Medical Policy

Subject:	Scoliosis Surgery		
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Description/Scope

This document addresses surgical treatments for scoliosis, specifically, use of a minimally invasive deformity correction system (ApiFix, Ltd, Misgav Business Park, Israel), vertebral body tethering, and vertebral body stapling. This document does not address spinal fusion for scoliosis treatment.

Position Statement

Investigational and Not Medically Necessary:

Use of a minimally invasive deformity correction system for the treatment of scoliosis is considered **investigational and not medically necessary.**

Vertebral body tethering for the treatment of scoliosis is considered **investigational and not medically necessary.**

Vertebral body stapling for the treatment of scoliosis is considered **investigational and not medically necessary.**

Rationale

Minimally Invasive Deformity Correction System
Primary treatments for scoliosis include exterior bracing or surgical spinal fusion. A new proposed fusionless, surgical correction treatment of scoliosis is a minimally invasive deformity correction system.

In a 2021 retrospective review, Floman and colleagues sought to determine if a motion-sparing posterior device could modulate growth in skeletally immature individuals with adolescent idiopathic scoliosis. There were 45 individuals evaluated, who had a follow-up of at least 2 years following surgery. The mean pre-operative curve was 46°. There were 16 participants in the Risser 0-1 stage, 15 participants in the Risser 2-3 stage, and 14 participants in the Risser 4-5 stage at the time of surgery. There were 35 participants with Lenke type 1 curves and 10 participants with Lenke type 5 curves. The average preoperative major curve magnitude, of both curve types, was similar among the three Risser groups, 47.6°, 46° and 41.5°. At final follow-up, curves were reduced to 26.4°, 20.4° and 26.2°, respectively. Thoracic kyphosis increased by 7° on average in the Lenke 1 curves and lumbar lordosis decreased by 4° in the Lenke 5 curves. Revision surgery was required by 4 participants, 1 was converted to vertebral body tethering and in 3 cases there was a malfunction in pedicle screws, nut loosening, or ratchet malfunction. None of the revision surgeries were converted to a spinal fusion procedure.

A 2021 prospective, industry sponsored study by Stadhouder and colleagues reported on the use of the minimally invasive deformity correction system in 20 participants with adolescent idiopathic scoliosis. Inclusion criteria were 12 to 17 years of age, skeletal immaturity (defined as Risser stage 1 to 4), a single structural curve (Lenke type 1 or 5), a major Cobb angle of 40° to 55°, reduction of the major curve to less than 35° on x-ray, and apical vertebral

rotation of less than 15°. With an average of 12 months of follow-up postoperatively, 7 of 20 participants showed signs of surgical failure and study recruitment was stopped. Subsequently, another 3 participants showed implant failures at further follow-up. Reasons for implant failures included pain, breakage/failure and osteolysis. Six of the participants required removal of the implant, 2 participants had revision to a new implant, and 2 participants had revision to posterior spinal fusion. The 10 remaining participants were followed for a mean of 3.8 years. The mean major curve for this group measured 45.4° preoperatively, 31.4° at 2 weeks postoperatively, and 31.0° at the time of the latest follow-up. The mean minor curve measured 31.3° preoperatively, 26.1° at 2 weeks postoperatively, and 24.2° at the time of the latest follow-up. There was no significant change in major or minor curve deformity after 2 weeks postoperatively. Lumbar lordosis and thoracic kyphosis remained unaltered and there were no changes in apical vertical rotation. The authors concluded the rate of implant-related complications along with no correction of the curve or distraction of the ratchet observed postoperatively was rationale for early study termination.

Currently there is a paucity of literature depicting reasonable conclusions on health outcomes. There is also a lack of conclusion that this technique is as beneficial as established alternative treatments.

Vertebral Body Tethering
Vertebral body tethering has been proposed as another alternative to bracing in the treatment of scoliosis.

