Anthem

Clinical UM Guideline

Subject: Vertical Expandable Prosthetic Titanium Rib
Guideline #: CG-SURG-07
Status: Revised

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Description

This document addresses the use of a vertical expandable prosthetic titanium rib (VEPTR™ DePuy SYNTHES® Spine Inc., West Chester, PA) device as a treatment of severe progressive spinal deformities associated with thoracic insufficiency syndrome (TIS), which includes severe forms of scoliosis. TIS is defined as the inability of the thorax to support normal respiration or lung growth. The VEPTR device consists of a curved rod that conforms to the shape of the thoracic cage. This device, with clearance from the U.S. Food and Drug Administration (FDA), is surgically implanted and vertically affixed to two ribs above and below expansion thoracostomies, which are placed at the site of the vertebral deformity.

Clinical Indications

Medically Necessary:

A vertical expandable prosthetic titanium rib device, is considered **medically necessary** when *all* of the following criteria have been met (A, B, and C):

A. Use includes
   1. Implantation; **or**
   2. Expansion (lengthening); **or**
   3. Exchange (replacement); **or**
   4. Conversion (rib to spine);
      and

B. The individual has *any* of the following conditions:
   1. Congenital scoliosis; **or**
   2. Neuromuscular scoliosis; **or**
   3. Idiopathic scoliosis (that is, infantile, juvenile, or adolescent) **or**
   4. Syndromic scoliosis;
      and

C. The individual meets *all* of the following:
   1. Skeletally immature; **and**
   2. Presence of the following;
      a. Severe, progressive spinal deformity; **or**
      b. Three-dimensional deformity of the thorax;
         and
   3. The deformity is associated with, or places the individual at risk for, thoracic insufficiency syndrome.

Not Medically Necessary:

Use of the vertical expandable prosthetic titanium rib device is considered **not medically necessary** when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
21899	Unlisted procedure, neck or thorax [when specified as implantation or related surgery with vertical expandable prosthetic titanium rib]
ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure code listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

TIS is a rare, life-threatening condition that involves the inability of the thorax to support normal respiration and lung growth (Campbell, 2003). The condition results from serious congenital defects that affect the ribs or chest wall including, but not limited to, flail chest syndrome, severe scoliosis, rib fusion (which may accompany scoliosis), and various hypoplastic thorax syndromes, which may include Jeune's syndrome, achondroplasia, Jarcho-Levin syndrome, and Ellis-van Creveld syndrome. Children with TIS show visible signs of the disease in a variety of ways. The syndrome is frequently terminal without surgical treatment, and each afflicted child has the potential to develop pulmonary hypertension, respiratory failure, right ventricular failure, cor pulmonale, and death.

The VEPTR device obtained U.S. Food and Drug Administration (FDA) clearance under a Humanitarian Device Exemption (HDE) in

2004. The data submitted to the FDA as part of the approval process consisted of a single-site feasibility study of 33 subjects and a prospective, multi-center, single treatment arm trial of 247 children, ranging from ages 6 months to 15 years. The children had various serious defects affecting their ribs or chest wall and their ability to breathe, including progressive scoliosis, flail chest syndrome, rib fusion and various hypoplastic thorax syndromes. The investigators reported study results for both trials that demonstrated probable benefit by enabling some of the children to breathe unassisted or be less dependent on ventilators. Treatment-emergent events were reported for the entire length of follow-up for both trials, (with a mean follow-up for the feasibility study of 84.8 months and 22.6 months for the multi-center trial). A total of 29 (88%) of 33 subjects in the feasibility study reported a total of 182 adverse effects, while a total of 68 adverse effects were considered to be related to the device in 21 subjects (64%). A total of 11 adverse events that were considered potentially life-threatening were reported for 2 subjects, and 13 adverse effects of fatal intensity were reported for 4 trial participants, none of which were considered to be device related.

In the multi-center trial, a total of 119 (56%) of 214 subjects reported a total of 356 adverse effects, while a total of 141 adverse effects, considered to be related to the device, were reported in 71 subjects (33%). The investigators reported that the majority of adverse events were related to device migrations that occurred after the subjects had been implanted with the VEPTR for 2 or more years. A total of 12 deaths were reported, none of which were related to a problem with the device.

