PriorityHealth

MEDICAL POLICY
No. 91505-R0

TITANIUM RIB

Effective Date: May 11, 2005	**Review Dates: 5/05, 4/06, 4/07, 2/08, 2/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19**
Date Of Origin: May 11, 2005	**Status: Current**

I. POLICY/CRITERIA

A. Priority Health will cover the vertical expandable prosthetic titanium rib (VEPTR) ("the titanium rib") when prior authorized by Priority Health and the FDA approved indications defined below are met.

B. The U.S. Food and Drug Administration have 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

C. According to the FDA, the VEPTR device should not be used under 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. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

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.

Background:

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

V. CODING INFORMATION

ICD-10 Codes that may apply:

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*

VI. REFERENCES

1. Aetna. Clinical Policy Bulletin, The Titanium Rib December 21, 2004. http://www.aetna.com/cpb/medical/data/500_599/0582.html (Originally retrieved March 18, 2005, January 7, 2015 & December 29, 2015; website address updated and retrieved January 4, 2017, January 4, 2018, & December 31, 2018)
2. Anthem Blue Cross. Clinical UM Guideline , Vertical Expandable Prosthetic Rib (VEPTR) CG-SURG-07. Effective Date: October 4, 2016. https://www11.anthem.com/ca/medicalpolicies/guidelines/gl_pw_a051147.htm (Retrieved January 4, 2017, January 4, 2018, & December 31, 2018)

3. Regence Blue Cross/Blue Shield. Medical Policy 159, Vertical Expandable Prosthetic Titanium Rib Effective Date: July 1, 2016.http://blue.regence.com/trgmedpol/surgery/sur159.pdf (Retrieved January 4, 2017, January 4, 2018, & December 31, 2018)
4. 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.

This document is for informational purposes only. 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. 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. 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.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.