Anthem

Medical Policy

Subject: Scoliosis Surgery
Document #: SURG.00097
Status: Revised

Publish Date: 12/28/2023
Last Review Date: 11/09/2023

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, vertebral body stapling, and magnetically controlled growing rods. This document does not address spinal fusion for scoliosis treatment.

Position Statement

Medically Necessary:

Vertebral body tethering for the treatment of scoliosis is considered **medically necessary** for **all** of the following criteria:

1. Curve progression following conservative management (for example, observation, exercise therapy, or bracing);**and**
2. Cobb angle 40 to 60 degrees;**and**
3. Curve flexibility greater than 30%;**and**
4. Skeletal immaturity, defined as either:
    a. Risser grade 0 or 1; **or**
    b. Sanders Maturity Scale less than or equal to 4.

Revision, replacement or removal of vertebral body tethering is considered **medically necessary** when there are complications associated with the device (for example, tether breakage or overcorrection).

Investigational and Not Medically Necessary:

Vertebral body tethering for the treatment of scoliosis is considered **investigational and not medically necessary** when the above criteria are not met and for all other indications.

Use of a minimally invasive deformity correction system 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.**

Use of magnetically controlled growing rods for the treatment of scoliosis is considered **investigational and not medically necessary.**

Revision, replacement or removal of vertebral body tethering is considered **investigational and not medically necessary** when the above criteria are not met**.**

Rationale

Vertebral Body Tethering
Primary treatments for scoliosis include exterior bracing or surgical spinal fusion. Vertebral body tethering has also been proposed as an alternative to bracing in the treatment of scoliosis.

The United States Food and Drug Administration (FDA) has 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 than 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 than 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.

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.

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 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. Most of the outcomes were considered successful, but 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 retrospective review by Mathew and colleagues (2022b) reported on the range of motion of the thoracolumbar and lumbar spine 1 year after vertebral body tethering surgery. They evaluated coronal bending x-rays and sagittal plane mobility on flexion and extension x-rays. With 20 participants included in the study, the mean preoperative major coronal curve was 52 ± 8 degrees. The latest follow-up mean postoperative major coronal curve was 27 ± 9 degrees. The mean preoperative coronal arc of motion over the instrumented segments was 38 ± 18 degrees. The mean postoperative coronal arc of motion was 17 ± 7 degrees. On flexion-extension lateral x-rays taken 1 year following surgery, the mean postoperative arc of motion was 30 ± 13 degrees. While the follow-up is short in this study and there is no control group for comparison, the authors conclude some spinal motion is preserved following vertebral body tethering surgery compared to spinal fusion where no motion is retained.

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°.

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.

Another recent study by Mathew and colleagues (2022a) reported on the 2-year outcomes of a matched case-control study of 26 individuals who underwent vertebral body tethering to 26 individuals who underwent posterior spinal fusion. Mean pre-operative Cobb angle was 50° in the tethering group and 52° in the fusion group. Blood loss was less, surgery time was less, and length of stay in the hospital was less in the tethering group compared to the fusion group. At the 2-year follow-up, curve correction was 46% in the tethering group compared to 66% in the fusion group. The authors defined successful tethering in this study as no fusion surgery and Cobb angle < 35° 2 years following surgery. There were 19/26 (73%) participants who met this criteria. By 2 years, there were 5

participants who had cord breakage. At 2-year follow-up, 2 participants in the tethering group developed pleural effusion and 1 participant required release of cord surgery due to overcorrection. There were 3 participants in the fusion group who developed wound infections. Successful outcome was noted in 23/26 (88%) participants in the spinal fusion surgery group. Tethering leads to shorter hospital stay, shorter operative time and less blood loss.

A retrospective chart review by Meyers in 2021 reports on the complications of 184 participants 90 days post-op vertebral body tethering. There were 12 participants who experienced 12 complications in this 90-day period following surgery. There were 6 participants with major complications including 3 chylothoraces, 2 hemothoraces, and 1 lumbar radiculopathy. Minor complications were experienced by 6 participants which included requirement of supplemental oxygen, superficial wound infection, prolonged nausea, and Raynaud phenomenon.

In a 2022 observational study by Caretti and colleagues, the authors reported the results of 25 participants with scoliosis (20 with idiopathic scoliosis and 5 with secondary scoliosis due to other pathologies) who underwent vertebral body tethering. A preoperative mean coronal Cobb angle was 57° and mean thoracic kyphosis was 16°. Skeletal maturity for all participants was Risser 0-3 and Sanders 1-5. Postoperative x-rays were done immediately following surgery then after 1 month, 3 months, 6 months, then yearly. The mean follow-up was 29 months. The latest mean coronal Cobb angle was 34° (with a mean correction of 40%). Mean kyphosis was 24°. There were four reported postoperative complications including postoperative thoracic bleeding, requirement of complete hardware removal, tether revision, and requirement of posterior spinal fusion due to distal junction failure.

