GORE® TAG®
Thoracic Branch Endoprosthesis

HOSPITAL INPATIENT CODING GUIDE 2024

Together, improving life

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Gore has used reasonable efforts to ensure the completeness and accuracy of the information contained herein as of the date this document was published. Health care providers are responsible for exercising their independent clinical judgment and following specific coverage guidelines and payer directives in selecting the codes that reflect the patient’s condition and the services provided. Health care providers should contact the individual Medicare contractor or other third-party payer if they have questions regarding reimbursement. Gore does not promote its products outside of their FDA-cleared or approved labeled indications.

GORE® TAG® Thoracic Branch Endoprosthesis (TBE) description

TBE is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery.*

The GORE® TAG® Thoracic Branch Endoprosthesis is an implantable branched stent graft designed for branched thoracic endovascular aortic repair (TEVAR) of the descending thoracic aorta requiring placement into an area of the arch (zone 2) that includes the left subclavian artery. It consists of at least 2 components which line the thoracic aorta and the left subclavian artery. The devices allow blood to flow into the left subclavian artery and the rest of the aorta while preventing blood from flowing to the affected area and does not require an open surgical procedure. The device extends from the left subclavian artery, including a portion of the aortic arch, to the descending thoracic aorta.

The GORE® TAG® Thoracic Branch Endoprosthesis is made of expanded polytetrafluoroethylene (ePTFE) with an outer metallic support structure known as a stent. See *Figure 1* for an image depicting the GORE® TAG® Thoracic Branch Endoprosthesis.

FDA Breakthrough Device Designation

The device was granted priority review status on July 17, 2015. This was based on meeting required criteria:

- Intended to treat a potentially life-threatening disease
- Potential to provide a clinically meaningful advantage over existing legally marketed technology
- Offering significant clinically meaningful advantages over existing legally marketed alternatives
- Availability is in the best interest of patients

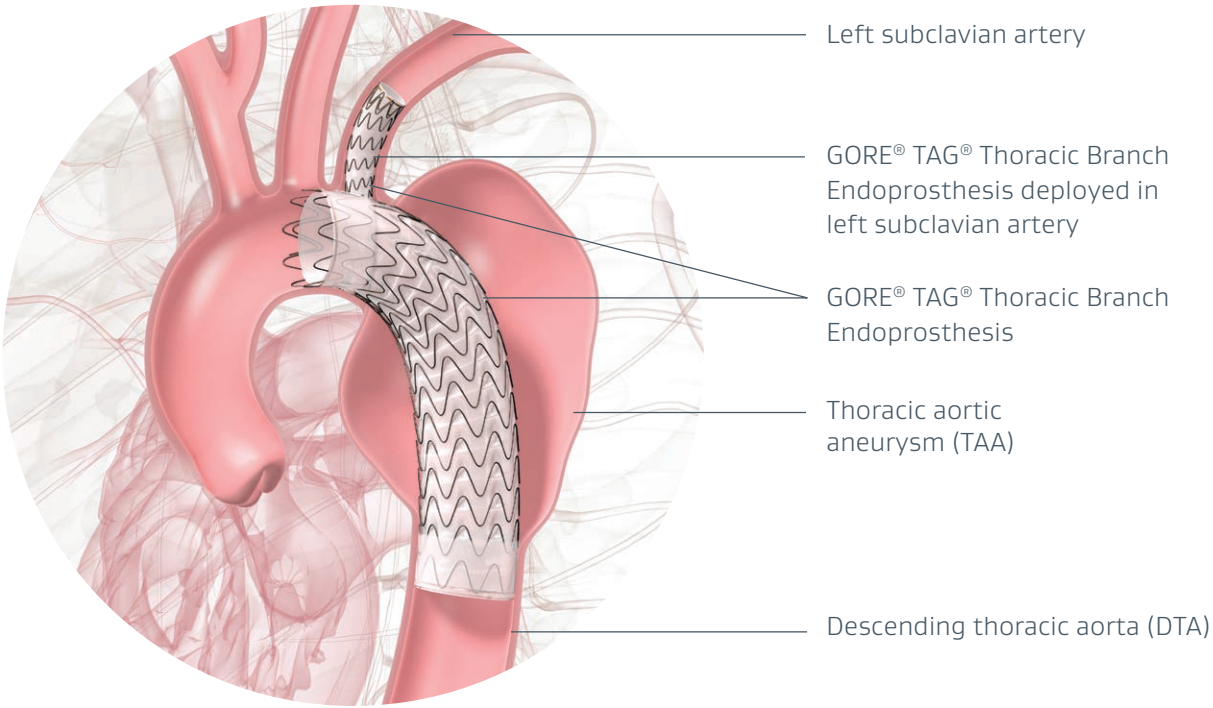

Figure 1. GORE® TAG® Thoracic Branch Endoprosthesis deployed in the left subclavian artery and the descending thoracic aorta.

* Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Table 1: Centers for Medicare and Medicaid Services (CMS) Fiscal Year 2024 Medicare Severity Diagnosis Related Groups (MS-DRGs)

The following MS-DRGs are the most commonly assigned for the TBE procedure. Other DRGs may apply based on documented procedures performed, patient's condition or complications.

Medicare Inpatient Proseptctive Payment System (IPPS)

MS-DRGs	Description	Relative weight	Medicare national unadjusted amount
219	Cardiac valve and other major cardiothoracic procedures without cardiac catheterization with major complication or comorbidity (MCC)	7.7112	$53,990.74
220	Cardiac valve and other major cardiothoracic procedures without cardiac catheterization with complication or comorbidity (CC)	5.2446	$36,720.59
221	Cardiac valve and other major cardiothoracic procedures without cardiac catheterization without CC/MCC	4.6486	$32,547.64

Reference: FY 2024 IPPS Final Rule Home Page | CMS

Table 2: International Classification of Diseases (ICD)-10-PCS

TBE must be reported with both of the assigned ICD-10-PCS codes below.
Code all other procedures documented applicable to case.

ICD-10-PCS	Description
02VW3DZ	Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach
02VX3EZ	Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach

Reference: 2024 ICD-10-PCS | CMS

Table 3: Current procedural terminology (CPT®) code

Surgery/cardiovascular system

Miscellaneous code 33999 should be utilized to report TBE procedure in absence of a descriptive code.
Code with all other interventions applicable.

Healthcare common procedure coding system (HCPCS)	Description	Pro fee facility total relative value units (RVUs)	Pro fee facility adjusted partial payment
33999	Unlisted procedure, cardiac surgery	0.00	$0.00

Comparator equals previous surgical procedural coding RVU for reporting purposes.
Individual payors contractual terms may differ according to miscellaneous code usage.
Gore suggests contacting and following payor contractual agreements for reporting purposes.

New Technology Add-on Payment (NTAP)*,[1]

The Centers of Medicare & Medicaid Services (CMS) created the NTAP to help ensure hospitals do not incur significant reimbursement shortfalls when adopting innovative new technologies. NTAP is additional payment on top of the Medicare Severity Diagnosis Related Group (MS-DRG) or TRICARE® DRG reimbursement.

Approval granted:

- Cost criterion: Cost for cases involving TBE "exceeds the case-weighted threshold amount."
- FDA marketing authorization May 13, 2022, for indication covered by its Breakthrough Device designation for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and have appropriate anatomy.†

Reporting add-on payment:

The International Classification of Diseases 10th Revision Procedure Coding System (ICD-10-PCS) code for reporting will be effective October 1, 2022. Hospitals can report the codes on claim forms for procedures‡ related to TBE to receive the add-on payment for eligible inpatient cases.

Details of the NTAP:

Eligible facilities	Acute care hospitals participating in the inpatient prospective payment system (IPPS) are eligible. Hospitals under the TRICARE® program are eligible.
Qualified patients	Traditional Medicare and dual-eligible (Medicare-Medicaid) fee-for-service patients or TRICARE® patients whose case totals exceed the MS-DRG rate payment are qualified.
Add-on payment	NTAP is limited to lesser of 65% of the cost of the new technology or 65% of the amount by which the cost of case exceeds the MS-DRG payment.
Payment amount	Total $27,807 per maximum amount. Effective October 1, 2022.
Duration	NTAP is approved for a minimum of two years and no more than three years; the maximum add-on payment amount is reassessed annually.
Coding requirements	**ICD-10-PCS Codes:** (Both must be reported on claim)[2] **02VX3EZ –** Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach. **02VW3DZ –** Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach.

