BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.110 Vertical Expandable Prosthetic Titanium Rib

Annual Effective Policy Date: July 1, 2024

Original Policy Date: September 2011

Related Policies:

None

Vertical Expandable Prosthetic Titanium Rib

Description

Description

The vertical expandable prosthetic titanium rib is a curved rod placed vertically in the chest to help shape the thoracic cavity. It is being evaluated in skeletally immature pediatric individuals with thoracic insufficiency syndrome to support thorax and lung development, and in pediatric individuals with scoliosis without thoracic insufficiency syndrome to slow or correct curve progression.

OBJECTIVE

The objective of this evidence review is to evaluate whether use of the vertical expandable prosthetic titanium rib improves net health outcomes in lung function and growth in children with progressive thoracic insufficiency syndrome, or with early-onset scoliosis without thoracic insufficiency syndrome.

POLICY STATEMENT

Use of the vertical expandable prosthetic titanium rib is considered **medically necessary** in the treatment of progressive thoracic insufficiency syndrome due to rib and/or chest wall defects in infants and children between 6 months of age and skeletal maturity.

Use of the vertical expandable prosthetic titanium rib for all other conditions, including but not limited to the treatment of scoliosis in individuals without thoracic insufficiency, is considered **investigational**.

POLICY GUIDELINES

Due to complexity of thoracoplasty and the young age of the individuals undergoing such a procedure, implantation of the vertical expandable prosthetic titanium rib should be performed in specialized centers. Preoperative evaluation should require input from a pediatric orthopedist, a pulmonologist, and a thoracic surgeon. In addition, preoperative evaluation should require (when possible) a test for positive nutritional, cardiac, and pulmonary function.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

The VEPTR™ (DePuy Synthes Spine, Raynham, MA) was initially cleared (in 2004) for marketing by the U.S. Food and Drug Administration (FDA) through a humanitarian device exemption for the treatment of thoracic insufficiency syndrome in skeletally immature patients.[1,] In 2014, the VEPTR/VEPTR II™ was cleared for marketing by the FDA through the 510(k) process. The VEPTR/VEPTR II device is indicated for skeletally immature patients with severe, progressive spinal deformities and/or 3-dimensional deformity of the thorax associated with or at risk of thoracic insufficiency syndrome. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis.

To identify potential individuals with thoracic insufficiency syndrome , the following categories are used:

- Flail chest syndrome;
- Rib fusion and scoliosis; and
- Hypoplastic thorax syndrome, including:
    - Jeune syndrome,
    - Achondroplasia,
    - Jarcho-Levin syndrome, and
    - Ellis-van Creveld syndrome.

FDA product code: MDI.

RATIONALE

Summary of Evidence

For individuals who have progressive thoracic insufficiency syndrome due to rib and/or chest wall defects in childhood who receive vertical expandable prosthetic titanium rib thoracoplasty, the evidence includes case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. Results from case series reported at different specialty centers have demonstrated improvement and/or stabilization in key measures with use of the vertical expandable prosthetic titanium rib in progressive thoracic insufficiency syndrome. This improvement has been noted in measures related to thoracic structure (eg, Cobb angle for those with scoliosis), growth of the thoracic spine and lung volumes, and stable or improved ventilatory status. While pulmonary function testing is difficult to track in patients suffering with thoracic insufficiency syndrome, a study has demonstrated an age-specific increase in forced vital capacity (FVC); further still, that same study reported a final FVC in the range of 50% to 70% of predicted value. Given the usual disease course of worsening thoracic volume and ventilatory status, the stabilization and/or improvement in the clinical measures outlined above would be highly unlikely if not for the intervention. Taken together, these outcomes demonstrate the positive impact of using the vertical expandable prosthetic titanium rib technology. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with early-onset scoliosis without thoracic insufficiency syndrome who receive vertical expandable prosthetic titanium rib thoracoplasty, the evidence includes a non-randomized controlled study, an uncontrolled cohort study, and a case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. The vertical expandable prosthetic titanium rib is being evaluated for curves greater than 45 in infants and juveniles without thoracic insufficiency. Similar to thoracic insufficiency syndrome, limited data are available on the use of the vertical expandable prosthetic titanium rib for early-onset scoliosis without thoracic insufficiency. Additionally, little is known about the disease progression of early-onset scoliosis, and therefore little is known regarding the risk-benefit trade-off of the vertical expandable prosthetic titanium rib surgery. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No relevant guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2011	New policy	
December 2011	Replace policy	Policy, rationale, and references updated, moved from previous policy,2.01.83 Interventions for Progressive Scoliosis.
September 2013	Replace policy	Policy updated with literature review, Reference 2 added; policy statements unchanged.
September 2014	Replace policy	Policy updated with literature review, reference 5 added; policy statements unchanged.
September 2015	Replace policy	Policy updated with literature review, reference 13 added; policy statements unchanged.
March 2017	Replace policy	Policy updated with literature review; reference 14 added. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; no references added. Policy statements unchanged, but "not medically necessary€š corrected to "investigational€š.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statements unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through March 6, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 14, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through February 8, 2024; no references added. Policy statements unchanged.