Policy
Aetna considers the vertical expandable prosthetic titanium rib (VEPTR) medically necessary for treatment of thoracic insufficiency syndrome in skeletally immature persons.

Note: Thoracic insufficiency syndrome may include flail chest syndrome, hypoplastic thorax syndrome (e.g., achondroplasia, Ellis van Creveld syndrome, Jarcho-Levin syndrome and Jeune's syndrome) as well as rib fusion and scoliosis.

Aetna considers VEPTR experimental and investigational as a treatment for scoliosis (including congenital scoliosis, early onset scoliosis, idiopathic infantile scoliosis, kyphoscoliosis, and scoliosis associated with spinal muscular atrophy) without thoracic insufficiency syndrome and all other indications (e.g., chest wall repair in Poland syndrome) because of insufficient evidence in the peer-reviewed literature.

Background
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. 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.

The U.S. Food and Drug Administration (FDA) has 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:

- Flail chest syndrome;
- Rib fusion and scoliosis;
- Hypoplastic thorax syndrome, including:
  - Achondroplasia
  - Ellis van Creveld syndrome
  - Jarcho-Levin syndrome
  - Jeune’s syndrome.

According to the FDA, the VEPTR device should not be used under the following conditions:

- Absence of proximal ribs for attachment of the VEPTR;
- Absent diaphragmatic function;
- Age below 6 months;
- Age beyond skeletal maturity;
- Inadequate soft tissue for coverage of the VEPTR;
- Inadequate strength of the bone (ribs/spine) for attachment
of the VEPTR;
- Infection at the operative site;
- Known allergy to any of the device materials.

Approval as a humanitarian use device was based on the results of a 14-year, prospective, multi-center 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% of patients, and the patient survival rate in the VEPTR clinical trial was 95.1%. The FDA determined that the probable benefits associated with patients implanted with the VEPTR device outweigh the risk present for this patient population. The FDA noted that TIS is frequently terminal with non-surgical treatment. The FDA noted that the ability of VEPTR to be expanded allows growth of the thoracic spine and lungs while controlling severe scoliosis. The use of the VEPTR may require a 6-week pre-operative period of halo traction.

Campbell et al (2004) reported on the outcome of VEPTR in 27 children (mean age of 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 of 2 to 6.7 years) post-operatively. The first post-operative test demonstrated a mean vital capacity of 0.679 L (range of 0.37 to 1.7 L), or 49% (range of 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 of 0.51 to 2.1 L), or 47% (range of 25% to 66%) of the predicted normal vital capacity. There was a total of 52 complications in 22 patients, with the most common being asymptomatic proximal migration of the device through the ribs in 7 patients.

Samdani et al (2009) examined bilateral use of the VEPTR attached to the pelvis as a novel treatment for children with severe, early onset scoliosis. A total of 11 children were
included in this study. The authors conducted a retrospective review and collected the following data: clinical diagnosis, age at surgery, number of lengthening procedures, and complications. In addition, pre- and post-operative radiographs were reviewed to measure maximum Cobb angle (both thoracic and lumbar), thoracic height, total spine height as measured from T1 to S1, thoracic kyphosis (T2 to T12), and lumbar lordosis (L1 to S1). The average patient age at surgery was 71 months; the mean pre-operative thoracic Cobb angle was 81.7 degrees. This angle was corrected to 50.6 degrees immediately post-operatively, and this correction was maintained; at the most recent follow-up the curves averaged 58 degrees. Similarly, the pre-operative kyphosis (T2 to T12) angle measured 43 degrees pre-operatively, 23 degrees immediately post-operatively, and 37 degrees at the most recent follow-up evaluation. Patients underwent a total of 41 lengthening procedures (average of 3.7 lengthening procedures per patient), and overall spine length increased from 23.1 cm pre-operatively, to 27.3 cm immediately post-operatively, to 29.4 cm at the final follow-up (average of 25 months). Four (36.4 %) of the 11 patients experienced complications. This was a small study; its findings need to be validated by future studies.

