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Medical Policy

Subject:	Vertebral Body Stapling and Tethering for the Treatment of Scoliosis in Children and Adolescents		
Document #:	SURG.00097	**Publish Date:**	0712/016/20210
Status:	Reviewed	**Last Review Date:**	11/05/2020

Description/Scope

This document addresses vertebral body stapling and vertebral body tethering as surgical treatments of scoliosis.

Position Statement

Investigational and Not Medically Necessary:

Vertebral body stapling and vertebral body tethering as treatment of scoliosis in children and adolescents are considered **investigational and not medically necessary.**

Rationale

Vertebral Body Stapling
Vertebral body stapling has been proposed as an alternative to bracing in the treatment of scoliosis in children and adolescents. 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. Limitations to this study include retrospective design and small sample size.

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 and small sample size. 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. While this study has limitations including the small sample size, 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."

Vertebral Body Tethering
Vertebral body tethering has been proposed as an alternative to bracing in the treatment of scoliosis in children and adolescents. 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 United States Food and Drug Administration (FDA) granted humanitarian device exemption (HDE) for The Tether™ Vertebral Body Tethering System (Zimmer Biomet Spine, Inc., Westminster, CO), 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. The FDA 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."

In summary, at the time of this review, the clinical evidence on vertebral body stapling and vertebral body 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

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 child grows while maintaining movement and flexibility and decreasing the risk for back pain in adulthood.

Historically, the use of staples for intervertebral procedures was problematic because the staples were not designed to withstand the movement of the spine. In light of this, the Nitinol (nickel-titanium alloy) staple is being investigated as a surgical device to treat scoliosis. At room temperature the staple is shaped like a clamp. However, when immersed in an ice bath, the staple can be straightened to allow spinal insertion. After the clamp is inserted into the spine with a thoracoscope under fluoroscopy, the body temperature warms the device causing it to deflect inward creating a "C" shaped configuration for secure fixation. There is no FDA market approval of the use of the Nitinol staple in the treatment of adolescent scoliosis.

Vertebral body stapling is being studied as an alternative to bracing because it is believed to be more comfortable and less embarrassing than bracing for the child. When compared to spinal fusion, vertebral body stapling offers the advantage of allowing the individual to retain the flexibility of their spine. It is likely that this procedure could gain significant preference over conventional techniques if its long-term effectiveness and safety can be established. However, at the time of this review, there is insufficient clinical evidence demonstrating the safety and efficacy of this surgical procedure for the treatment of scoliosis.

Vertebral Body Tethering
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.

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 tethering~~]

ICD-10 Procedure

	For the following codes, when specified as vertebral body stapling or tethering:
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

	Note: the following codes are effective 10/01/2021
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

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Betz RR, D'Andrea LP, Mulcahey MJ, Chafetz RS. Vertebral body stapling procedure for the treatment of scoliosis in the growing child. Clin Orthop Relat Res. 2005; (434):55-60.
2. Betz RR, Kim J, D'Andrea LP, et al. An innovative technique of vertebral body stapling for the treatment of patients with adolescent idiopathic scoliosis: a feasibility, safety, and utility study. Spine (Phila Pa 1976). 2003; 28(20):S255-S265.
3. Betz RR, Ranade A, Samdani AF, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. Spine (Phila Pa 1976). 2010; 35(2):169-176.
4. Cahill PJ, Auriemma M, Dakwar E, et al. Factors predictive of outcomes in vertebral body stapling for idiopathic scoliosis. Spine Deform. 2018; 6(1)28-37.
5. Guille JT, D'Andrea LP, Betz RR. Fusionless treatment of scoliosis. Orthop Clin North Am. 2007; 38(4):541-545, vii.
6. Hoernschemeyer DG, Boeyer ME, Robertson ME, et al. Anterior vertebral body tethering for adolescent scoliosis with growth remaining: a retrospective review of 2 to 5-year postoperative results. J Bone Joint Surg Am. 2020; 102(13):1169-1176.
7. Laituri CA, Schwend RM, Holcomb GW 3rd. Thoracoscopic vertebral body stapling for treatment of scoliosis in young children. J Laparoendosc Adv Surg Tech A. 2012; 22(8):830-833.
8. Murray E, Tung R, Sherman A, Schwend RM. Continued vertebral body growth in patients with juvenile idiopathic scoliosis following vertebral body stapling. Spine Deform. 2020; 8(2):221-226.
9. Newton PO, Bartley CE, Bastrom TP, et al. Anterior spinal growth modulation in skeletally immature patients with idiopathic scoliosis: a comparison with posterior spinal fusion at 2 to 5 years postoperatively. J Bone Joint Surg Am. 2020; 102(9):769-777.
10. Newton PO, Kluck DG, Saito W, et al. Anterior spinal growth tethering for skeletally immature patients with scoliosis: a retrospective look two to four years postoperatively. J Bone Joint Surg Am. 2018; 100(19):1691-1697.
11. Pehlivanoglu T, Oltulu I, Ofluoglu E, et al. Thoracoscopic vertebral body tethering for adolescent idiopathic scoliosis: a minimum of 2 years' results of 21 patients. J Pediatr Orthop. 2020 May 15. Online ahead of print.

12. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. Spine (Phila Pa 1976). 2014; 39(20):1688-1693.
13. Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: One-year results on the first 32 patients. Eur Spine J. 2015; 24(7):1533-1539.
14. Theologis AA, Cahill P, Auriemma M, et al. Vertebral body stapling in children younger than 10 years with idiopathic scoliosis with curve magnitude of 30° to 39°. Spine. 2013; 38(25):E1583-E1588.
15. Torre-Healy A, Samdani AF. Newer technologies for the treatment of scoliosis in the growing spine. Neurosurg Clin N Am. 2007; 18(4):697-705.
16. Trupia E, Hsu AC, Mueller JD, et al. Treatment of idiopathic scoliosis with vertebral body stapling. Spine Deform. 2019; 7(5):720-728.
17. Wong HK, Ruiz JNM, Newton PO, Gabriel Liu KP. Non-fusion surgical correction of thoracic idiopathic scoliosis using a novel, braided vertebral body tethering device: minimum follow-up of 4 years. JB JS Open Access. 2019; 4(4):e0026.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration (FDA) 510 (k) Premarket Notification Summary. OSStaple™ Staple System. No. K061385. Rockville, MD. FDA. May 30, 2007. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061385.pdf. Accessed on October 7, 2020.
2. U.S. Food and Drug Administration (FDA) HDE Notification Summary. The Tether™ Vertebral Body Tethering System. No. H190005. Rockville, MD. FDA. August 16, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005A.pdf. Accessed on October 7, 2020.
3. Zimmer Biomet. Safety and efficacy study of spinal tethering. NLM Identifier: NCT02897453. Last updated on August 20, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02897453?cond=NCT02897453&rank=1. Accessed on October 7, 2020.

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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
	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	Medical Policy & Technology Assessment Committee (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.

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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.