



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 06/05/18
LAST REVIEW DATE:
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ARCHIVE DATE:

ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA (cont.)

Description:

Thoracic endovascular aneurysm repair (TEVAR) involves the percutaneous placement of a stent graft in the descending thoracic or thoracoabdominal aorta. It is a less invasive alternative to open surgery for the treatment of dissections and isolated lesions such as aneurysms, penetrating ulcers, isolated hematomas or rupture. TEVAR is performed through a small groin incision to access the femoral artery, followed by delivery of catheters across the diseased portion of the aorta. A tubular stent graft composed of fabric and metal is then deployed under fluoroscopic guidance. The stent graft is then fixed to the proximal and distal portions of the aorta.

Stent grafts include the GORE TAG® Thoracic Endoprosthesis, Relay® Thoracic Stent-Graft with Plus Delivery System, Talent™ Thoracic Stent Graft System, Valiant™ Thoracic Stent Graft with the Captivia® Delivery System and the Zenith TX2® TAA Endovascular Graft.

Criteria:

For angioplasty and endovascular stent placement, see BCBSAZ Medical Coverage Guideline #O270, “Angioplasty and Endovascular Stent Placement”.

For carotid artery angioplasty with or without endovascular stent placement, see BCBSAZ Medical Coverage Guideline #O710, “Carotid Artery Angioplasty”.

For endovascular procedures for intracranial arterial disease, see BCBSAZ Medical Coverage Guideline #O754, “Endovascular Procedures for Intracranial Arterial Disease”.

For endovascular stent grafts for abdominal aortic aneurysms, see BCBSAZ Medical Coverage Guideline #O751, “Endovascular Stent Grafts for Abdominal Aortic Aneurysms”.

➤ Endovascular stent grafts for the treatment of descending thoracic aortic aneurysm using devices approved by the FDA for their approved specifications is considered **medically necessary** with documentation of **ONE** of the following:

1. Aortic inner diameter of 23-37 mm when using the GORE TAG Thoracic Endoprosthesis
2. Aortic inner diameter of 19-42 mm when using the Relay Thoracic Stent-Graft with Plus Delivery System
3. Aortic inner diameter of 18-42 mm when using the Talent Thoracic Stent Graft System
4. Aortic inner diameter of 18-42 mm when using the Valiant Thoracic Stent Graft
5. Aortic diameter measured outer wall to outer wall of 24-38 mm when using the Zenith TX2 TAA Endovascular Graft

ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA (cont.)

Criteria: (cont.)

- Endovascular stent grafts using devices approved by the FDA for treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection are considered **medically necessary**.
- Endovascular stent grafts using devices approved by the FDA for the treatment traumatic descending thoracic aortic tears or rupture are considered **medically necessary**.
- Endovascular stent grafts for the treatment of descending thoracic aortic disorders for all other indications not previously listed or if above criteria not met are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Uncomplicated aortic dissection

- Endovascular stent grafts for the treatment of ascending aortic disorders are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Thoracic aortic arch aneurysms



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Resources:

Literature reviewed 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 08/21/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.86 BCBS Association Medical Policy Reference Manual. Endovascular Stent Grafts for Disorders of the Thoracic Aorta. Re-issue date 05/04/2018, issue date 12/18/2002.

FDA Premarket Approval Database for GORE TAG Thoracic Endoprosthesis:

- FDA-approved indication: Endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy including:
 - 1) adequate iliac/femoral access
 - 2) aortic inner diameter in the range of 23-37 mm
 - 3) ≥ 2 cm non-aneurysmal aorta proximal and distal to the aneurysm

FDA Premarket Approval Database for Relay Thoracic Stent-Graft with Plus Delivery System:

- FDA-approved indication: Endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:
 - 1) Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices and/or accessories
 - 2) Non-aneurysmal aortic neck diameter in the range of 19 - 42 mm
 - 3) Non-aneurysmal proximal aortic neck lengths between 15 and 25 mm and distal aortic neck lengths between 25 and 30 mm, depending on the diameter stent-graft required

ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Talent Thoracic Stent Graft System:

- FDA-approved indication: Endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including:
 - 1) iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices and/or accessories
 - 2) non-aneurysmal aortic diameter in the range of 18-42mm
 - 3) non-aneurysmal aortic proximal and distal neck lengths \geq 20mm

FDA Premarket Approval Database for Valiant Thoracic Stent Graft with the Captivia Delivery System:

- FDA-approved indication: Endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having the appropriate anatomy, including:
 - 1) iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, or accessories
 - 2) non-aneurysmal aortic diameter in the range of 18 to 42 mm (fusiform and saccular aneurysms/penetrating ulcers), or 18 mm to 44 mm (blunt traumatic aortic injuries), or 20 mm to 44 mm (dissections)
 - 3) non-aneurysmal aortic proximal and distal neck lengths \geq 20 mm. The proximal extent of the landing zone must not be dissected

FDA Premarket Approval Database for Zenith TX2 TAA Endovascular Graft:

- FDA-approved indication: Endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:
 - 1) adequate iliac/femoral access compatible with the required introduction systems
 - 2) non-aneurysmal aortic segments (fixation sites) proximal and distal to the aneurysm or ulcer: a) with a length of at least 25 mm and b) with a diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkido go éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkido beehaz'áanii hółq díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodíłnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، ف لديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