Shah and colleagues (2009) stated that surgical correction is generally indicated as the primary form of management in children with severe early onset scoliosis. Even so, conservative, non-surgical treatment is always considered first, as surgical correction carries significant concomitant consequences, including but not limited to crankshaft phenomenon and, more importantly, inhibition of further spine, lung, and chest growth in skeletally immature patients. Fusionless surgical procedures assuage some of these risks, as they are characteristically associated with techniques necessitating spinal fusion. One device looks particularly promising in treating and managing severe early onset scoliosis -- the VEPTR is a device that was initially targeted toward children with TIS. Despite its promising results in correction of severe early onset scoliosis, as well as associated rib and chest
wall deformities, the VEPTR nevertheless has a complication rate comparable to other fusionless techniques. Continued modifications and research will hopefully beget a device that permits thoracic and spinal growth in skeletally immature patients yet with fewer post-operative complications.

In a retrospective study, Smith et al (2009) reviewed their experience in treating patients with idiopathic infantile scoliosis (IIS), especially as newer technologies, such as the VEPTR, emerge. These investigators reviewed 31 consecutive patients with a primary diagnosis of IIS. Patients were screened to ensure that there were no confounding congenital anomalies or co-morbidities that may have contributed to the spinal deformity. The average age at the time of initial treatment was 25 months. Treatment modalities included bracing, serial body casting, and VEPTR. Pre-treatment, post-treatment, and most recent Cobb angles were compared to assess the overall curve correction, and patient charts were reviewed for the occurrence of complications. Of the 31 patients, 17 were treated with a brace, 9 of whom had curve progression and went on to other forms of treatment. Of the 8 who did respond, there was an overall improvement of 51.2 %. The 10 patients who received body casts, who had a mean pre-operative Cobb angle of 50.4 degrees, demonstrated an average correction of 59.0 %, with only a few skin irritations reported. The 10 patients treated with VEPTR devices demonstrated a mean pre-operative Cobb angle of 90.0 degrees, and an average correction of 33.8 % was attained. Three of the VEPTR-treated patients (33 %) experienced minor problems. The authors concluded that these findings suggested that body casting has utility for patients with smaller, flexible spinal curves. Bracing had limited utility, with high levels of progression and the need for secondary treatments. The VEPTR device appears to be a viable alternative for large-magnitude curves.

Reinker and colleagues (2011) examined if VEPTR controls progression in patients with kyphoscoliosis and, if so, what methods might be used to improve control of deformity.
progression in these patients. These researchers retrospectively reviewed 14 patients who had VEPTR treatment of early-onset kyphoscoliosis. Degrees of kyphosis and scoliosis before, during, and after treatment were measured, and levels of instrumentation, thoracic dimensions, and complications were recorded. Minimum follow-up was 1.7 years (average of 5.8 years; range of 1.7 to 12.8 years). While scoliosis was stabilized, kyphosis increased a mean of 22° at last follow-up. Supple kyphosis became rigid during treatment. Proximal cradle cut-out was a recurring problem. Distal anchors placed too proximally had inadequate lever arms to control kyphosis. The authors concluded that progression of kyphosis can be minimized during VEPTR treatment by early extension of the construct to the second ribs bilaterally, distal extension of hybrid constructs to the pelvis, use of bilateral hybrid VEPTR implants, and use of re-designed VEPTR constructs that enhance fixation at the upper end. They noted that while these early findings suggest these devices control progression of kyphosis, longer follow-up with more patients are needed to confirm the concept in these patients.

Gadepalli and colleagues (2011) noted that VEPTR insertion and expansion has been advocated to increase thoracic volume and pulmonary function in patients with TIS. These investigators reviewed their experience with VEPTR implantation to determine if lung function and growth is augmented, to determine the children's functional status, and if the scoliosis is controlled. From 2006 to 2010, 29 insertions and 57 expansions were performed in 26 patients at the authors' institution. Demographic data were reviewed in conjunction with complications, scoliosis angles, pulmonary function tests (PFTs), and computed tomography-guided 3D reconstructions to determine lung volumes; and quality of life scores were determined using a modified Scoliosis Research Society (SRS) questionnaire pre-operatively and post-operatively. The groups were also stratified by age (because of lung growth potential), disease (congenital or infantile scoliosis, Jeune syndrome, neuromuscular, other structural thoracic disorders), and sex. Analyses using SPSS
(SPSS, Chicago, Ill) were performed with \( p < 0.05 \) considered significant. Each patient underwent \( 3.03 \pm 1.8 \) surgeries, spending \( 0.97 \pm 1.8 \) days in the intensive care unit and \( 4.41 \pm 6 \) days in the hospital for each procedure. Mean age was \( 90.7 \pm 41 \) months. Of the 36 complications, most were because of infection \((n = 12)\), half requiring operative repair (hardware removal). The average PFT percent predicted values for forced expiratory volume in 1 second, forced vital capacity, and RV were \( 54.6 \pm 22, 58.1 \pm 24, \) and \( 145.3 \pm 112, \) respectively, pre-operatively and \( 51.8 \pm 20, 55.9 \pm 20, \) and \( 105.6 \pm 31, \) respectively, post-operatively. The lung volumes measured by computed tomography when corrected for age do not increase significantly post-operatively. The mean Cobb measurement for the pre-operative major curves was \( 64.7^\circ \) and post-operatively was \( 46.1^\circ \) for those curves measured pre-operatively, for a 29 \% curve improvement. All post-operative curves had a mean of \( 56.4^\circ \) and \( 58.1^\circ \) at final follow-up, a 3 \% curve increase. The SRS scores for patients remained unchanged and no statistical difference was seen from pre-operative to post-operative values.

No statistically significant difference was seen in complications, PFT (forced expiratory volume in 1 second, forced vital capacity, RV), lung volumes, scoliosis angles, and SRS scores between sex, age, and disease categories. The authors concluded that there was mild improvement in scoliosis angles but no improvement in lung function and volume.

Scoliosis Research Society scores indicated that the children have near normal function both before and after VEPTR placement. Pulmonary function, lung volume, and patient subjective assessments did not increase dramatically after VEPTR placement, although scoliosis angles improved.

Lieber et al (2012) noted that various surgical techniques have been described for repair of chest wall defects in Poland syndrome. These investigators 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. This approach might be
considered an effective 1-stage treatment option of this condition in post-pubescent boys. The findings of this case study need to be validated by well-designed studies.

In a retrospective analysis of prospectively collected data of a case series, Abol Oyoun et al (2014) 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 we 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), arthrogryposis (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° ± 20.5° to 49.9° ± 15.7°), as did lumbar curvature (61.6° ± 19.5° to 35° ± 21.2°), 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° ± 8° to 5.2° ± 5.2°), and the ilio-lumbar angle (15° ± 8° to 10.06° ± 7.1°). 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.

In a review on “Surgical aspects of spinal growth modulation in scoliosis correction”, Jain and colleagues (2014) states that “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”.

Dede and associates (2014) states that “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”.

Karlin et al (2014) stated that Jarcho-Levin syndrome represents a spectrum of clinical and radiographic irregularities including abnormal vertebral segmentation or formation defects, rib deformities, and short-trunk dwarfism. These abnormalities cause reduced thoracic capacity for lung development, resulting in TIS. These investigators reviewed outcome measures related to scoliotic curve correction, thoracic growth, and respiratory function following VEPTR treatment in patients with Jarcho-Levin syndrome. A total of 29 patients with Jarcho-Levin syndrome, sub-classified as spondylo-costal dysostosis (SCD) or spondylo-thoracic dysplasia (STD), were treated with VEPTR expansion thoracoplasty and followed for at least 2 years since the initial implantation. Spinal and respiratory measures were collected prior to the initial VEPTR implantation, immediately
after implantation, and at the most recent follow-up. Vertical expandable prosthetic titanium rib treatment was associated with improved clinical respiratory function and with increases in thoracic height (by 50% in the SCD group and 42% in the STD group) and thoracic width (by 37% in the SCD group and 28% in the STD group). Vertical expandable prosthetic titanium rib treatment resulted in scoliosis curve correction (improvement in the Cobb angle of 41% [22°] in the SCD group and 26% [3.7°] in the STD group) and in improved thoracic symmetry in patients with SCD. Patients with SCD displayed increased lumbar lordosis, and both groups of patients developed increased thoracic kyphosis approaching normal. The authors concluded that VEPTR treatment improved thoracic symmetry, controlled spinal deformity, and was associated with improved clinical respiratory function.

O’Brien et al (2015) noted that Jeune’s syndrome (JS) often results in lethal TIS. Since 1991, VEPTR dynamic postero-lateral expansion thoracoplasty was used at these investigators’ institution for treatment of JS. This study evaluated the safety and effectiveness of this procedure. A total of 24 JS patients were treated, 2 lost to follow-up, 17 with a minimum of 2-year follow-up retrospectively reviewed for clinical course: Assisted ventilation rate, respiratory rate, capillary blood gases, pulmonary function tests, and complications. Upright antero-posterior/lateral radiographs were measured for Cobb angle, kyphosis, lordosis, thoracic width, and thoracic/lumbar spinal height. Computed tomography scan lung volumes were obtained in 12 patients. Mean age at initial implant was 23 months (7 to 62) with an average 8.4 years (2.3 to 15.6) of follow-up. Average chest width increased from 121 to 168 mm at follow-up (p < 0.001). Pre-operatively, 7/17 (41%) patients had scoliosis. The remainder developed scoliosis during treatment, 8 requiring additional implants. Thoracic and lumbar spinal height was normal pre-operatively and stayed normal during treatment. Thoracic kyphosis/lumbar lordosis was stable. Average computed tomography scan total lung volumes increased 484 to 740 mm (p < 0.001), and assisted ventilation rate status tended to improve (p = 0.07). Average
forced vital capacity was 34 % predicted at first test and 27 % predicted at last follow-up. Early demise after surgery was common with multi-system disease. Mean respiratory rate decreased from 35 to 24 bpm at last follow-up (p < 0.05). Survival rate of the 22 patients was 68 %. Migration of the rib cradles/titanium slings occurred in 12 patients, superficial infections in 5 patients, deep infections in 4 patients, and wound dehiscence in 5 patients. Infection rate was 4.6 % per procedure. The authors concluded that the survival rate in JS with surgery was nearly 70 % (compared with 70 % to 80 % mortality without treatment) with less ventilator dependence. Both C1 stenosis and scoliosis are common in JS. Spinal height in JS is normal. Complications are frequent, but tolerable in view of the clinical gains and increase in survival.

**Congenital Scoliosis:**

Balioglu et al (2015) evaluated the effect of VEPTR on growth in congenital scoliosis (CS). A total of 4 female patients in whom VEPTR was applied were retrospectively evaluated. Antero-posterior (AP) and lateral Cobb angles that were measured pre-operatively and during the last control, space available for lung (SAL), T1-S1 and T1-T12 distances, coronal and sagittal balances were compared. The authors concluded that VEPTR may provide a good correction, and they observed a growth in the spine height and SAL following the treatment of congenital deformities. Moreover, they stated that long-term, multi-center, prospective studies that compare the spinal height, respiratory functions, the severity of the deformity, and the spinal balance are needed in order to evaluate the effectiveness of VEPTR for the treatment of CS.

In a case-series study, Murphy et al (2016) examined the effectiveness of VEPTR in sagittal/coronal curve correction and spine growth and compared its complication rate to the use of VEPTR in other conditions and to other treatment methods used for CS. A multi-center database was queried for patients with CS without fused ribs treated with VEPTR. Antero-posterior and lateral radiographs were used to measure
parameters at 3 time-points (pre-operative, immediate post-operative, and latest follow-up): coronal Cobb angle, sagittal kyphosis, and thoracic and lumbar spine heights.