When potential complications arise it may be clinically appropriate to revise, replace, or remove vertebral body tethering, for instance when the tether breaks or if curve overcorrection occurs. Tether removal or exchange may also be required following complete correction of scoliosis curve if there is risk of the spine curving in the opposite direction or if the curve worsens.

Broken tethers can lead to a loss of correction. However, some breakages may not have a negative effect on curve correction. A 2022 retrospective review by Trobisch and colleagues analyzed tether breakage rates following vertebral body tethering and the influence of breakage on curve behavior. There were 10 participants who had surgical revisions with 15 curves and 80 segments re-evaluated in vivo. Tether breakage was found in 36 segments. Of the 36 segments, 21 were suspected to have a tether breakage prior to revision surgery. During revision surgery 20 of 21 suspected breakages were confirmed. One suspected breakage measured an angular difference of 6.2° but was not found to be broken intraoperatively. Of the segments with an intraoperative confirmed breakage, 3 of them had a decreased segmental Cobb angle which was felt most likely due to growth modulation before the breakage occurred. For all confirmed cases of breakage, the average segmental loss of correction was 6.6°. While broken tethers are a potential complication of vertebral body tethering surgery, not all breakages have a negative impact on the correction.

In a 2022 retrospective review by Baroncini and colleagues, the authors measured pulmonary function before and after vertebral body tethering surgery of 51 participants at 6 weeks, 6 months, and 12 months postoperatively. Parameters measured were total lung capacity (TLC), forced expiratory volume in 1 second (FEV1), and forced vital capacity (FVC). TLC preoperatively was 98% ± 15, at 6 weeks was 93% ± 15, at 6 months was 96% ± 17, and at 12 months was 99% ± 15. FEV1 preoperatively was 85% ± 16, at 6 weeks was 80% ± 14, at 6 months was 84% ± 14, and at 12 months was 89% ± 9. FVC preoperatively was 91% ± 17, at 6 weeks was 90% ± 17, at 6 months was 90% ± 16, and at 12 weeks was 86% ± 9. The authors note that longer follow-up is necessary to evaluate the long-term effect of vertebral body tethering on pulmonary function and a comparison of pulmonary function between fusion surgeries and vertebral body tethering surgeries should be done to determine whether tethering is as beneficial as fusion in respect to pulmonary function.

Another study in 2022 assessed the rate of tether breakage at 2-year follow-up. Shankar and colleagues performed a retrospective review of 69 participants with adolescent idiopathic scoliosis who were treated with vertebral body tethering. At 1-year follow-up, tether breakage rate was 3% and 27% at 2-year follow-up. All but one individual had tether breakage at a single vertebral level. Most of the breakages occurred in the thoracolumbar curves (75%) at the L2-L3 vertebral level. Continued long-term study is necessary to assess efficacy.

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.

Two systematic reviews in 2022 reported on outcomes and efficacy of vertebral body tethering in treating adolescent idiopathic scoliosis. Zhang and colleagues looked at 25 studies. With an average follow-up time of 28.5 months, the average preoperative Cobb angle was 40.1-56°. The average postoperative Cobb angle was 14.0-38°. Average Cobb angle at the latest follow-up was -3 to 38°. There were 22 studies which included complication data and 20 studies which included revision data. Overall, the most common complication was confirmed or suspected broken tether followed by pulmonary complications, and overcorrection. The revision rate was 13.1%. Bizzoca and colleagues looked at 7 studies. In these studies, 117/163 (71.8%) of participants showed a nonprogressive curve at skeletal maturity. Success rate in the studies ranged from 52% to 95.24%. Postoperative complication rate was 17.8% and these were pulmonary in nature. There were 23 participants (14.11%) who required unplanned surgical revision due to curve overcorrection (11 participants), broken tether with curve progression (8 participants), adding on (2 participants), and progression of the untethered curve (2 participants). There were 18/163 participants (11%) who converted to posterior spinal fusion surgery.

A systematic review and meta-analysis in 2023 by Roser and colleagues reported the expected curve reduction and potential complications for individuals following vertebral body tethering. There were 19 studies included with 16 studies having enough data for a meta-analysis. Follow-up was at least 2 years. The median Risser score was 0, and the median Sanders was 3. The initial mean major curve Cobb angle was 47.8° with a decrease to 22.2° at 2 years postoperatively. The initial mean thoracic major curve Cobb angle was 31°-81° with a final follow-up range of -26°-62°. There were 17 studies that reported complications; those included tether breakage (21.9%), overcorrection (11.4%), re-operation (11.4%), spinal fusion (7.2%), and postoperative pulmonary complications (6.7%).