The United States Food and Drug Administration (FDA) granted Humanitarian Device Exemption (HDE) for vertebral body tethering. The exemption was based on a clinical trial of 56 participants who had spinal tethering around 12 years of age. In this clinical trial the participants, on average, had a Cobb angle curve reduction by more than 50%, from 40.4 degrees to 17.6 degrees, at or beyond 24 months post-procedure. Of the 43 participants with a pre-operative Cobb angle of less 45 degrees, 35 (81.4%) achieved a Cobb angle less than 30 degrees; of the 12 participants with a pre-operative Cobb angle of greater or equal to 45 degrees, a Cobb angle less than 30 degrees was achieved in 8 (61.5%). The most common complications included back pain, overcorrection of the curve, nausea/vomiting, arm and leg pain, temporary numbness in the chest and hip, and the need for additional surgery. Eight of the participants required an additional surgery to fix overcorrections, cord breakage, development of a new curve in another area of the spine, and slippage in the spine unrelated to the tethering.

A 2014 retrospective review by Samdani and colleagues reported on the 2-year results of 11 participants with scoliosis who underwent vertebral body surgery (8 participants had tethering and 3 participants had tethering and stapling). All of the participants were skeletally immature prior to undergoing surgery. The tethering was done on an average of 7.8 levels. Preoperative thoracic Cobb angle averaged 44.2 ± 9.0° and corrected to 20.3 ± 11.0° on first erect, and 2-year Cobb angle 13.5 ± 11.6°. The preoperative lumbar curve of 25.1 ± 8.7° showed correction (first erect = 14.9 ± 4.9° and 7.2 ± 5.1° at 2 years). Thoracic axial rotation as measured by a scoliometer went from 12.4 ± 3.3° preoperatively to 6.9 ± 3.4° at the most recent measurement. There were no neurological, infectious or hardware-related complications noted. Two of the participants required an additional surgery to loosen the tether secondary to overcorrection. One participant had persistent atelectasis. Further studies with larger sample sizes and longer follow-up periods are necessary to determine the long-term safety and efficacy of vertebral body tethering.

Samdani and colleagues (2015) reported on retrospective chart review of another cohort of individuals with scoliosis who underwent vertebral body tethering. Following 32 skeletally immature participants with a 1-year follow-up, the participants had tethering of an average of 7.7 levels. The mean preoperative thoracic curve was 42.8° ± 8.0° which corrected to 21.0° ± 8.5° on first erect and 17.9° ± 11.4° at most recent. The pre-operative lumbar curve of 25.2° ± 7.3° showed correction at first erect 18.0° ± 7.1° and 1-year correction of 12.6° ± 9.4°.

Preoperative thoracic axial rotation measured 13.4° with correction to 7.4° at the most recent measurement. There were no neurological, infectious or hardware-related complications noted. Overcorrection occurred in three participants who the authors note may require an adjustment of the tether. The authors state "These early results appear promising, but the true benefit of the technique must stand the test of time." Longer follow-up is necessary to assess the safety and efficacy of vertebral body tethering.

In a single-center phase 2A pilot study by Wong and colleagues (2019), the authors reported on the use of an anterior ultra-high molecular weight polyethylene tether in 5 children with thoracic scoliosis. Participants were followed for a minimum of 4 years. The preoperative mean thoracic Cobb angle was 40.1°. The degree of correction at 4 years ranged from 0-133.3%. There were 20 adverse events postoperatively, 4 of which were considered to be of moderate severity including pneumonia, distal decompensation, and curve progression. Overcorrection occurred in 3 of the participants, of which 2 required fusion surgery. Further studies with a larger number of participants and longer follow-up are necessary to better evaluate the outcomes of vertebral body tethering.

A 2020 retrospective review by Hoernschemeyer and colleagues reported on 31 participants with scoliosis who had vertebral body tethering. Two participants were lost to follow-up. The average follow-up was 3.2 years. In this study, outcomes were considered successful where there was a residual curve of less than 30° when the participants were skeletally mature and did not require fusion surgery. A total of 20/27 participants showed a curve magnitude of less than 30°. There were 14 participants found to have broken tethers (5 occurred during the first 2 years, 8 occurred between year 2 and 3, and 4 occurred after the third year of follow-up). Of the 14 participants found to have a broken tether, 7 participants were considered clinically successful, 5 were unsuccessful, and 2 had fusion surgery for continued curve progression. The study is limited by the retrospective design and lack of outcomes reported by the participants. Two of the participants in this study have not reached skeletal maturity so their clinical success remains unknown.