According to the original FDA approved product label, the VEPTR is indicated for:

> The treatment of thoracic insufficiency syndrome in skeletally immature patients and it should not be used under the following conditions:

- Inadequate strength of bone (ribs/spine) for attachment of the VEPTR;
- Absence of proximal and distal ribs for attachment of the VEPTR;
- Absent diaphragmatic function;
- Inadequate soft tissue for coverage of the VEPTR;
- Age beyond skeletal maturity;
- Age below six months;
- Known allergy to any of the device materials;
- Infection at the operative site (FDA, 2004).

According to the FDA summary of safety and probable benefit data, during the course of these 14 years of study, as the children experienced normal growth or as the spine and thorax required further correction, the device would require expansions or replacement of the components to increase the overall size of the device. As a guideline, children with scoliosis or flail chest syndrome were scheduled for expansion of the device when the Cobb angle increased by 5 degrees or greater. Studies have typically involved expansion (lengthening) of the device at 4-to-6-month intervals depending on growth rates. In some cases, a device exchange was needed for growth, and device conversion from rib-rib to rib-spine was also reported. In one series, the mean number of lengthenings performed per individual was 3.5 ± 2.6 (Emans, 2005). The FDA concluded from the submitted trial results that the probable benefits associated with VEPTR implantation outweighed the risks for the high-risk population of skeletally immature individuals with TIS.

In 2014, the FDA Center for Devices and Radiological Health (CDRH) cleared the VEPTR®-VEPTR II™ device which was reclassified as a Class II device that is considered substantially equivalent to other similar predicate devices through the 510(k) approval process for the following indications:

> For skeletally immature patients with severe, progressive spinal deformities and/or three dimensional deformity of the thorax associated with, or at risk of, Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis (FDA, 2014).

Due to the rarity of TIS, there have been few published clinical trials of VEPTR device implantation with outcomes data. In 2007, Waldhausen and colleagues performed a retrospective chart review to analyze the cases of 22 children who received 36 VEPTR devices between October 2001 and December 2005; 2 of the implanted trial subjects had Jeune syndrome, 19 had scoliosis, and 1 had a chest wall resection for a tumor. The majority of trial participants had pulmonary restrictive disease, carbon dioxide retention or respiratory failure. A total of 11 had multiple fused ribs requiring an opening wedge thoracostomy. All but the most recently treated cases had undergone sequential VEPTR expansion; 7 cases required revision for erosion through the bone or device dislodgment with three devices requiring removal. A total of five devices were outgrown and removed or replaced, and one eroded the soft tissue causing superficial infections that resolved with operative revision. The postoperative ventilation/perfusion scans showed the most improvement in the younger treated children with 2 of the 3 children with carbon dioxide retention pre-VEPTR showed reductions in carbon dioxide levels post-VEPTR. The authors concluded that the VEPTR may decrease carbon dioxide retention in some cases and may be most beneficial in younger children.

The 2014 expansion of the FDA labeling for VEPTR was based on results of post marketing follow-up data from the original multi-center trial previously described. Additional trial results have consisted of small case series with outcomes data for 2 to 3 years that demonstrated some improvement in pulmonary function, thoracic height and the degree of Cobb angle deformity associated with severe scoliosis. Multiple additional expansion surgical procedures were necessary in the majority of cases to accommodate normal growth patterns, and high incidences of adverse events were seen in the reported outcomes. The investigators of these small studies concluded that the benefits outweighed the risks for the high-risk population with severe progressive scoliosis associated with TIS (Campbell, 2004; Farley, 2014; Flynn, 2013).