Peer-reviewed published literature regarding vertebral body tethering shows outcomes of vertebral body tethering as a treatment for skeletally immature adolescent idiopathic scoliosis is an effective alternative to spinal fusion. Vertebral body tethering is associated with satisfactory correction of the deformity. Tethering has been shown to improve net health outcomes and is at least as good as the alternative fusion surgery. Additional study is necessary to continue to evaluate long-term efficacy and improvement of net health outcomes.

Minimally Invasive Deformity Correction System

A 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.

A retrospective review by Zygogiannis and colleagues (2023) reported the prevalence and recurrence of surgical site infection following surgery with minimally invasive deformity correction system for adolescent idiopathic scoliosis. With the records reviewed for 44 participants, 3 participants developed surgical site infection (SSI) postoperatively with 1 of those participants developing a recurrence. Initial treatment included intravenous (IV) antibiotics and dressing changes. Two participants required irrigation and debridement and 1 participant required eventual implant removal. The authors note “Recurrent SSI may exhibit a strong indication for implant removal.”

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 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 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.”

Magnetically Controlled Growing Rods
As an alternative to repeated surgeries for scoliosis, magnetically controlled growing rods are being proposed for the treatment of early-onset scoliosis.

A 2014 study by Hickey and colleagues reported on the results of 8 individuals with early-onset scoliosis who had treatment via magnetically controlled growing rods. Mean follow-up time was 28 months. Four of the participants had magnetic expansion control rods as their primary procedure. Mean Cobb pre-operative angle was 74° with postoperative angle of 42°. Mean Cobb angle remained at 42° at the most recent follow-up visit. Two of the 4 individuals experienced complications including a rod fracture and four proximal screws pulled out. There were 4 other individuals who had magnetically controlled growing rods inserted as a revision procedure. Mean pre-operative Cobb angle was 45° with a postoperative angle of 42°. Mean Cobb angle at the most recent follow-up visit was 44°. Complications also occurred in 2 of these individuals which was loss of distraction in both. The authors note further study is necessary to determine “the optimum initial correction, rate of distractions and method of monitoring spinal growth.”

In 2014 Akbarnia and colleagues compared the effectiveness of magnetically controlled growing rods to traditional growing rods for treatment of early-onset scoliosis. There were 17 participants who received magnetically controlled growing rods. These participants were matched with another participant who received traditional growing rods. Mean follow-up period for the magnetic rods was 2.5 years and the mean follow-up period for the traditional rods was 1.6 years. There were no statistically significant differences in curve magnitudes between the two groups. In the magnetically controlled rods group, there were eight complications which were implant related which necessitated four revision surgeries. In the traditional rods group, 13 implant-related complications in which 3 required unplanned revision surgeries. In this retrospective study, the procedures were done at multiple institutions which led to variations in surgical techniques and postoperative care. The matched cohort wasn’t matched by curve pattern or levels of instrumentation. The authors note there should be longer follow-up periods and best practice guidelines for use of magnetically controlled growing rods.

In 2016, Teoh and colleagues reported on the 4-year outcome of the cohort in the Hickey study described above. For those who had the magnetically controlled growing rods as the primary procedure, the latest follow-up mean Cobb angle was 38°. For those who had magnetically controlled growing rods as a revision procedure, the latest follow-up mean Cobb angle was 43°. One individual was found to have a deep infection of staph aureus. There were 6 individuals who required revision surgeries for non-functioning rods, proximal screw pull-out, broken pins in magnetic rod, broken magnetic rod at distal end, and development of proximal junction kyphosis. In this cohort, 4 individuals continued with their magnetically controlled growing rods, whereas the other 4 individuals had their rods removed and revised to other systems. The authors conclude “Medium-term results are not as promising as previously reported early results.” Use of magnetically controlled growing rods should be used with caution and further long-term data is necessary.

Another study in 2016 reported on the use of magnetically controlled growing rods for early-onset scoliosis in a cohort of 19 individuals (Thompson, 2016). The mean follow-up time was 22.4 months. Implantation of magnetically controlled growing rods was a primary procedure in 11 individuals and as a revision procedure in 8 individuals. Mean pre-operative Cobb angle was 62°. Post-operative Cobb angle was 45.1° and 43.2° at the latest follow-up. There were two complications in those who had rod insertions as their primary procedure; one instance of pull-out of proximal hook which required a revision surgery, and one superficial wound infection treated with dressings and antibiotics. Of the 8 individuals who had rod insertions as their revision procedures, there were

two instances of pull-out of proximal fixations which required surgery. While use of magnetically controlled growing rods showed decrease in Cobb angle, further study is needed to assess efficacy and complication rates with longer periods of follow-up.