Clinical data included age, time to follow-up, and complications. A total of 25 patients (13 females, 12 males) were identified. The average age at implantation was 5.7 years, with an average follow-up of 50 months. Several parameters improved from pre-operative to latest follow-up: coronal Cobb angle (69 to 54 degrees, p < 0.0001), thoracic spine height (T1-T12) in the AP (13.3 to 15.9 cm, p < 0.0001) and lateral (14.8 to 17.4 cm, p = 0.0024) planes, and lumbar spine height (L1-S1) in the AP (8.8 to 11.4 cm, p < 0.0001) and lateral (9.9 to 11.9 cm, p = 0.0002) planes. Kyphosis increased over the study period (36 to 41 degrees, p = 0.6); 15 patients (60%) had 41 complications (average of 2.75; range of 1 to 12). Twenty-eight complications (68%) were device-related, and 13 (32%) were disease-related. The most common complications were infection, wound dehiscence, and device migration; 6 complications (15%) altered the course of treatment. Thoracic spine height increased 79% of expected growth. The authors concluded that VEPTR is an effective treatment for patients with CS without fused ribs, as evidenced by improved radiographic parameters and increased spinal height, with a complication rate which is high but similar to other methods of treatment. The main drawbacks of this study were its small sample size (n = 25) and medium-term follow-up (average of 50 months); thus, the level of evidence was low (Level IV).

Weiss and Moramarco (2016) noted that CS is a lateral deformity of the spine with a disturbance of the sagittal profile caused by malformations of vertebra and ribs. Typically, early surgical intervention is the suggested treatment (before 3 years of age) for young patients with CS. While a previous study was conducted in 2011 to investigate long-term studies supporting the necessity for this recommendation and no evidence was found, this current review, is an updated search for evidence published from 2011 through March 2015. This also failed to find any prospective or randomized controlled trials (RCTs) to support the hypothesis that spinal fusion surgery in patients...
with CS should be considered as evidence-based treatment. Contradictory results exist on the safety of hemi-vertebra resection and segmental fusion using pedicle screw fixation. When using the VEPTR device, studies showed a high rate of complications exist. The authors concluded that it is difficult to predict the final outcome for patients with CS. However, it is possible that many patients with CS may be able to avoid spinal surgery with the application of advanced bracing technology. Thus, it is only prudent to advocate for conservative management first before spinal surgery is considered.

<table>
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<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

**ICD-10 codes will become effective as of October 1, 2015:**

There is no specific CPT or HCPCS code for vertical expandable prosthetic titanium rib (VEPTR):

**ICD-10 codes covered if selection criteria are met:**

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<thead>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>M41.00</td>
<td>Scoliosis [if resulting in thoracic insufficiency syndrome]</td>
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<tr>
<td>M41.9</td>
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<tr>
<td>M96.5</td>
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<tr>
<td>M95.4</td>
<td>Acquired deformity of chest and rib [if resulting in thoracic insufficiency syndrome]</td>
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<tr>
<td>Q67.5</td>
<td>Congenital deformity of spine [if resulting in thoracic insufficiency syndrome]</td>
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<tr>
<td>Q76.3</td>
<td>Congenital scoliosis due to congenital bony malformation [if resulting in thoracic insufficiency syndrome]</td>
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<td>Q76.6</td>
<td>Other congenital malformations of ribs [if resulting in thoracic insufficiency syndrome]</td>
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<td>Q76.7</td>
<td>Congenital malformation of sternum [if resulting in thoracic insufficiency syndrome]</td>
</tr>
<tr>
<td>Q78.9</td>
<td>Osteochondrodysplasia, unspecified [if resulting in thoracic insufficiency syndrome]</td>
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<td>Code</td>
<td>Description</td>
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<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>Q77.6</td>
<td>Chondroectoderman dysplasia [if resulting in thoracic insufficiency syndrome]</td>
</tr>
<tr>
<td>S22.5XX+</td>
<td>Flail chest [if resulting in thoracic insufficiency syndrome]</td>
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**ICD-10 codes not covered for indications listed in the CPB (not all inclusive):**

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<tr>
<td>Q79.8</td>
<td>Other congenital malformations of musculoskeletal system [Poland syndrome]</td>
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</tbody>
</table>

**The above policy is based on the following references:**

6. Alberta Heritage Foundation for Medical Research (AHFMR). Treatment of thoracic insufficiency syndrome with the vertical expandable prosthetic titanium rib. Technote. TN 38. Edmonton, AB; AHFMR; December
2002.


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0582
Titanium Rib

There are no amendments for Medicaid.

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Updated 01/2017