Waldenhausen and colleagues (2016) published the results of a prospective cohort study involving 65 subjects being treated for TIS with VEPTR. Several versions of the VEPTR device were used, including VEPTR I (n=35), VEPTR II (n=30) rib-to-rib and rib-to-spine devices, as well as modified VEPTR devices. The average age at time of implantation was 9.6 years (range 1.3-24.8) and the mean follow-up was 6.9 years (range 0.4-14.8). The overall average number of expansions was 5.5. Complication rates for those subjects classifiable using the early onset scoliosis classification system (C-EOS) were 21.7% for subjects with congenital scoliosis, 58.3% for those with neuromuscular scoliosis, 28.5% for those with syndromic scoliosis, and 50% for those with idiopathic scoliosis. Due to the small numbers, no significant differences were reported. For those not classifiable with C-EOS, the complication rate was 35.7%. Complications were experienced by 22 subjects with 37 total complications reported, 35 of which were deemed to have been device-associated. Most complications required at least 1 unplanned surgery, with 2 subjects needing device removal and 1 subject proceeding to a fusion procedure. Migration of the device was reported in 12 subjects who needed additional procedures to address. One subject experienced post-operative radiculopathy that spontaneously resolved. Implant fracture occurred in 3 subjects. The authors concluded that, “Use of the VEPTR for TIS was associated with significant complications.” and that, “VEPTR is usually salvaged, and abandonment of a growth-friendly strategy is unusual.”

No definitive recommendations specific to VEPTR implantation have been issued by any of the specialty medical societies, to date. However, there is general consensus in the practice community that surgery is warranted to correct a spinal curvature with a Cobb

angle greater than 45 degrees in skeletally immature individuals, in order to prevent further progression of the spinal curvature and the associated potential for pulmonary compromise.

The results of a prospective cohort study involving 63 subjects with early-onset scoliosis (EOS) and no rib abnormalities treated with VEPTR and followed for a mean of 2.2 years was reported by El-Hawary and others (2017). The mean age at time of implantation was 6.1 years and involved subjects with congenital (n=6), neuromuscular (n=36), syndromic (n=4), and idiopathic (n=17) scoliosis. The authors reported that the scoliosis major curve improved from a mean of 72 ± 18 degrees prior to treatment to 47 ± 17 degrees after surgery ($p<0.0001$). At 2 years, the mean measurement increased to 57 ± 18 degrees but still remained significant ($p<0.0001$). Similar results were reported for the secondary curve, with a mean of 42.8 degrees at baseline, 35 degrees postoperatively, and 39.6 degrees at 2 years ($p=0.009$). Subjects with syndromic or neuromuscular EOS had a higher percentage of change in sagittal spine length (SSL) and a decrease in kyphosis after 2 years. The authors noted that there was no correlation between pre-treatment severity and percentage of correction of the major curve. However, they did note that there was a larger percent correction of the secondary scoliosis in subjects with severe (>90 degrees) preoperative scoliosis. Successful treatment with VEPTR, defined as either the magnitude of scoliosis or truncal height as greater than or equal to preoperative measures, was noted in 54 subjects. SSL increased during the distraction phase of treatment in 82% of subjects for T1-T12 and 84% of subjects in T1-S1. Spine height growth during the 2-year follow-up represented 144% of expected age-matched coronal T1-T12 growth and 193% of expected age-matched coronal T1-S1 growth. Complications were reported in 31 (49%) of subjects, with a total of 58 complications reported. Device-related causes were identified for 39 of the complications. The highest number of complications were due to device migration (n=15). Overall, 86% of subjects had an improvement in scoliosis severity and 94% had an increased spinal height vs. preoperative measures. The authors concluded that, “This study proved that the spine continues to grow after VEPTR instrumentation during the distraction phase” and “We find this growth important as it proves continuous spine growth with VEPTR treatment.”

A paper published by Nossov (2017) reported the results of a retrospective cohort study investigating the impact of VEPTR on the need for respiratory assistance in 77 subjects with TIS and EOS who underwent VEPTR implantation while less than 10 years of age. All subjects had greater than 2 years follow-up data available and the mean was 5.6 years. The assisted ventilation rate (AVR) changed in 28 subjects (36%), with 29 (24%) improving and 90 (12%) deteriorating. The remaining 49 (64%) subjects had no change in AVR. Age was a significant factor in improvement, with the average age of subjects with improvement being 4, and the average age of subjects deteriorating was 6.7 ($p<0.01$). In total, 16 subjects improved to a normal AVR at last follow-up.

Almajali and colleagues (2020) performed a retrospective analysis of prospectively collected data of a case series that included 40 children with scoliosis of different etiologies. The following were the primary diagnoses identified for the participants: 13 neuromuscular scoliosis, 12 juvenile idiopathic scoliosis, 8 congenital scoliosis, 5 syndromatic individuals, and 2 with arthrogryposis. All 40 individuals received percutaneous rib-to-pelvis or rib-to-vertebra or rib-to-rib VEPTR implantation between January 2016 and January 2018. The individuals were assessed based on the radiographic improvement of their scoliosis, spinal height and sagittal and coronal correction, and at 2 years follow-up. Complications that were encountered during the January 2016 and January 2018 timeframe were also included. The average initial correction in Cobb angle immediately after the index surgery was 14.4° (5°-26°) and the average final correction of Cobb which is measured after the last expansion procedure (Cobb angle of the major curve measured after last expansion minus initial preoperative Cobb angle of the major curve) was 7.3° (12%). The average of preoperative coronal T1-S1 length was 25.6 cm with an average initial correction achieved immediately after implantation of VEPTR of2.8 cm (1.2-5.1cm) which is 10.9%, and the average coronal length gain at 2 years follow up was 5.7 cm (3.7-9.8cm) that is 22.2%. Complication occurred in 18 of the individuals (45%). It was shown that early results of VEPTR for childhood scoliosis were encouraging and that follow-up until skeletal maturity will best determine future indications.

Bachabi and colleagues (2020) utilized two multicenter early-onset scoliosis databases to identify individuals with idiopathic spine abnormalities treated with traditional growing rods (TGR) versus VEPTR. Included individuals underwent at least four lengthenings, had at least 5 year follow-up, and other demographic parameters were similar. In total, 50 individuals were treated with TGR and 22 treated with VEPTR. Mean age at surgery was 5.5 (±2.0) years for the TGR group versus 4.3 (±1.9) years for the VEPTR group ($p=0.044$). The overall mean follow-up duration was 8.3 years for the TGR group vs. 7.7 years for the VEPTR group ($p=0.566$),VEPTR group had more procedures than the TGR group ($p=0.001$). Unilateral constructs were present in 18% (4 of 22) of VEPTR, and 16% (8 of 50) of TGR individuals. Individuals treated with bilateral constructs were exposed to 1.6 fewer procedures than those treated with unilateral constructs. The use of bilateral VEPTR failed to produce greater curve correction but was associated with increased incidence of implant complications. Curve correction was similar between both construct groups. The results demonstrated that individuals treated with TGR experienced greater curve correction (50%) than VEPTR individuals (27%, $p<0.001$), and achieved a greater percentage of thoracic height gain (24%) than those with VEPTR (12%, $p=0.024$). TGR individuals also had a lower rate of wound complications (14%) than those with VEPTR (41%, $p=0.011$). The authors concluded that those treated with TGR had greater initial correction of major spinal curves, greater thoracic height gains during the lengthening period, and better maintenance of their initial correction at follow-up compared with VEPTR. Notably, TGR individuals also had lower incidence of wound-related complications.

Peiro-Garcia and colleagues (2021) performed a retrospective, single-center cohort study to examine whether surgical treatment of EOS with magnetically controlled growing rods (MCGR) or a VEPTR resulted in fewer short-term complications and reoperation at the 2 year follow-up. The researchers reviewed the medical records of 35 individuals who underwent spine instrumentation with VEPTR or MCGR. There were 20 (n=20) participants included in the VEPTR group, and 15 participants (n=15) included in the MCGR group. Inclusion criteria for participation included the following: EOS of any etiology, no history of spine surgery, no history of systemic disease or primary chest wall deformity, exhaustion of all nonoperative treatment, had a progressive spinal deformity of greater than 10 degrees over a 6 month period or a major curve Cobb angle greater than or equal to 40 degrees, and completed a minimum of 2 years clinical follow-up. The results revealed significant differences found in the complication rate at 2 years, with 65 % complications in the VEPTR group and 13.3 % complications in the MCGR group ($p<0$ .001). Sixteen complications in 13 participants were documented in the VEPTR cohort, whereas, in the MCGR cohort only 3 complications were reported in 2 participants. No significant differences were found in infection rates between the VEPTR and MCGR cohorts, 10% and 6.7%, respectively (VEPTR, 2/20 participants; MCGR, 1/15 participant; ($p=0.727$). Implant failures requiring surgery within 1 year of index surgery were higher in the VEPTR group (VEPTR, 7/20, 35%; MCGR, 2/15, 13.3%; $p=0.048$). The reoperation rate at 2 years was higher in the VEPTR group, with 50 % versus 13.3 %in the MCGR group ($p =0.0009$). The limitations of this study include sample size, the fact that it was a single-center study, and the short follow-up timeframe. The researchers concluded that individuals managed with MCGR have both lower complication rates and unplanned surgery rates than VEPTR at 2 years post-surgery. The staged approach could contribute to the low rate of implant complications at 2 years in the MCGR group. Longer-term follow-up is needed to determine the durability of benefits.

Definitions

Cobb angle: A measurement of the degree of spinal curvature. This is considered the standard measurement used in the practice community to quantify a scoliosis for the purpose of measuring curve progression over time. A curve is considered to be scoliosis at a Cobb angle of 10º or more. Any increase greater than 5º is considered a significant change indicative of curvature progression with

scoliosis considered mild at 10º-24º, moderate at 25º-50º and severe at greater than 50º in skeletally mature individuals. Cobb angles greater than 45º are considered severe in skeletally immature persons.

Ellis-van Creveld syndrome: Autosomal recessive genetic disorder characterized by skeletal dysplasia.

Jarcho-Levin syndrome: Heritable axial skeleton growth disorder associated with malformation of the vertebral column and ribs.

Jeune syndrome: Congenital dwarfism associated with asphyxiating thoracic dystrophy.

Scoliosis: A musculoskeletal condition that involves abnormal lateral curvature of the spine. There are several different types of scoliosis that affect children and adolescents. The most common type is considered idiopathic but additional types of scoliosis include congenital, neuromuscular and syndromic scoliosis.

Thoracic insufficiency syndrome (TIS): This rare condition is defined by the FDA as, “The inability of the thorax to support normal respiration or lung growth. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis” (FDA, 2014).

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Government Agency, Medical Society, and Other Authoritative Publications:

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN statement and hierarchy formatting in Clinical Indications section. Updated Discussion and References sections.
Reviewed	05/12/2022	MPTAC review. Discussion, References and Websites sections updated.
Reviewed	05/13/2021	MPTAC review. Discussion, References and Websites sections updated. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. References and Index sections were updated.
Reviewed	06/06/2019	MPTAC review. References were updated.
Reviewed	07/26/2018	MPTAC review. References were updated.
	05/03/2018	The document header wording updated from “Current Effective Date” to “Publish Date.”
Reviewed	08/03/2017	MPTAC review. Removed acronym from title. Updated Discussion and References sections.
Revised	08/04/2016	MPTAC review. Acronyms removed from medically necessary criteria. References were updated. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. The medically necessary indications and criteria for the VEPTR device were expanded to include certain severe, progressive spinal deformities, associated with, or at risk for, TIS including scoliosis in skeletally immature individuals. The Discussion section, Definitions and References were updated.
Reviewed	08/14/2014	MPTAC review. Discussion and References sections updated.
Reviewed	08/08/2013	MPTAC review. Discussion and References sections updated.
Reviewed	08/09/2012	MPTAC review. Definition and References sections updated.
Reviewed	08/18/2011	MPTAC review. Discussion, Definition, References and Index sections updated.
Reviewed	08/19/2010	MPTAC review. Discussion and reference link updated.
Reviewed	08/27/2009	MPTAC review. Discussion and references updated. Definition section added.
Reviewed	08/28/2008	MPTAC review. Description, discussion and references updated.
Reviewed	08/23/2007	MPTAC review. Addition of Not Medically Necessary statement for clarification. References updated.
Revised	09/14/2006	MPTAC review. Updated language in criteria, description and discussion sections, references and coding. Added language about expansion, exchange and conversion procedures as medically necessary.
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Guideline Number	Title
Anthem, Inc.			No document
WellPoint Health Networks, Inc.	09/23/2004	3.07.20	Vertical Expandable Prosthetic Titanium Rib (VEPTR)