Using the same cohort of participants in the Thompson study above, in 2018, Subramanian and colleagues evaluated additional participants (for a total of 31 participants) to evaluate magnetically controlled growing rods. Mean follow-up time was 47.3 months. Mean Cobb angle was 53.8° preoperatively and was 39.6° immediately postoperatively. There were 21 participants who had complications, and 20 of them required further surgery. The complications presented at a mean of 38 months postoperatively.

A 2018 systematic review by Thakar and colleagues reported on the results of 15 studies for magnetically controlled growing rods used for treatment of early-onset scoliosis. The average follow-up was 29.7 months. Average pre-operative Cobb angle was 64.8°, post-operative angle was 36.4° and 34.9° at the latest follow-up. There were 141 non-medical recorded complications with an average of 44.5% complication rate. There were 103 unplanned re-operations with an average unplanned re-operation rate of 33%. The rate of screw or hook pull-out was 11.8%, rate of implant failure was 11.7%, and rod or rod foundation breakage was 10.6%. Three of the studies addressed timing of when revisions of magnetically controlled growing rod were required and found on average this happened at 88.9 months post-operative. Long-term data is necessary to assess efficacy and potential complications.

In a 2020 retrospective review by Abdelaal and colleagues, 44 children underwent insertion of magnetically controlled growing rods for early-onset scoliosis. Mean follow-up was 4.1 years with a minimum follow-up of 2 years. All individuals had records available for analysis. Mean pre-operative Cobb angle was 71° with a mean postoperative angle of 35°. The last follow-up mean Cobb angle was 39°. During the course of treatment, there were 10 individuals with 18 clinical complications. These included rod motor failure, jamming of the extensor mechanism, dislodgement, rod fracture, prominence of metal, infection, distal decompensation, and proximal junctional kyphosis. There were 9 individuals who went on to have definitive fusion surgery with another 4 on the list. Mean Cobb angle went from 53° pre-fusion to 39° post-fusion. Further study is needed to investigate the various failure mechanisms involved with this technology.

A retrospective review by Calderaro and colleagues in 2020 assessed 24 participants who had insertion of magnetically controlled growing rods for scoliosis (6 for idiopathic scoliosis and 18 for nonidiopathic scoliosis). There were 9 participants who had primary insertion of magnetically controlled growing rods and 15 participants had magnetically controlled growing rods inserted after traditional growing rods were removed. Mean follow-up was 29.2 months. Mean preoperative Cobb angle of the main curve was 57°. At the last follow-up, the mean Cobb angle was 36.6°. The mean preoperative T1-T12 kyphosis angle was 48.4° with a mean thoracic kyphosis angle of 38.7° at last follow-up. There were no intraoperative complications reported. Early postoperative complications included wound breakdown, wound necrosis, and temporary urinary retention. Delayed postoperative complications included broken rods in 2 participants, a fractured actuator pin in 1 participant, 2 instances of hook pull-out which required revision surgery, and 1 instance of deep infection requiring posterior spinal fusion. Limitations include the retrospective design and history of previous growing rod surgery in some participants. Further study is necessary.

A 2020 systematic review by Guan and colleagues reported on 13 studies which used magnetically controlled growing rods for treatment of early-onset scoliosis. The mean Cobb angle improved from 61.6° initially to 36.4° postoperatively to 37.1° at the last follow-up. There were 10 studies which presented complication data. There were 70 total complications reported with 47 unplanned surgeries on 42 individuals.

Saarinen and colleagues conducted a retrospective review in 2022 on 44 participants who had magnetically controlled growing rods inserted for treatment of early-onset scoliosis. These participants were compared to a matched cohort who had traditional growing rods performed for early-onset scoliosis. Follow-up was 2 years. Objective was to compare clinical, radiographic and quality of life questionnaires. The mean preoperative major curve was 104°. Postoperatively it was 53° in the magnetically controlled group and 57° in the traditional rods group. At the 2-year follow-up, the mean major curve was 52° in the magnetically controlled group and 66° in the traditional rods group. There were 7 participants in the magnetically controlled rod group who had at least 1 complication compared to 17 participants in the traditional rods group. For those in the magnetically controlled rods group, the pulmonary function domain was reported as better compared to the traditional rods group, otherwise there were no differences between the two groups. The retrospective design and short-term follow-up limit the ability to draw firm conclusions about the efficacy of this technology.

