an investigational device exemption (IDE) study that has been approved by Medicare. Medicare-approved IDE studies can be found on the [CMS website](#). All TAVR and TEER devices must still meet the NCD coverage criteria referenced above. (For information regarding Category A and B IDE guidelines, see Cross References.)

CROSS REFERENCES

[Clinical Trials and Investigational Device Exemption \(IDE\) Studies](#), Medicine, Policy No. M-150

[Coverage with Evidence Development \(CED\) Studies and Registries](#), Medicine, Policy No. M-156

REFERENCES

1. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, [§290 – Transcatheter Aortic Valve Replacement \(TAVR\)](#) (See all related subsections)
2. CMS Manual System [Change Request 7897](#) Dated September 24, 2012
3. CMS Manual System [Change Request 11660](#) Dated June 10, 2020
4. Medicare Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) ([CAG-00430N](#)) [Cited 06/25/2025]
5. Medicare Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) ([CAG-00430R](#)) [Cited 06/25/2025]
6. CMS Manual System [Change Request 9002](#) Dated December 5, 2014
7. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, [§340 – Transcatheter Mitral Valve Repair \(TEER\)](#) (See all related subsections)
8. Decision Memo for Transcatheter Mitral Valve Repair (TMVR) ([CAG-00438N](#))

CODING

NOTE: There are various approaches for performing various transcatheter heart valve procedures and many of those approaches have a specific CPT code available. However, not all approaches do have a specific code available (e.g., TAVR performed via the carotid artery). Therefore, the appropriate code for reporting these procedures would be 33999. CPT code 93799 would not be considered appropriate for transcatheter valve procedures.

Codes	Number	Description
CPT	33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
	33362	; open femoral approach
	33363	; open axillary artery approach
	33364	; open iliac artery approach
	33365	; transaortic approach (e.g., median sternotomy, mediastinotomy)
	33366	; transapical exposure (e.g., left thoracotomy)
	33367	; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
	33368	; 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)
	33369	; 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)
	33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
	33419	; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
	33999	Unlisted procedure, cardiac surgery
	0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
	0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed (e.g., Tiara® [Neovasc])
	0484T	; transthoracic exposure (eg, thoracotomy, transapical)
	0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae (e.g., Harpoon and NeoChord)
	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture (e.g., Edwards Cardioband™ Mitral Valve Reconstruction System [Edwards Lifesciences])
	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach (e.g., Edwards Cardioband™ Tricuspid Valve Reconstruction System [Edwards Lifesciences])

0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis (e.g., TriClip™ [Abbot])
0570T	; each additional prosthesis during same session (list separately in addition to code for primary procedure)
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
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
HCPCS	None

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.