A 2020 retrospective study by Newton and colleagues compared the outcomes of participants with scoliosis who received vertebral body tethering (n=23) to a matched cohort who were treated with posterior spinal fusion (n=26). The mean follow-up was 3.4 years in the vertebral body tethering group and 3.6 years in the spinal fusion group. Preoperative mean thoracic curve was 53° in the tethering group and 54° in the fusion group. At the final follow-up, the mean thoracic curve was 33° in the tethering group and 16° in the fusion group. In the tethering group, there were 9 revisions and no revisions in the fusion group. Revision procedures occurred at a mean time of 2.3 years postoperatively. Broken tethers were experienced by 12 participants and 3 of the participants had revision due to curve progression from the tether breakage. In the tethering group, 12 participants were considered to have clinical success as evidenced by thoracic curve less than 35° without a secondary spinal fusion. All of the participants in the spinal fusion group had curves of less than 35°. The authors concluded "Clearly additional studies in larger cohorts with follow-up to beyond maturity are required."

A multicenter, retrospective review by Miyanji and colleagues (2020) reported on the clinical efficacy of vertebral body tethering in skeletally immature individuals with idiopathic scoliosis. In this study, 57 individuals had vertebral body tethering surgery. The mean follow-up was 40.4 months. The mean preoperative major curve was 51° which improved to a mean of 24.6° following surgery. At one year post-op, the mean major curve was 16.3° and at final follow-up it was 23°. There were 16 complications with 8 individuals who required an additional 9 unplanned revision surgeries. An additional five participants had fusion for insufficient correction and progression of deformity. While most of the outcomes were considered successful, the outcomes varied due to the 28.1%

complication rate and 15.8% of participants requiring further surgery with a mean follow-up of 40.4 months. The authors concluded "a minimum two-year follow-up is not an adequate benchmark for these patients and clearly longer follow-up is required to make any definitive statements about the true value of this technique."

Baker and colleagues completed a retrospective chart review in 2021 and reported on 17 participants with adolescent idiopathic scoliosis. The objective was 2-4 year outcomes following vertebral body tethering surgery. There were nine curves in 9/17 participants which were considered successful. Preoperative kyphosis averaged 26° in the successful group and 14° in the unsuccessful group. The authors looked at both lumbar and thoracic levels and noted correction was greater for the lumbar region compared to thoracic tethering. There were nine broken tethers and four participants required revision procedures. The authors concluded the technology has potential for those with adolescent idiopathic scoliosis looking for an alternative to spinal fusion surgery, however predicting those who will have successful outcomes is a challenge and long-term outcomes remain unknown.

In 2021 Samdani and colleagues published study results from the FDA Investigational Device Exemption for vertebral body tethering. This industry sponsored, single center study included 57 skeletally immature subjects who underwent vertebral body tethering with 56 participants included in the final analysis. Follow-up lasted for an average of 55.2 months. Mean main thoracic Cobb angle was 40.4° with correction to 19.3° at the first erect measurement and 13.8° at the 2-year follow-up. Most recent follow-up showed mean major thoracic Cobb angle at 18.7°. There were 45/56 subjects with curves less than 30° at the latest follow-up. Mean preoperative proximal thoracic lumbar curve was 25.0° and lumbar curve was 23.7°. At the latest follow-up, mean proximal thoracic curve was 17.9° and lumbar curve was 15.7°. Mean preoperative kyphosis measured 15.5°, 17° postoperatively and 19.6° at the most recent follow-up. There was no significant change in lumbar lordosis from preoperative measurement to the most recent evaluation. Seven of the subjects required revision surgery (5 had tether release for overcorrection and 2 had tether extension for adding-on). The tether release did not stop the curve overcorrection in one of the subjects and later had posterior spinal fusion surgery.

