

FEP 7.01.110 Vertical Expandable Prosthetic Titanium Rib

Effective Date: July 15, 2018

Related Policies:
2.01.83 Interventions for Progressive Scoliosis

Vertical Expandable Prosthetic Titanium Rib

Description

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

FDA REGULATORY STATUS

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

To identify potential TIS patients, the following categories are used:

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

U.S. Food and Drug Administration product code: MDI.

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 six 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 patients without thoracic insufficiency, is considered **investigational**.

FEP 7.01.110 Vertical Expandable Prosthetic Titanium Rib

POLICY GUIDELINES

Due to complexity of thoracoplasty and the young age of the patient population undergoing such a procedure, implantation of the vertical expandable prosthetic titanium rib (VEPTR®) 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).

RATIONALE

Summary of Evidence

For individuals who have progressive TIS due to rib and/or chest wall defects in childhood who receive VEPTR thoracoplasty, the evidence includes a few case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. TIS occurs in a limited patient population. For example, the Boston Center reported results on 31 children treated from 1999 to 2005. The natural history of progressive TIS is worsening pulmonary function and pulmonary insufficiency. Results from case series reported at different specialty centers have demonstrated improvement and/or stabilization in key measures with use of the VEPTR in progressive TIS. 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 TIS, a study has demonstrated an age-specific increase in forced vital capacity; further still, that same study reported a final forced vital capacity 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 VEPTR technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with early-onset scoliosis without TIS who receive VEPTR thoracoplasty, the evidence includes a few case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. The VEPTR is being evaluated for curves greater than 45° in infants and juveniles without thoracic insufficiency. Similar to TIS, very limited data are available on the use of the VEPTR 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 tradeoff of the VEPTR surgery. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

FEP 7.01.110 Vertical Expandable Prosthetic Titanium Rib

Medicare National Coverage

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

REFERENCES

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POLICY HISTORY

Date	Action	Description
September 2011	New Policy	
December 2011	Update Policy	Policy, rationale, and references updated, moved from previous policy, 2.01.83 Interventions for Progressive Scoliosis.
September 2013	Update Policy	Policy updated with literature review, Reference 2 added; policy statements unchanged.
September 2014	Update Policy	Policy updated with literature review, reference 5 added; policy statements unchanged.
September 2015	Update Policy	Policy updated with literature review, reference 13 added; policy statements unchanged.
March 2017	Update Policy	Policy updated with literature review; reference 14 added. Policy statements unchanged.
December 2017	Update Policy	Policy updated with literature review through June 22, 2017; no references added. Policy statements unchanged, but "not medically

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FEP 7.01.110 Vertical Expandable Prosthetic Titanium Rib

June 2018	Update Policy	necessary” corrected to “investigational”. Policy updated with literature review through February 5, 2018; no references added. Policy statements unchanged.
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