Exclusion criteria:

- Hospitals not reimbursed under the IPPS – (Include but not limited to critical access hospitals, excluded cancer hospitals, long-term acute care hospitals, Veterans Affairs [VA] hospitals, Department of Defense [DoD] facilities and hospitals in the state of Maryland are not eligible to receive add-on payments).

* Outlier payments are still applicable when eligible and all payments vary by hospital and are case-dependent. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier

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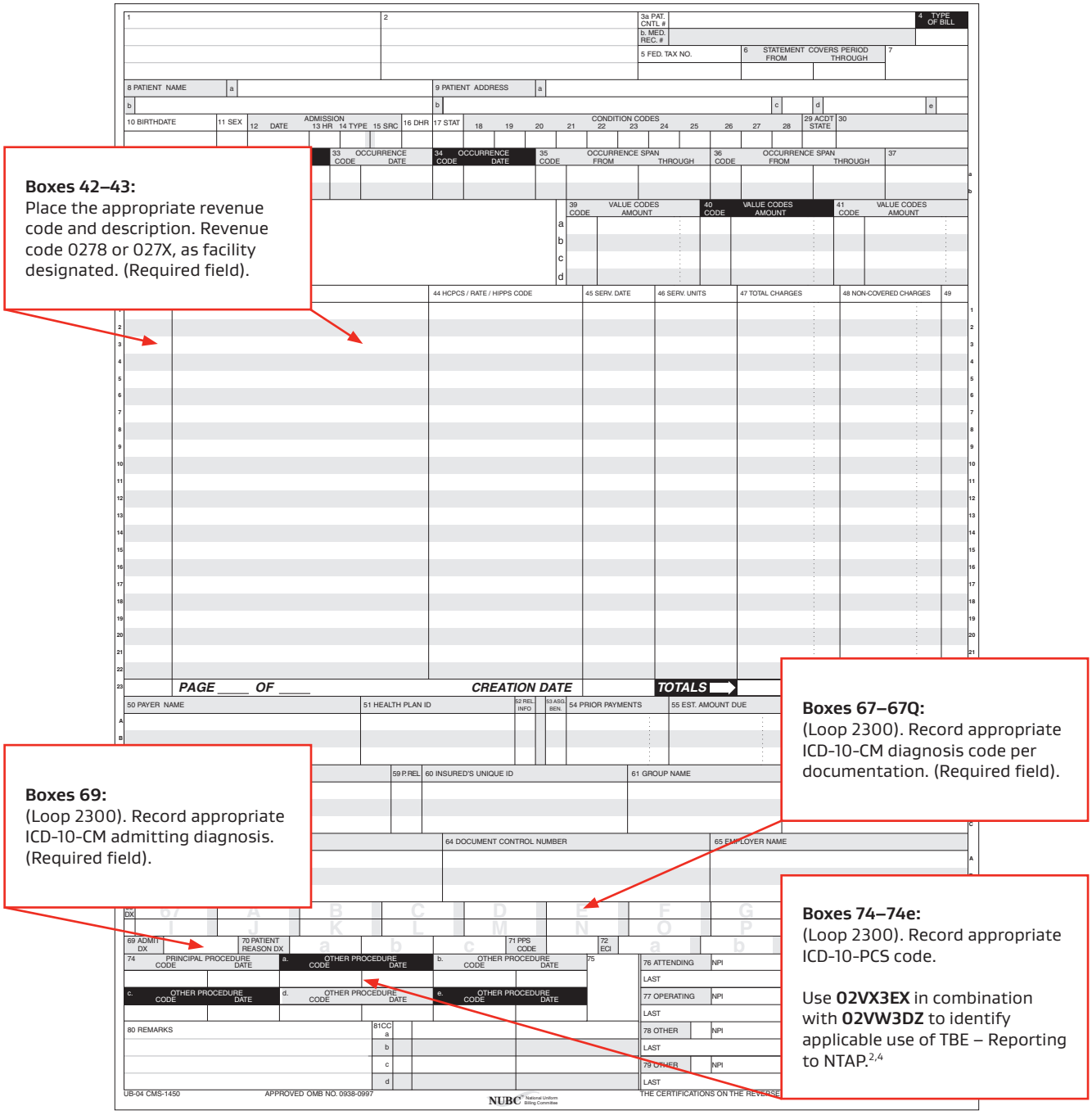
‡ Hospitals remain responsible for determining correct coding and reimbursement reporting.