A 2020 prospective case series by Rushton and colleagues sought to determine the efficacy of vertebral body tethering in 112 skeletally immature subjects with idiopathic scoliosis. Indications for tethering included progressive major main thoracic and/or lumbar curves greater than or equal to 40°. Outcomes were measured preoperatively, radiograph at first erect, 1-year postoperatively, and at most recent follow-up. Clinical success was defined as lack of waiting for or completed surgical fusion and tethered curve less than 35°. Mean follow-up was 37 months. Preoperative mean coronal Cobb curve was 50.8°, corrected to 26.6° at the first erect x-ray. From first erect to 1-year follow-up, mean Cobb curve was 23.1°. There were 36 tethers suspected or confirmed broken postoperatively, 2 of which were replaced by most recent follow-up. The remaining 34 suspected/confirmed broken tethers at follow-up had an increase Cobb angle from 26.1° at 1-year to 35.1° at most recent follow-up. The subjects with intact tethers maintained a mean Cobb angle of 21.7° at 1-year to 21.8° at most recent follow-up. Kyphosis preoperatively was 18.6° which was stable at 1-year then increased to 21.4° at most recent follow-up. At most recent follow-up, 7 subjects had undergone or were waiting to have fusion surgery. The remaining 80 subjects had tethered curve less than 35° were considered clinically successful in this study. There were 25 subjects who had 28 complications including atelectasis, hemothorax, pneumonia, cerebrospinal fluid leaks, additional surgery for bleeding control with 15 subjects requiring 18 revision procedures. Confirmed tether breakage was found in 3 cases. X-rays suggested tether breaks in 33 subjects. The authors state "Further work is needed to examine the variability seen in patient responses to tethering and impact of tether breakage. Prolonged follow up of AVBT patients will be needed until we can understand the true value of this technique."

A 2021 study by Pehlivanoglu and colleagues reported on the clinical and functional outcomes of comparing vertebral body tethering to posterior spinal fusion. There were 21 subjects who had vertebral body tethering and 22 subjects who had fusion surgery. Average follow-up for the tethering group was 37.1 months and 37.8 months for the fusion group. Functional evaluation performed at the last follow-up appointment was measured by average lumbar range of motion, anterior lateral lumbar bending flexibility, flexor and extensor endurances of trunk, and average motor strength of trunk muscles. Scoliosis Research Society (SRS-22) and Short Form Survey (SF-36) scores were used to evaluate functional outcome and health-related quality of life. Preoperative average major curve magnitude in the tethering group was 48.2° and 48.8 in the fusion group. Average major curve magnitude at the last follow-up was 9.1° in the tethering group and 9.7° in the fusion group. In the tethering group, average flexion lumbar range of motion was 78.2, average extension was 34.6, average lateral bending was 34.4, average rotation was 45.4, average anterior lumbar flexibility was 3.7 and average lateral lumbar flexibility was 22.4. In the fusion group, average flexion lumbar range of motion was 58.1, average extension was 19.4, average lateral bending was 18.3, average rotation was 24.1, average anterior lumbar flexibility was 23.4 and average lateral lumbar flexibility was 11.3. In the tethering group, average flexor trunk endurance was 65.1 and extensor endurance was 60.8 with average motor strength of trunk muscles 4.7. In the fusion group, , average flexor trunk endurance was 19.1 and extensor endurance was 28.7 with average motor strength of trunk muscles 3.2. Average pre-operative SRS-22 score in the tethering group was 3.2 and 4.9 at the latest follow-up. Fusion group had average pre-operative SRS-22 score of 3.2 and 3.8 at latest follow-up. Average pre-operative SF-36 scores for MCS in the tethering group was 52.7 and for PCS was 46.8. The fusion group had MCS 52.3 and PCS 47.1. At the latest follow-up, the average SF-36 MCS in the tethering group was 56.9 and PCS 57.2. Fusion group had MCS 52.3 and PCS 53.1. Limitations include the three-year follow-up, retrospective nature, and matching process of the two procedure types and inclusion criteria between the two surgical groups could also be considered a possible weakness.

