Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP310

Section: Medical Benefit Policy

Subject: Vertical Expandable Titanium Rib

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Vertical Expandable Titanium Rib

II. Purpose/Objective:

To provide a policy of coverage regarding Vertical Expandable Titanium Rib

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION: Vertical expandable prosthetic titanium rib (VEPTR and VEPTR II) is designed to mechanically stabilize and distract the thorax to improve respiration and lung growth in children diagnosed with or at risk of developing thoracic insufficiency syndrome (TIS) secondary to severe deformities of the chest, spine and ribs. Progressive TIS leads to respiratory insufficiency, and progressive thoracic deformity with loss of chest wall mobility. This progression may lead to the need for supplemental oxygen and/or mechanical ventilation.

INDICATIONS: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR or designee
The U.S. Food and Drug Administration approved VEPTR and VEPTR II as a medical device under the Humanitarian Device Exemption Program when the following criteria are met:

- The member is greater than age 6 months; and
- The member is skeletally immature; and
- A diagnosis of thoracic insufficiency syndrome exits or is at risk; and
- One of the following underlying diagnoses have been made:
  - Flail chest syndrome
  - Scoliosis (idiopathic, congenital or syndromic)
  - Hypoplastic thorax syndrome

EXCLUSIONS:
The use of VEPTR and VEPTR II for the treatment of any condition or use in conjunction with any contraindication as defined by the Food and Drug Administration including, but not limited to, skeletal maturity and age less than 6 months is considered **experimental, investigational or unproven** and **NOT COVERED**.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Vertical Expandable Titanium Rib
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

21899 Unlisted procedure, neck or thorax

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
U.S. Food and Drug Administration. Vertical Expandable Prosthetic Titanium Rib (VEPTR®, DePuy Synthes® Spine, Raynham, MA). Approval Order, Summary of Safety and Probable Benefit, Professional and Patient Labeling, and Other Consumer Information. Humanitarian Device Exemption No. H030009. Rockville, MD: FDA. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=H030009.

U.S. Food and Drug Administration. 510(k) Premarket Notification Database. Vertical Expandable Prosthetic Titanium Rib (VEPTR®-VEPTR II™, DePuy Synthes® Spine, Raynham, MA). Summary of Safety and Effectiveness. No. K142587. Rockville, MD: FDA. http://www.accessdata.fda.gov/cdrh_docs/pdf14/k142587.pdf.

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Farley FA, Li Y, Jong N, et al. Congenital scoliosis SRS-22 outcomes in children treated with observation, surgery, and VEPTR. Spine (Phila Pa 1976). 2014; 39(22):1868-1874

Karlin JG, Roth MK, Patil V, et al. Management of thoracic insufficiency syndrome in patients with Jarcho-Levin syndrome using VEPTRs (vertical expandable prosthetic titanium ribs). J Bone Joint Surg Am. 2014; 96(21):e181.

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El-Hawary R, Kadhim M, Vitale M, et al. VEPTR implantation to treat children with early-onset scoliosis without rib abnormalities: Early results from a prospective multicenter study. J Pediatr Orthop. 2017;37(8):e599-e605.

Nossov SB, Curatolo E, Campbell RM, et al.; Children's Spine Study Group. VEPTR: are we reducing respiratory assistance requirements? J Pediatr Orthop. 2019; 39(1):28-32.

Almajali A, Obeidat M, Bashmaf O, et al. Early childhood scoliosis management by vertical expandable prosthetic titanium rib (VEPTR): Experience of Royal Medical Services (RMS). Med Arch. 2020;74(6):433-438

Bachabi M, McClung A, Pawelek JB, et al. Idiopathic early-onset scoliosis: Growing rods versus vertically expandable prosthetic titanium ribs at 5-year follow-up. J Pediatr Orthop. 2020;40(3):142-148

Studer D, Hasler CC. Long term outcome of vertical expandable prosthetic titanium rib treatment in children with early onset scoliosis. Ann Transl Med. 2020;8(2):25.

Elmallah R, Fortin T, Thimothee J, et al. Outcomes of vertical expandable prosthetic titanium ribs in children with early-onset scoliosis secondary to cerebral palsy. Cureus. 2021;13(3):e13690.

Peiro-Garcia A, Bourget-Murray J, Suarez-Lorenzo I, et al. Early complications in vertical expandable prosthetic titanium rib and magnetically controlled growing rods to manage early onset scoliosis. Int J Spine Surg. 2021;15(2):368-375

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 02/21

Revised:

Reviewed: 2/22, 2/23, 2/24

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies