

Vertical Expandable Prosthetic Titanium Rib for Spinal Disorders

Policy MP-021

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

Description:

Thoracic insufficiency syndrome is a complex condition that involves chest wall deformities that affect normal breathing and lung growth. In most cases, children with thoracic insufficiency syndrome are also born with congenital spinal disorders, such as scoliosis.

Thoracic insufficiency syndrome is the inability of the thorax to support normal breathing or lung growth. The thorax is the part of your child's body between the neck and abdomen that includes the spine, ribs and sternum (breastbone). In normal developing children, lung growth parallels chest and spine growth. In children with thoracic insufficiency syndrome, lung growth is limited by rib deformities and spinal curves.

As children with thoracic insufficiency syndrome grow, their rib cage and spine do not keep pace. As a result, their chest wall becomes deformed (sunken) and the children may become dependent on nasal oxygen or ventilator support to breathe.

Historically, thoracic insufficiency was treated with complex and invasive spine surgery which involved straightening and fusing the spine. In recent years, vertical expandable prosthetic titanium rib (VEPTR/VEPTR II) has replaced more invasive surgery. The VEPTR/VEPTR II is a surgically implanted device used to treat thoracic insufficiency syndrome (TIS) in pediatric patients. The VEPTR device is a curved metal rod that is attached to ribs near the spine using hooks located at both ends of the device. The VEPTR II is a modification of the VEPTR device in which additional implants have been added to the VEPTR. These additional implants provide

the surgeon more surgical options to address the child's chest wall/or spine defects. The VEPTR/VEPTR II device helps straighten the spine and separate ribs so that the lungs can grow and fill with enough air to breathe. The length of the device can be adjusted as the patient grows.

During surgery, the VEPTR/VEPTR II device is adjusted to fit the patient and attached vertically on the patient's ribs near the spine. Lengthening the device enlarges the rib cage and increases the amount of lung space in the patient's chest. The VEPTR/VEPTR II device will be lengthened or replaced at specific times to allow for the patient's growth and to further correct spinal or chest wall deformity. Adjustments to the length of the VEPTR/VEPTR II device are made during surgery through a small cut (incision) in the patient's back.

An update to the VEPTR technology is the development of magnetically adjustable spinal implants. The MAGnetic Expansion Control (MAGEC) Spinal Bracing and Distraction System (NuVasive Specialized Orthopedics™ [NSO] San Diego, CA) received 510(k) clearance on January 24, 2014. The U.S. Food and Drug Administration (FDA) approved indication for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with those at-risk of Thoracic Insufficiency Syndrome (TIS). It is secured using standard commercially available fixation components, such as laminar hooks and/or pedicle screws. Both VEPTR/VEPTR II and the MAGEC rods are available in 4.5 mm and 5.5 mm diameters.

The MAGEC system differs from the VETPR in that adjustments can be made using magnetic distraction in the office without the need for the patient going to surgery; anesthesia is also not necessary. Routine x-ray or ultrasound is used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of the patient by the treating surgeon. Published studies have shown distractions to typically occur every 1 to 3 months after implantation.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers adjustable spinal implantation systems including the vertically expanding titanium rib (VEPTR/VEPTR II) and the MAGnetic Expansion Control System (MAGEC) systems for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients in situations that meet the FDA indications.

Conditions for which Adjustable Spinal Implantation Systems are covered include:

- A. Flail chest syndrome
- B. Rib fusion and scoliosis
- C. Hypoplastic thorax syndrome, including:
 - i. Jeune's syndrome
 - ii. Achondroplasia

- iii. Jarcho-Levin syndrome
 - iv. Ellis-van Creveld syndrome
- D. Progressive scoliosis of congenital or neurogenic origin without rib anomaly

Contraindications:

The VEPTR/ VEPTR II and the MAGEC implant systems should NOT be used under the following conditions:

- A. Inadequate strength of the bone (ribs/spine) for attachment of the titanium support rod
- B. Absence of proximal ribs for attachment of the spinal implant supports
- C. Absent diaphragmatic function
- D. Inadequate soft tissue for coverage of the spinal implant
- E. Age beyond skeletal maturity
- F. Age below 6 months
- G. Known allergy to any of the device materials
- H. Infection at the operative site

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

The first quality literature identified related to VEPTR was performed in February 2011, when a literature review identified 3 new studies using the HDE indications. The first by Hasler et al. performed a retrospective review on 23 children treated with vertical expandable prosthetic titanium rib for correction of non-congenital early onset spine deformities. The device was lengthened at 6-month intervals and the average follow-up time was 3.6 years. Diagnosis included 1 early onset idiopathic scoliosis, 11 neuromuscular, 2 post-thoracotomy scoliosis, 1 Sprengel deformity, 2 hyperkyphosis, 1 myopathy and 5 syndromic. Of the 187 surgeries, 149 were device expansions, and 15 unplanned surgeries. 23 complications (0.13 per surgery) included 10 skin sloughs, 5 implant dislocations, 2 rod breakages, and 6 infections. Their conclusion identified the VEPTR as an alternative to dual growing rods for non-congenital early onset spine deformities. The complication rate was lower, the control of the sagittal plane and the pelvic obliquity was as good, but the correction of the coronal plane deformity

was less than growing rods. It was suggested VEPTR's spine-sparing approach might provoke less spontaneous spinal fusion and ease the final correction at maturity.

The second study was a retrospective study by Ramirez et al., reviewing 17 patients with early onset scoliosis. The patient population consisted of 17 primary VEPTR implantations and 33 expansion surgeries with a mean follow-up of 25 months. Results show that there was an improvement in the coronal plane deformity. The thoracic kyphosis was maintained at anatomically normal values and preserved the space available for the lung. The complication rate was 13%, which includes infection, device migration, and rib fracture. The analysis of the data shows that the natural history of the progressive spinal deformity was improved in all patients.

White et al. published the third study which identified 57 patients with thoracic insufficiency syndrome. Fourteen of these 50 patients had placement of a spine-to-spine construct using a VEPTR implant in combination with standard spinal implants. Five had prior rib-based VEPTR or growing implants with an average of 2 failures before this surgery. Radiographic variables, preceding treatment, complications, and changes in ambulatory status, were recorded. The minimum follow-up was 2 years (mean, 35 months; range, 2–4 years). After an average of 5 expansions in these 14 patients, positive changes were recorded for space available for the lung. Complications included 2 rod fractures, 2 superficial infections, and 1 deep infection with rod removal. The study suggests growing constructs using VEPTR can be used with relatively few complications and extends the potential uses of this instrumentation system.

Related to Poland syndrome, Lieber et al. (2012) noted that various surgical techniques have been described for repair of chest wall defects. This single case study described the case of a 16-year old boy who underwent autologous rib transposition after sternal osteotomy. Chest wall stabilization was achieved using a combination of K-wires and VEPTR. Reconstruction of the soft tissue defect was accomplished by combined latissimus dorsi muscle flap and Permacol patch. The authors suggested this approach might be considered an effective 1-stage treatment option of this condition in post-pubescent boys, but noted the findings needed to be validated by well-designed studies.

In a different retrospective analysis of prospectively collected data of a case series, Abol Oyoum et al. (2013) reported the preliminary results of the use of VEPTR in an Eiffel Tower construct in children with neuromuscular scoliosis in regard to coronal and sagittal profiles, space available for the lungs (SAL), and spinal growth. The report listed the complications faced during the follow-up of 1.33 years after the index procedure. A total of 20 non-ambulatory children (mean age of 8.9 years) with neuromuscular scoliosis were included in this analysis. Their primary diagnoses were myelomeningocele ($n = 7$), cerebral palsy ($n = 3$), spinal muscular atrophy ($n = 2$), myopathies ($n = 3$), arthrogyrosis ($n = 1$), and syndromic scoliosis ($n = 4$). All 20 patients received percutaneous rib-to-pelvis VEPTR implantation. Mean operative time was 2 hours, and mean hospital stay was 12 days. None of them needed blood transfusion. They underwent 20 primary implantations and 39 lengthenings. Patients were assessed based on physiologic measures, that is, the radiographic improvement of their scoliosis, SAL, pelvic tilt, spinal height, and sagittal and coronal decompensation. At the latest follow-up, thoracolumbar curvature improved significantly ($65.7^\circ \pm 20.5^\circ$ to $49.9^\circ \pm 15.7^\circ$), as did lumbar curvature ($61.6^\circ \pm 19.5^\circ$ to $35^\circ \pm 21.2^\circ$), thoracic (17.2 ± 2.3 to 20 ± 2.3 cm) and lumbar spinal height (9.9 ± 1.7 to 11.9 ± 1.8 cm), SAL (86.5 ± 8.9 to 97 ± 10), pelvic obliquity ($12.5^\circ \pm 8^\circ$ to $5.2^\circ \pm 5.2^\circ$), and the ilio-lumbar angle ($15^\circ \pm 8^\circ$ to $10.06^\circ \pm 7.1^\circ$). Nine patients suffered complications in the form of proximal cradle migration ($n = 5$), implant breakage ($n = 5$), deep wound infection ($n = 3$), and dislodged iliac hooks ($n = 2$). The authors concluded that early results of VEPTR for neuromuscular scoliosis are encouraging; follow-up till skeletal maturity will best determine future indications.