In 2020, the Pediatric Orthopaedic Society of North American along with the Scoliosis Research Society released a position statement on payor coverage for vertebral body tethering for skeletally immature individuals with idiopathic scoliosis. The recommendation is "payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements." However, it should be noted these recommendations are not based on robust trials.

Vertebral Body Stapling

Another proposed alternative to bracing in the treatment of scoliosis is vertebral body stapling. The staples are surgically inserted into the vertebrae of the individual and designed to prevent further curvature of the spine.

Betz and colleagues (2003) reported the results of a study carried out at the Shriners Hospital (Philadelphia) to determine the efficacy of vertebral body stapling in 21 individuals (27 curves) with adolescent idiopathic scoliosis. No major, but three instances of minor complications were noted. One individual experienced an intraoperative segmental vein bleed which resulted in an estimated blood loss of 1500 cc as compared to the average estimated blood loss of 247 cc for all participants. One subject developed a chylothorax and another developed pancreatitis. None of the individuals experienced staple dislodgement or movement during the follow-up period (mean 11 months, range 3-36 months), and no adverse effects specifically related to the staples were identified. Utility (defined as curve stability) was evaluated in 10 individuals with stapling with greater than 1-year follow-up (mean 22.6 months) and preoperative curve less than 50 degrees. Treatment failure was considered progression of greater than or equal to 6 degrees or beyond 50 degrees. Of these 10 individuals, 4 (40%) progressed and 6 (60%) remained stable or improved. One of 10 (10%) in the stapling group had progressed beyond 50 degrees and underwent spinal

fusion. Six of the subjects required stapling of a second curve, 3 as part of the primary surgery, and 3 as a second stage because a second untreated curvature progressed. The authors concluded that vertebral body stapling for the treatment of scoliosis in adolescents was feasible and safe in this group of 21 subjects. However, the results need to be considered with caution, inasmuch as the follow-up period was short and there was no comparison of this technique with conventional treatment, such as bracing.

In 2005, Betz and colleagues carried forward their clinical series and presented the retrospective findings of 39 consecutive individuals (52 curves) who received vertebral body stapling as treatment for idiopathic scoliosis or scoliosis associated with other conditions, such as Marfan syndrome or skeletal dysplasia (syndromic scoliosis). Complications were reported in 6 cases. A 4-year-old with infantile idiopathic scoliosis developed a rupture of a pre-existing undiagnosed diaphragmatic hernia which required emergency repair. One participant experienced a puncture in a segmental spinal vein secondary to a staple prong and required both transfusion and conversion to an open procedure to control blood loss. One subject developed chylothorax as a result of a staple puncture of the thoracic duct at T12. This individual was treated with a chest tube and total parenteral nutrition. Another participant experienced mild pancreatitis. Clinically significant atelectasis was experienced by 2 individuals and 2 other participants required prolonged chest tube drainage (greater than 4 days). In 31 subjects who were followed for an average of 12 months, there were no reports of staple dislodgement or migration. However, there was one report of staple fracture. Five participants (15%) progressed during follow-up and required spinal fusion.

In another study, Betz and colleagues (2010) reported the findings of vertebral body stapling in 28 individuals with idiopathic scoliosis for a minimum follow-up period of at least 2 years. The authors reported a success rate (curves corrected to within 10 degrees of preoperative measurement or decreased > 10 degrees) in 87% of all of the lumbar curves and 77% in thoracic curves measuring less than 35 degrees. In the cases of thoracic curves, which measured greater than 35 degrees, vertebral body stapling was not considered successful and required alternative treatments. In the conclusions section of the article, the authors acknowledged the limitations of the study and cautioned the reader that the "results should be considered preliminary as follow-up to skeletal maturity will be needed before definitive results can be described."

