



MEDICAL COVERAGE GUIDELINES  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 07/10/12  
LAST REVIEW DATE: 06/11/14  
LAST CRITERIA REVISION DATE: 06/26/13  
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## VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### **Description:**

#### Vertical Expandable Prosthetic Titanium Rib (VEPTR)

The vertical expandable prosthetic titanium rib (VEPTR) is a curved rod that is placed vertically in the chest to help shape the thoracic cavity in skeletally immature individuals with thoracic insufficiency syndrome (TIS) and to slow or correct progression in pediatric individuals with scoliosis without TIS. It is designed to be expanded every 4 to 6 months as growth occurs and also to be replaced if necessary.

TIS is the inability of the thorax to support normal respiration or lung growth. It is caused by defects affecting the ribs or chest wall such as rib fusion, severe scoliosis and Jarcho-Levin and Jeune's syndromes. Progressive TIS includes loss of chest wall mobility, respiratory insufficiency, worsening thoracic deformity and/or worsening pulmonary function tests.

The VEPTR (Synthes Spine Co.) received U.S. Food and Drug Administration approval under a Humanitarian Device Exemption.



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## VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR) (cont.)

### Criteria:

#### Vertical Expandable Prosthetic Titanium Rib (VEPTR):

1. Vertical Expandable Prosthetic Titanium Rib (VEPTR) for the treatment of progressive thoracic insufficiency syndrome (TIS) is considered **eligible for coverage** based upon its Humanitarian Device Exemption issued by the Food and Drug Administration with documentation of **ALL** of the following: *Procedure being performed in a center specialized for this procedure.*
2. Progressive thoracic syndrome is due to **ONE** of the following rib and/or chest wall defects:
  - Flail chest syndrome
  - Severe scoliosis **or** rib fusion
  - Hypoplastic thorax syndrome, including:
    - Achondroplasia
    - Ellis van Creveld syndrome
    - Jeune's syndrome
    - Jarcho-Levin syndrome
3. Individual is not less than 6 months of age
4. Individual is not skeletally mature <sup>1</sup>

- Vertical Expandable Prosthetic Titanium Rib (VEPTR), with or without expansion thoracoplasty, for all other indications not previously listed is considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*

- Treatment of scoliosis in individuals without thoracic insufficiency

<sup>1</sup> The definition of skeletally mature is radiographic evidence of epiphyseal closure.



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## **VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR) (cont.)**

### **Resources:**

1. 7.01.110 BCBS Association Medical Policy Reference Manual. Vertical Expandable Prosthetic Titanium Rib. Re-issue date 05/22/2014, issue date 04/17/2007.

FDA Humanitarian Device Exemption for Vertical Expandable Prosthetic Titanium Rib (VEPTR):

- The HDE allows Synthes Spine to market the above device for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients.