NO. 91505-R1

TITANIUM RIB

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy outlines the clinical indications, coverage criteria, limitations, and regulatory framework for the use of the vertical expandable prosthetic titanium rib (VEPTR) in the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients.

Related policies: None

I. MEDICAL NECESSITY CRITERIA

A. Inclusions: Priority Health considers the **vertical expandable prosthetic titanium rib (VEPTR)** ("the titanium rib") to be medically necessary for U.S. Food and Drug Administration (FDA) approved indications, as defined below.

The FDA has granted a humanitarian use device approval for VEPTR for treatment of **thoracic insufficiency syndrome (TIS)** in skeletally immature patients. The FDA defines TIS as the inability of the thorax to support normal respiration or lung growth. The FDA notes that, for purposes of identifying potential TIS patients, the categories in which TIS patients fall are as follows:

1. Flail chest syndrome
2. Rib fusion and scoliosis
3. Hypoplastic thorax syndrome, including:

    a. Jeune's syndrome
    b. Achondroplasia
    c. Jarcho-Levin syndrome
    d. Ellis van Creveld syndrome

B. Exclusions: Following FDA restrictions, Priority Health considers the VEPTR **NOT** medically necessary under any of the following conditions:

1. Inadequate strength of the bone (ribs/spine) for attachment of the VEPTR
2. Absence of proximal ribs for attachment of the VEPTR
3. Absent diaphragmatic function
4. Inadequate soft tissue for coverage of the VEPTR
5. Age beyond skeletal maturity
6. Age below 6 months
7. Known allergy to any of the device materials
8. Infection at the operative site

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

The **vertical expandable prosthetic titanium rib (VEPTR)** ("the titanium rib") (Synthes Spine, West Chester, PA) has been used in expansion thoracoplasty to treat **thoracic insufficiency syndrome (TIS)** in children. In this procedure, the titanium rib is used as a chest wall distractor to directly treat segmental hemithorax hypoplasia from fused ribs by lengthening and expanding the constricted hemithorax, and improve the capacity of the underlying lung. The titanium rib is curved like a ribcage and has holes that allow the surgeons to expand the device in outpatient surgery every six months. In addition, the titanium rib may indirectly correct scoliosis in the young child without the need for spine

fusion. Surgical alternatives to the titanium rib include *in situ* spinal fusion, implantation of plastic sheets, artificial ribs from cadaver donor ribs or autograft (rib sections split from contralateral ribs). However, unlike the titanium rib, these surgical procedures are static treatments and are not adaptable as the child grows.

Approval as a humanitarian use device was based on the results of a 14 year, prospective, multicenter clinical trial of the VEPTR device in 247 children with TIS between 6 months of age up to the age of skeletal maturity. Treatment with the VEPTR device was shown to maintain or improve the **assisted ventilatory rating (AVR)** scores in 92 percent of patients, and the patient survival rate in the VEPTR clinical trial was 95.1 percent. The FDA determined that the probable benefits associated with patients implanted with the VETPR device outweigh the risk present for this patient population. The FDA noted that TIS is frequently terminal with nonsurgical treatment. The FDA noted that the ability of VEPTR to be expanded allows growth of the thoracic spine and lungs while controlling severe scoliosis.

Campbell, et al. (2004) reported on the outcome of VEPTR in 27 children (mean age 3.2 years at time of surgery) with congenital scoliosis associated with fused ribs who were followed for a mean duration of 5.7 years. Interval pulmonary function studies were analyzed to determine trends with regard to changes in vital capacity in the period following treatment. Sixteen subjects had such interval studies, at a mean of 3.1 years (range, two to 6.7 years) postoperatively. The first postoperative test demonstrated a mean vital capacity of 0.679 liters (L) (range, 0.37 to 1.7 L), or 49% (range, 33% to 68%) of the predicted normal vital capacity, whereas the mean vital capacity at the time of follow-up was 0.91 L (range, 0.51 to 2.1 L), or 47% (range, 25% to 66%) of the predicted normal vital capacity. There was a total of fifty-two complications in twenty-two patients, with the most common being asymptomatic proximal migration of the device through the ribs in seven patients.

COMPLICATIONS: From the feasibility and multi-center clinical trials, a total of 247 patients were evaluated for adverse events. Following is a list of potential adverse effects that may occur with treatment with TIS with the VEPTR device.

- Failure to stabilize or correct thoracic deformities
- Failure to support normal respiration or lung growth
- Failure to stabilize or correct progressive scoliosis
- Device migration (dislodgement, cut-out)
- Device fracture or bending
- Device disassembly
- Development of allergy to the implant materials (titanium)
- Need for additional surgical procedures, including expansions, replacements, removals
- Infection (abscess, cellulites, fever, pneumonia, urinary tract infections)
- Pain (back, check, neck)
- Pulmonary (effusions, atelectasis, respiratory distress, respiratory acidosis)
- Skin or wound (dermatitis, rash, skin necrosis, abnormal healing, scar formation)
- Neurologic (peripheral neuropathy, spinal cord injury, dural tear, CSF leak, convulsions, hypokinesis)
- Death

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
None identified	None identified

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Humanitarian Device Exemption (HDE) Number	Decision Date
Vertical Expandable Prosthetic Titanium Rib (VEPTR) (Synthes Spine)	H030009 S002 – S010	07/11/2005 – 11/27/2012

Note: no records were found with **HDE Number:** *H030009* **Supplement Type:** *HDE Original*

Humanitarian Device Exemption

In accordance with the **Orphan Drug Act (ODA)** of 1984, a rare disease is defined as a disease or condition that affects fewer than 200,000 people in the United States. Currently, in the United States, only a portion of the 7,000 known rare diseases have approved treatments. By definition, rare diseases or conditions occur in a small number of patients. As a result, it has been difficult to gather enough clinical evidence to meet the FDA standard of reasonable assurance of safety and effectiveness.