2014 saw the publication of two studies on VEPTR. The first by Jain and colleagues (2014) in a review on “Surgical aspects of spinal growth modulation in scoliosis correction,” stated: “In patients with early onset scoliosis, a hybrid construct with vertebral stapling and growing rods or a vertical expandable prosthetic titanium rib has been suggested. A failure of the spinal growth modulation procedure does not preclude spinal fusion. None of the devices for spine growth modulation have been approved by the FDA for human use and are still investigational. Early results are promising, and continued clinical studies are necessary.”

The second study by Dede and associates (2014) stated: “The experience with growing rods has been increasing, along with expanding indications. Several self-lengthening instrumentation systems have been introduced aiming for guided spinal growth. There has been considerable progress in the clinical and laboratory studies using magnetically controlled growing rod constructs. Growing rods and vertical expandable prosthetic titanium rib (VEPTR) systems provide deformity control while allowing for spinal growth along with a risk of spontaneous vertebral fusions. VEPTR may cause rib fusions as the implants overlie the thoracic cage, and therefore, the use in pure spinal deformities is controversial. There have been exciting recent advances concerning the treatment of spinal deformities in young children. Despite these advances, the surgical treatment of early-onset scoliosis remains far from optimal and more development is on the way.”

By 2017 a prospective, multi-center, observational cohort study by El-Hawary and associates was published which evaluated the effectiveness of VEPTR in preventing further progression of scoliosis without impeding spinal growth in children with progressive early-onset scoliosis (EOS) without rib abnormalities. Sixty three patients met inclusion in this study, and erect radiographs were analyzed for coronal and sagittal curve and height measurements at pre-implant, immediate post-operative, and at 2-year follow-up. Mean age at time of implantation was 6.1 ± 2.4 years. The authors concluded that at 2-year follow-up, VEPTR was effective in treating EOS without rib abnormalities with 86% of patients having an improvement in scoliosis and 94% of patients having an increased spinal height as compared with pre-operative values. This study proved that spine continued to grow after VEPTR instrumentation during the distraction phase. This amount of growth represented about 40% for T1 to T12 and 31% for T1 to S1 spine of the expected age-matched growth based on Dimeglio reference numbers. The authors found this growth important as it proved continuous spine growth with VEPTR treatment.

In a retrospective analysis of prospectively collected data of a case-series study, Almajali and co-workers (2020) reported their experience and results regarding the use of VEPTR in children with scoliosis in regard to coronal profiles (length and deformity angle), spinal growth, and the complications faced during the follow-up of 2 years after the index procedure. A total of 40 children with scoliosis of different etiologies were included in this analysis. Their primary diagnoses were neuromuscular scoliosis in 13, juvenile idiopathic scoliosis in 12, congenital Scoliosis in 8, syndromic patients 5 and 2 with arthrogyryposis. All 40 patients received percutaneous rib-to-pelvis or rib-to-vertebra or rib-to-rib VEPTR implantation between January 2016 and January 2018. None of them needed blood transfusion. They underwent 56 primary implantations, 16 (40%) bilateral system and 24 (60%) unilateral followed by lengthening procedure in a period of 4 to 6 months. The average initial correction in Cobb angle immediately after the index surgery was 14.4° (5° to 26°) and the average final correction of Cobb which was measured after the last expansion procedure (Cobb angle of the major curve measured after last expansion minus initial pre-operative Cobb angle of the major curve) was 7.3° (12%). The average of pre-operative coronal T1 to S1 length was 25.6 cm with an average initial correction achieved immediately after implantation of VEPTR of 2.8 cm (1.2 to 5.1 cm) which was 10.9%, and the average coronal length gain at 2-year follow-up was 5.7 cm (3.7 to 9.8 cm) that was 22.2%. Complication occurred in 18 of the patients (45%). The authors concluded that early results of VEPTR for childhood scoliosis were

encouraging. Moreover, these researchers stated that follow-up investigations until skeletal maturity will best determine future indications.

MAGEC System: In assessing the modification of VEPTR using magnetic distraction, two systematic reviews and 8 primary studies were identified which met inclusion criteria for review. The publications from 2012 to 2014 involved outcomes on 64 patients. Patients' ages ranged from between 3.6 and 12.6 years old. The studies provided outcomes out to 24 months follow-up and included outcomes on both single and double rod placement. For comparative complications to the standard titanium rod implants, Bess et al. demonstrated 5 to 13.6% of patients needed an additional surgery because of complications with conventional growing rod surgery. Watanabe et al., illustrated that 57% of patients undergoing growing rod surgery had a complication (i.e., implant failures, infections, and neurological impairments). These numbers appear to be commensurate with complications in general and complications which would necessitate a reoperation.

