



CMS Grants Additional Reimbursement for GORE® TAG® Thoracic Branch Endoprosthesis (TBE)

Effective October 1, 2022

New Technology Add-on Payment (NTAP)

The Centers for Medicare and Medicaid Services (CMS) created the NTAP to help ensure hospitals do not incur significant reimbursement shortfalls when adopting innovative new technologies and to facilitate patient access for qualifying new medical technologies that substantially improve the diagnosis or treatment of Medicare beneficiaries.

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.*

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	<u>ICD-10-PCS Codes:</u> (Both must be reported on claim) 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.

Reference: <https://www.federalregister.gov/documents/2023/08/28/2023-16252/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

* Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable applications, warnings, precautions and contraindications for the markets where this product is available. ^{Rx only}

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



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for Use
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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. ^{Rx only}

Products listed may not be available in all markets.

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