Laituri and colleagues (2013) reported the results of a retrospective study on children who underwent thoracoscopic vertebral body stapling for juvenile scoliosis from January 2007 to December 2010. Only individuals with a follow-up of at least 2 years were included in this study group. Data considered were demographics, indications for vertebral body stapling, degree of curvature, treatment, complications, and follow-up. Cobb angle was used to measure the initial degree of curvature on a standing posterior-anterior spine X-Ray. During the study period, 11 individuals underwent thoracoscopic vertebral body stapling for juvenile idiopathic scoliosis using single lung ventilation in a lateral position. The study group consisted of 7 subjects between the ages of 8-11 years with at least a 2-year follow-up. Indications for stapling in these 7 participants were progression of scoliosis (n=3), noncompliance with brace (n=3), and double curve with progression (n=1). The mean preoperative Cobb angle was 34.1 ± 5° (range, 25-41°), and the mean immediate postoperative Cobb angle measurement was 23 ± 5° (range, 16-30°). The staples encompassed a mean number of 6.4 vertebral bodies. The mean duration of chest drainage was 2.7 days, the mean length of hospitalization was 3.9 days and the mean operative time was 156.2 ± 39.5 minutes. The authors indicated there were no intraoperative complications or mortality. During the postoperative period, 1 individual developed a pleural effusion on the contralateral side that required drainage. These 7 participants were followed for a mean of 34 months (range, 29-44 months). The mean Cobb angle at last follow-up was 24.7° (range, 15-38°). At the time of last follow-up, none of the participants required postoperative bracing or spinal fusion. The

authors concluded that thoracoscopic vertebral body stapling is a safe and effective method for treating progressive scoliosis in young children.

Theologis and colleagues (2013) evaluated 12 females older than 10 years of age with idiopathic thoracic or lumbar scoliosis of 30° to 39° who were treated with vertebral body stapling. The participants were followed for a minimum of 24 months. Outcome variables included curve progression and magnitude, surgical complications and a need for reoperation. The preoperative and postoperative curve magnitudes were compared. A total of 13 curves were treated with vertebral body stapling (lumbar: n=4, thoracic: n=9). The follow-up period ranged from 2.2-5.4 years and averaged 3.4 years. The average preoperative curve magnitude was 33.4° (range, 30-39°) compared to most recent curve magnitude measurement at follow-up of 23.0° (range, 10-34°). All curves, both thoracic and lumbar, were treated successfully. Postoperative curve magnitudes did not change significantly between the first erect radiographs and the most recent follow-up. Two of the study participants had pneumothorax, and 1 participant had symptomatic pleural effusion. None of the study participants required definitive fusion for curve progression. The authors concluded that vertebral body stapling is an effective method to control curve progression in the high-risk group of children younger than 10 years with idiopathic scoliosis between 30° and 39° in whom bracing may be ineffective.

In 2018, Cahill and colleagues performed a retrospective review on 63 subjects between 7 to 15 years of age with idiopathic scoliosis. The aim of this study was to evaluate the change in Cobb angle measurements over time in subjects treated with vertebral body stapling. Outcomes were assessed by using three categories. Cahill (2018) stated:

> "Improvement" was defined as a decrease in the preoperative Cobb angle of greater than 10°. "No change" was defined as a +10° to -10° change in the preoperative Cobb angle (both values inclusive). "Progression" was defined as an increase of the curve by greater than 10°. These assessments allowed for the classification of success versus failure, with ''success'' defined as either improvement or no change and ''failure'' defined as progression.

The authors reported that of the subjects who had vertebral body stapling of the lumbar curve, 82% were successful, and of the subjects who had vertebral body stapling of the thoracic curve, 74% were successful.