In order to address this challenge, Congress included a provision in the Safe Medical Devices Act of 1990 to create a regulatory pathway for products intended for diseases or conditions that affect small (rare) populations. This is the Humanitarian Device Exemption (HDE) Program.

Humanitarian Device Exemption is:

- a marketing application for a **Humanitarian Use Device (HUD)*** (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.
- the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

*** Humanitarian Use Device (HUD)**: a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255).

VI. CODING

ICD-10 Codes that may support medical necessity

J99	Respiratory disorders in diseases classified elsewhere
J98.4	Other disorders of lung
Q67.5	Congenital deformity of spine
Q67.8	Other congenital deformities of chest
Q76.2	Congenital spondylolisthesis
Q76.3	Congenital scoliosis due to congenital bony malformation
Q76.425	Congenital lordosis, thoracolumbar region
Q76.6	Other congenital malformations of ribs
Q76.8	Other congenital malformations of bony thorax
Q76.9	Congenital malformation of bony thorax, unspecified
Q77.2	Short rib syndrome
Q77.4	Achondroplasia
Q77.5	Diastrophic dysplasia
Q77.9	Osteochondrodysplasia with defects of growth of tubular bones and spine, unspecified
Q78.9	Osteochondrodysplasia, unspecified
R06.00	Dyspnea, unspecified
R06.09	Other forms of dyspnea
R06.89	Other abnormalities of breathing
S22.5xxS	Flail chest, sequela

CPT/HCPCS Codes

20999	Unlisted procedure, musculoskeletal system, general
21899	Unlisted procedure, neck or thorax

(Explanatory notes must accompany claims billed with unlisted codes)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

1. Abol Oyoun N, Stuecker R. Bilateral rib-to-pelvis Eiffel Tower VEPTR construct for children with neuromuscular scoliosis: a preliminary report. Spine J. 2014 Jul 1;14(7):1183-91. doi: 10.1016/j.spinee.2013.07.484. Epub 2013 Oct 23. PMID: 24161365.
2. Bachabi M, McClung A, Pawelek JB, El Hawary R, Thompson GH, Smith JT, Vitale MG, Akbarnia BA, Sponseller PD; Children's Spine Study Group, Growing Spine Study Group. Idiopathic Early-onset Scoliosis: Growing Rods Versus Vertically Expandable Prosthetic Titanium Ribs at 5-year Follow-up. J Pediatr Orthop. 2020 Mar;40(3):142-148. doi: 10.1097/BPO.0000000000001202. PMID: 32028476.
3. Campbell RM Jr, Adcox BM, Smith MD, Simmons JW 3rd, Cofer BR, Inscore SC, Grohman C. The effect of mid-thoracic VEPTR opening wedge thoracostomy on cervical tilt associated with congenital thoracic scoliosis in patients with thoracic insufficiency syndrome. Spine (Phila Pa 1976). 2007 Sep 15;32(20):2171-7. doi: 10.1097/BRS.0b013e31814b2d6c. PMID: 17873807.
4. Campbell RM Jr, Smith MD, Mayes TC, Mangos JA, Willey-Courand DB, Kose N, Pinero RF, Alder ME, Duong HL, Surber JL. The characteristics of thoracic insufficiency syndrome associated with fused ribs and congenital scoliosis. J Bone Joint Surg Am. 2003 Mar;85(3):399-408. doi: 10.2106/00004623-200303000-00001. PMID: 12637423.
5. Campbell RM Jr, Smith MD, Mayes TC, Mangos JA, Willey-Courand DB, Kose N, Pinero RF, Alder ME, Duong HL, Surber JL. The effect of opening wedge thoracostomy on thoracic insufficiency syndrome associated with fused ribs and congenital scoliosis. J Bone Joint Surg Am. 2004 Aug;86(8):1659-74. doi: 10.2106/00004623-200408000-00009. PMID: 15292413.

6. Campbell RM Jr. VEPTR: past experience and the future of VEPTR principles. Eur Spine J. 2013 Mar;22 Suppl 2(Suppl 2):S106-17. doi: 10.1007/s00586-013-2671-2. Epub 2013 Jan 26. PMID: 23354777; PMCID: PMC3616470.
7. Karlin JG, Roth MK, Patil V, Cordell D, Trevino H, Simmons J, Campbell RM, Joshi AP. Management of thoracic insufficiency syndrome in patients with Jarcho-Levin syndrome using VEPTRs (vertical expandable prosthetic titanium ribs). J Bone Joint Surg Am. 2014 Nov 5;96(21):e181. doi: 10.2106/JBJS.M.00185. PMID: 25378514.
8. Peiro-Garcia A, Bourget-Murray J, Suarez-Lorenzo I, Ferri-De-Barros F, Parsons D. Early Complications in Vertical Expandable Prosthetic Titanium Rib and Magnetically Controlled Growing Rods to Manage Early Onset Scoliosis. Int J Spine Surg. 2021 Apr;15(2):368-375. doi: 10.14444/8048. Epub 2021 Apr 1. PMID: 33900996; PMCID: PMC8059403.
9. Reinker K, Simmons JW, Patil V, Stinson Z. Can VEPTR(®) control progression of early-onset kyphoscoliosis? A cohort study of VEPTR(®) patients with severe kyphoscoliosis. Clin Orthop Relat Res. 2011 May;469(5):1342-8. doi: 10.1007/s11999-010-1697-6. PMID: 21116753; PMCID: PMC3069267.
10. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Vertical expandable prosthetic titanium rib (VEPTR). Summary of Safety and Probable Benefit Data. Humanitarian Device Exemption No. H030009. Rockville, MD: FDA; August 24, 2004.

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