Sample CMS-1450 (UB04) claim form*,†,[3]

The information below refers to the paper format of the CMS-1450 (UB-04). Providers submitting claims for TBE via electronic software systems are urged to translate claim information into compatible formats for input into their software system.



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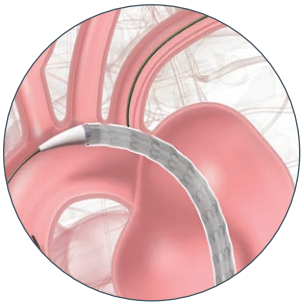
Procedural steps

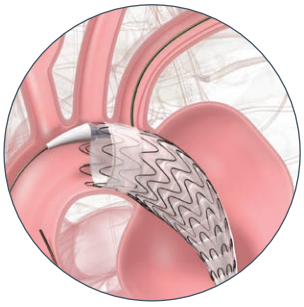
The procedure for implanting the GORE® TAG® Thoracic Branch Endoprosthesis consists of the delivery of the stent grafts into the aorta and the left subclavian artery. While the endovascular procedure is similar for trauma or dissection repair, below is an example of the steps included in an aneurysm repair.

The main body stent graft is implanted using fluoroscopy, or real-time X-ray images, and is viewed on a monitor following these steps:

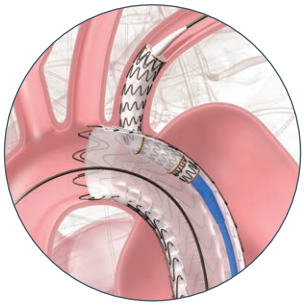
1. The delivery catheter, which contains the stent graft, is inserted into the femoral or iliac artery and carefully guided through the abdomen into the chest to the site of the diseased or injured aorta.
2. Once the stent graft is correctly positioned in the aorta and aligned with the left subclavian artery, it is released, or deployed, from the delivery catheter. The device self-expands to the diameter of the aorta and the delivery catheter is withdrawn from the body.
3. A second, smaller stent graft is inserted into the femoral or iliac artery and positioned through the opening of the first stent graft into the left subclavian artery.
4. Once the second stent graft is correctly positioned within the left subclavian artery, it is released, or deployed, from the delivery catheter. The delivery catheter is then removed.
5. Following deployment, an endovascular balloon may be inflated inside the device to aid the device in opening completely, allowing the device to achieve better seal.



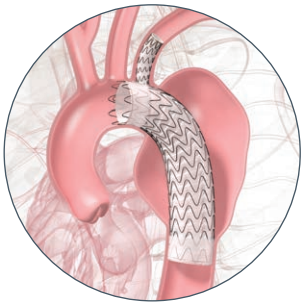
Positioning aortic component at left subclavian artery



Deployment of aortic component



Positioning of side branch component into left subclavian artery



Final GORE® TAG® Thoracic Branch Endoprosthesis system

In some cases, it may be necessary to utilize an additional component(s) to extend proximal into the aortic arch or distal into the descending aorta. Physicians determine the actual devices utilized based on individual patient needs.

References

1. Department of Health & Human Services. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS). Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation. A Rule by the Centers for Medicare & Medicaid Services on 08/10/2022. *Federal Register* 2022;87(153):48780-49499. https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf
2. U.S. Centers for Medicare & Medicaid Services. 2024 ICD-10 Procedure Coding System (ICD-10-PCS). Updated May 26, 2022. Accessed November 4, 2022. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-pcs
3. National Uniform Billing Committee (NUBC). Billing information. American Hospital Association. Accessed November 4, 2022. https://www.nubc.org/
4. U.S. Centers for Medicare & Medicaid Services. 2022 ICD-10 Procedure Coding System (ICD-10-PCS). Updated 01/12/2022. Accessed November 4, 2022 https://www.cms.gov/medicare/icd-10/2022-icd-10-pcs

For coding and/or reimbursement support, contact:

REVENUE CYLE CODING STRATEGIES® (RCCS) at +1 888 812 0322 or visit goremedical.com/coding

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery and have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the left subclavian artery and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16–42 mm; Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0–4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Left Subclavian Landing Zone:** Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Left subclavian artery minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16–42 mm; Non aneurysmal, dissected, heavily calcified or heavily thrombosed landing zone; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft.

CONTRAINDICATIONS: The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only - Heparin (CBAS® Heparin Surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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