A retrospective chart review by Trupia and colleagues (2019) reported on 10 skeletally immature participants with adolescent idiopathic scoliosis who underwent vertebral body stapling. The participants had curves ranging from 25° to 35° prior to surgery. The average duration of follow-up was 6.4 years. At the first postoperative visit, all participants showed curve correction. At the final follow-up visit, half of the participants showed curve progression greater than 5° while the other half of the participants either remained stable or corrected over time. The 5 participants who showed curve progression were younger than those who remained stable (10.8 years versus 12.8 years respectively). Four of these participants required further surgery for worsening of scoliosis. Three participants had hardware-related complications including breaking of a distal staple and asymptomatic loosening of a staple. None of the complications required further intervention. Limitations include the retrospective design. The authors state "In light of these results and the potential for surgical and hardware-related complications, we no longer recommend vertebral stapling, regardless of curve size or skeletal maturity."

In a 2020 retrospective case series, Murray and colleagues reported on 7 children with juvenile idiopathic scoliosis who underwent vertebral body stapling. Using radiologic imaging, the aim of the study was to measure the rate of

growth of vertebral bodies for 6 years following surgery. The average preoperative Cobb angle was 30°, with a decrease to 20° at the first postoperative visit. One participant has shown an improvement of greater than 10°, 4 participants have shown no change in their curve, and 2 participants have shown progression of their curves by more than 10°. Average growth rate for all participants was 0.86 mm/year per vertebral body on the side which was stapled compared to 0.83 mm/year per vertebral body on the unstapled side. There was no significant difference in the growth rate of the vertebral bodies between the stapled and unstapled sides and the authors conclude "the staple does not generate sufficient force to modulate growth."

Summary
While the use of a motion-sparing posterior device may show promise for treatment of adolescent idiopathic scoliosis, at this time there is a lack of published peer-reviewed medical literature which shows reasonable conclusions on health outcomes. The clinical evidence on vertebral body stapling and tethering is not robust enough to make determinations regarding its safety and efficacy. There is still considerable risk of curve progression for these study participants and it may be premature to conclude that vertebral body stapling and vertebral body tethering are effective means of controlling curve progression in high-risk individuals who have not reached skeletal maturity. Study results once the individuals have reached skeletal maturity are warranted in order to determine the definitive benefit of vertebral body stapling and vertebral body tethering in these individuals at high risk for continued curve progression.

Background/Overview

Minimally Invasive Deformity Correction System
The minimally invasive deformity correction system is a fusion-less surgical treatment for scoliosis, It is a ratchet-based, expandable rod which attaches to the spine using pedicle screws. This internal brace, like the vertebral body tethering and stapling, achieves correction without the need for spinal fusion. It is implanted posteriorly on one side of the spine. An example is the ApiFix system which received HDE from the FDA in 2019. The device is indicated for treatment of individuals with adolescent idiopathic scoliosis. The Summary of Safety and Probable Benefit document by the FDA lists potential adverse events associated with the use of the device some of which include screw/nut loosening, device migration or breakage, and inadequate curve correction or loss of curve correction.

Vertebral Body Tethering
Vertebral body tethering is a technique in which bone screws are anchored to the front of each vertebral bone in the curved area of the spinal column. A flexible cord, or tether, is attached to the screws and tensioned to attain the desired degree of spine straightening. In August 2019, the FDA granted HDE for The Tether™ Vertebral Body Tethering System (Zimmer Biomet Spine, Inc., Westminster, CO). The device is indicated for skeletally immature individuals with idiopathic scoliosis (major Cobb angle of 30 to 65 degrees) who have failed bracing and/or are intolerant to brace wear. Some of the benefits to vertebral body tethering include allowing for continued growth and mobility, faster recovery time, spinal motion sparing, and less placement of hardware. However, concerns for vertebral body tethering include the possibility of overcorrection of the curve, potential disc degeneration within the instrumented spine, potential for fixation failure or cord breakage, and infection.

Vertebral Body Stapling
Vertebral body stapling is being studied as an alternative to bracing or spinal fusion for the treatment of progressive idiopathic scoliosis in skeletally immature individuals. Because this procedure avoids fusion of the spine, it is proposed that this treatment will permit a gradual correction of the spinal curvature as the individual grows while

maintaining movement and flexibility and decreasing the risk for back pain in adulthood. Benefits include it is believed to be more comfortable and less embarrassing than wearing a brace. Unlike spinal fusion, stapling offers the advantage of allowing the individual to retain the flexibility of their spine. However, complications involving the staples may include breakage, loosening, or dislodging.