In 2023, Marquez-Lara and colleagues evaluated magnetically controlled growing rods for maintenance of curve correction and analyzed complications including unplanned returns to the operating room. Records of 24 participants were reviewed. All participants received a dual magnetically controlled growing rod construct. During the study, 3 participants were lost to radiographic follow-up after 2 years due to a move and 1 participant died of unknown causes. For the remaining 20 participants, the average follow-up was 6.2 years. The average preoperative curve angle of the major curve was 61.1°. The initial curve correction was to 32.7°. At 2 years, the mean curve angle was 35.9°. At the final follow-up, the mean curve angle was 36.1°. The average time to unplanned return to the operating room was 2.5 years. There were 4/13 returns which were due to screw pull out or malposition within the first 2 years. After 2 years, 3/13 were due to failure to lengthen, with 5/13 due to running out of room. Of the 20 participants followed past 2 years, 15 required conversion to posterior spinal fusion. The authors conclude “Further research is needed to continue to evaluate the efficacy and safety of MCGR in this challenging patient population.”

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 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 is an 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 in these individuals at high risk for continued curve progression. Magnetically controlled growing rods can be an alternative to conventional growing rods for treatment of early-onset scoliosis. However, there is a paucity of evidence on long-term effects and complication rates. Further study is needed.

Background/Overview

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.

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 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.

Magnetically Controlled Growing Rods
When casts or bracing cannot control early-onset scoliosis, another treatment is growing rods. The purpose of the rods is to control the scoliosis while allowing one's spine to continue to grow until a definitive correction can be made when nearing skeletal maturity. The implanted rod braces the spine during growth to minimize the progression of scoliosis. Traction is applied between proximal and distal anchors joined by expandable rods. As a child grows, the rods must be lengthened by surgery (approximately every 6 months). In order to avoid multiple surgeries, newer technology distraction rods are now available which comprises an implantable rod and an external remote controller. The rod is made with magnets and a motor inside the rod that allow it to extend. The external remote control used outside the body also contains powerful magnets that "talk to" the magnets within the rod. The rod can then be made longer or shorter as needed. This allows for distraction of the rod to be done non-invasively without the need for repeated surgeries like the traditional growing rods.

One such magnetic distraction rod is the MAGnetic Expansion Control (MAGEC®) System. This system received FDA clearance and is intended for skeletally immature individuals less than 10 years old who have severe progressive spinal deformities that are associated with or at risk of thoracic insufficiency syndrome.

Definitions

Cobb angle: Determined by radiographs, a standard measurement to diagnose and track progression of scoliosis. The angle is determined by the intersection of tangential lines which are drawn from the superior end plate of the superior vertebra and the inferior end plate of the inferior vertebra.

Curve flexibility: The percentage of change in Cobb angle from standing upright images to flexibility images.

Risser score: A grading system used to measure ossification of the iliac apophysis.

Sanders hand score: A predictor of the curve acceleration phase of growth based on an x-ray of the left hand.

Scoliosis: A spinal disorder characterized by abnormal lateral curvature of the spine and vertebral rotation.

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.

Vertebral body tethering
When services may be Medically Necessary when criteria are met:

CPT	
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments
0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or more vertebral segments
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed

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

ICD-10 Diagnosis	
M41.00-M41.9	Scoliosis
Q67.5	Congenital deformity of spine (congenital scoliosis NOS)

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or for all other diagnoses not listed.

Other procedures
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 or magnetic expansion adjustable growing rods]
ICD-10 Procedure	
	For the following codes, **when specified as vertebral body stapling or implantation of magnetic expansion adjustable growing rods**:
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:

ICD-10 Procedure	
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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Minimally Invasive Deformity Correction System
Nitinol Staple
OSStaple™
Reflect™ Scoliosis Correction System
The Tether™ Vertebral Body Tethering System

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	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revision to Position Statement formatting. Added MN and INV/NMN criteria for revision, replacement, or removal of vertebral body tethering to Position Statement. Updated Rationale, References and Index sections. Updated Coding section with 01/01/2024 CPT changes; added 22836, 22837, 22838, 0790T and descriptor revisions for 0656T, 0657T.
Revised	11/10/2022	MPTAC review. Added magnetically controlled growing rods to scope of document in INV/NMN statement. Updated Description/Scope, Rationale, Background/Overview, Coding, References, and Index sections.
Revised	05/12/2022	MPTAC review. Added MN criteria for vertebral body tethering. Added Definitions and Websites for Additional Information sections. Updated Rationale, Coding and References sections.
Revised	11/11/2021	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.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.