The MAGEC system has been subject to several FDA safety communications. The first was issued in February 2020 recalling its MAGEC devices to address a mechanical component failure where the endcap was separating from the rod part of the device. In 2020, NuVasive made changes to the MAGEC device design to address endcap separation problems. The risk associated with endcap separation is unanticipated exposure of patient's tissue to internal components of the device that have not been completely tested for biocompatibility. In July 2020, the FDA cleared a new version of the MAGEC X rod, and this version of the MAGEC X device (MAGEC 2b) is designed to mitigate endcap separation. The recommendations in this communication apply to all MAGEC devices, including the modified MAGEC Model X rod cleared by the FDA in July 2020.

In July 2020, the FDA cleared a modified version of the MAGEC Model X rod, designed to mitigate endcap separation events. Additional biocompatibility concerns potentially related to the existing endcap failures were raised in December 2020 when NuVasive issued an updated Field Safety Notice. In addition, the FDA began receiving reports in early 2021 describing local tissue reactions potentially related to endcap separation events with the MAGEC devices.

The second was issued July 15, 2021. In this instance, the FDA is informing patients, their caregivers, and health care providers of potential mechanical failures and concerns about tissue incompatibility (biocompatibility) associated with components of the NuVasive Specialized Orthopedics' MAGEC devices including the MAGEC Spinal Bracing and Distraction System, MAGEC System, MAGEC System Model X device, MAGEC System Model X rod, and MAGEC System Rods. On April 5, 2021, and updated April 9, 2021, NuVasive informed health care providers of biocompatibility testing concerns, and voluntarily placed all MAGEC devices on a global ship hold. On July 15, 2021, NuVasive posted an updated statement informing U.S. health care providers that the ship hold in the U.S. has been lifted for the MAGEC devices. The FDA believes it is in the best interest of patients to make the modified MAGEC X device available in the U.S. at this time because of the following:

1. The overall benefits of the device outweigh the known risks for on-label use in the U.S. compared to alternative treatments;
2. The U.S. indications and instructions for use, which restrict use to patients less than 10 years old and for a two-year implantation time, further mitigate known risks;
3. The modified MAGEC X (MAGEC 2b) device, designed to mitigate endcap separation events and related biocompatibility concerns, will be the only device version currently available for sale in the U.S.; and
4. The U.S. labeling has been updated to include a discussion of known risks associated with the device.

The FDA currently recommends the device only be used consistent to its label which allows for the implant to be implanted for no longer than 2 years and be implanted only in skeletally immature patients less than 10 years of age with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). See current device labeling for the complete Indications for Use Statement.

As NuVasive continues to investigate the root cause of these issues, the FDA is working with the manufacturer to evaluate new biocompatibility testing results and assess whether there is any clinically meaningful impact to patients with MAGEC devices. To evaluate whether the components covered by the endcap are biocompatible and to satisfy updated testing standards, NuVasive has been conducting additional biocompatibility testing. The FDA is working with the manufacturer to evaluate the new biocompatibility testing results.

No comparative, head-to-head trials have been completed comparing MAGEC to VEPTR or any other standard surgical therapy. However, based on assessment of VETPR studies and MAGEC studies, it would appear the MAGEC rods have lower complications specifically related to surgery such as postsurgical infections due to the need for fewer surgeries but similar complications such as fractured rods requiring replacement, etc. Efficacy of both rod systems also appears similar. Additionally, given the reduction in operative adjustments necessary with MAGEC rods there is a potential for improved cost effectiveness.

Applicable Coding

CPT Codes

22899 Unlisted procedure, spine

HCPCS Codes

No applicable codes

ICD-10 Codes

M41.00-M41.08	Infantile idiopathic scoliosis	M41.50-M41.57	Other secondary scoliosis
M41.112-M41.119	Juvenile idiopathic scoliosis	M41.80-M41.87	Other forms of scoliosis
M41.122-M41.129	Adolescent idiopathic scoliosis	M41.9	Scoliosis, unspecified
M41.20-M41.27	Other idiopathic scoliosis	Q67.5	Congenital deformity of spine (Congenital postural/NOS scoliosis)
M41.30-M41.35	Thoracogenic scoliosis	Q76.3	Congenital scoliosis due to congenital bony malformation
M41.40-M41.47	Neuromuscular scoliosis		

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