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 are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

22899	Unlisted procedure, spine [when specified as vertebral body stapling or implantation of a posterior (dynamic) distraction device]

ICD-10 Procedure

	For the following codes, when specified as vertebral body stapling:
0PH404Z	Insertion of internal fixation device into thoracic vertebra, open approach
0PH434Z	Insertion of internal fixation device into thoracic vertebra, percutaneous approach
0PH444Z	Insertion of internal fixation device into thoracic vertebra, percutaneous endoscopic approach
0QH004Z	Insertion of internal fixation device into lumbar vertebra, open approach
0QH034Z	Insertion of internal fixation device into lumbar vertebra, percutaneous approach
0QH044Z	Insertion of internal fixation device into lumbar vertebra, percutaneous endoscopic approach

ICD-10 Diagnosis

M41.00-M41.9	Scoliosis
Q67.5	Congenital deformity of spine (congenital scoliosis NOS)

When services are also Investigational and Not Medically Necessary:

CPT

0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments

ICD-10 Procedure

0PS403Z	Reposition thoracic vertebra with spinal stabilization device, vertebral body tether, open approach
0PS443Z	Reposition thoracic vertebra with spinal stabilization device, vertebral body tether, percutaneous endoscopic approach

0QS003Z	Reposition lumbar vertebra with spinal stabilization device, vertebral body tether, open approach
0QS043Z	Reposition lumbar vertebra with spinal stabilization device, vertebral body tether, percutaneous endoscopic approach
XNS00C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, open approach, new technology group 7
XNS03C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7
XNS40C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, open approach, new technology group 7
XNS43C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7

ICD-10 Diagnosis

All diagnoses

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Index

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.

Document History

Status	Date	Action
Revised	11/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Title changed to Scoliosis Surgery. Added minimally invasive deformity correction system to the scope of the document and Position Statement. Updated Description/Scope, Rationale, Background/Overview, References, and Index sections. Updated Coding section; added codes XNS00C7, XNS03C7, XNS40C7, XNS43C7.
	07/01/2021	Updated Coding section with 07/01/2021 CPT changes and 10/01/2021 ICD-10-PCS changes; added 0656T, 0657T and 0PS403Z, 0PS443Z, 0QS003Z, 0QS043Z.
Reviewed	11/05/2020	MPTAC review. Updated Rationale, References, and Index sections.
Revised	11/07/2019	MPTAC review. Revised scope of document to include vertebral body tethering. Title changed. Added vertebral body tethering to INV/NMN statement. Updated Description/Scope, Rationale, Background/Overview, References, and Index sections.
Reviewed	01/24/2019	MPTAC review.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Updated the review date, References and History sections of the document.

Reviewed	02/04/2016	MPTAC review. Updated the review date, References and History sections of the document. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated the review date, Description/Scope, References and History sections of the document.
Reviewed	02/13/2014	MPTAC review. Updated the review date, Rationale, References and History sections of the document.
Reviewed	02/14/2013	MPTAC review. Updated the review date, References and History sections of the document.
Reviewed	02/16/2012	MPTAC review. Updated the review date, References and History sections of the document.
Reviewed	02/17/2011	MPTAC review. Updated the review date, Rationale, References and History sections of the document.
Reviewed	02/25/2010	MPTAC review. Updated the review date, Description/Scope, Rationale, Background/Overview, References and History sections of the document.
Reviewed	02/26/2009	MPTAC review. Changed title to "Vertebral Body Stapling for the Treatment of Scoliosis in Children and Adolescents." Revised Position Statement to indicate that vertebral body stapling is investigational and not medically necessary as a treatment of scoliosis in both children and adolescents. Updated review date, Rationale, Background/Overview, References and History sections of the document.
Reviewed	02/21/2008	MPTAC review. Updated review date, References and History sections of the document. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
New	03/08/2007	MPTAC review. Initial document development.