



2022 Comprehensive Reimbursement Resource Guide

Prepared by Musculoskeletal Clinical Regulatory Advisers, LLC. Version March 2022.

The Tether™ Vertebral Body Tethering System

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Reimbursement Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of April 2022 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payers is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the American Medical Association (AMA), relevant medical societies, Centers for Medicare & Medicaid Services (CMS), your local Medicare Administrative Contractor, (MAC) and other health plans to which you submit claims. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payers. The decision as to how to complete a reimbursement form, including the amount to bill, is exclusively the responsibility of the provider.

PRODUCT TECHNOLOGY OVERVIEW

TECHNOLOGY DESCRIPTION

The Tether™ Vertebral Body Tethering System is a non-fusion spinal device intended for treatment of idiopathic scoliosis. Anchors and vertebral body screws are typically placed laterally from a thoracoscopic or thoracotomy approach into the vertebral body on the convex side of a spinal deformity. A SULENE® polyethylene terephthalate (PET) tensioning cord is secured to the vertebral body screws with set screws to connect the levels of the construct. The device provides a lateral tension band across the convex side of the spine that, on insertion and tensioning, partially corrects the curvature, and subsequently can arrest or correct the deformity through modulation of remaining spinal growth. In addition, the subject system includes instrumentation for insertion, manipulation, and removal of the implants.



FDA INFORMATION ON The Tether™ Vertebral Body Tethering System

H190005 August 16, 2019.

The U.S. Food and Drug Administration today approved the first spinal tether device intended to be used in children and adolescents to correct the most common form of scoliosis, called idiopathic scoliosis, that has not responded to conservative treatment options, such as external bracing. The device, called The Tether – Vertebral Body Tethering System, is intended to treat growing children and adolescents whose spinal curves are approaching or have reached the range where surgical treatment is an option.

The Tether – Vertebral Body Tethering System provides an alternative for patients with idiopathic scoliosis that don't respond to bracing. As a patient grows, The Tether – Vertebral Body Tethering System is designed to continue to correct the curvature while maintaining a fuller range of motion when compared to spinal fusion procedures.

The FDA reviewed data for The Tether – Vertebral Body Tethering System through the humanitarian device exemption (HDE) process. A Humanitarian Use Device (HUD) is a device intended to benefit patients by treating or diagnosing a disease or condition that affects not more than 8,000 individuals in the U.S. per year.

INDICATIONS FOR USE

The Tether™ - Vertebral Body Tethering System is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear.

Please refer to the full IFU for other warnings and useful information.

CONTRAINDICATIONS

The Tether™ Vertebral Body Tethering System should not be implanted in patients with the following conditions:

1. Presence of any systemic infection, local infection, or skin compromise at the surgical site.
2. Prior spinal surgery at the level(s) to be treated.
3. Known poor bone quality defined as a T-score -1.5 or less.
4. Skeletal maturity.
5. Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patients' unwillingness or inability to cooperate with post-operative care instructions.

DEVICE &/OR IMPLANT PROCEDURE

For surgical placement of The Tether™ Vertebral Body Tethering System, patients are positioned in the lateral decubitus position with the convex side of the curve to be instrumented facing upwards. As most idiopathic thoracic curves are convex towards the right side, a left lateral decubitus position will be the most common position utilized for instrumentation of thoracic curves. For recommended surgical site preparation, positioning, and technique details, please see the Surgical Technique Guide.

For thoracoscopic surgery, standard anesthesia protocol should be observed. However, it is recommended to use a single lung ventilation technique such as a double-lumen endotracheal tube to aid surgical exposure if necessary. Anchor use is recommended at all levels. Consideration should be given to the osseous structure at each level to determine if both a bone screw and anchor are needed to adequately support the construct and anticipated loads. Please refer to the Surgical Technique Guide if implant removal is required (including revision). Close wound(s) and apply wound dressing using standard techniques.

PRIVATE PAYER COVERAGE DETERMINATIONS

Commercial insurance coverage policies vary, and many require prior authorization for any procedure. We encourage health care professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for The Tether™ Vertebral Body Tethering System.

MEDICARE PHYSICIAN CODING AND 2022 MEDICARE PAYMENT

CPT CODE ⁱ	DESCRIPTION	2022 MEDICARE NATIONAL AVERAGE PHYSICIAN PAYMENT ⁱⁱ
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	\$0.00
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	\$0.00
20680	Removal of implant; deep (eg, buried wire, pin, screw, metal band, nail, rod or plate)	\$428.77
22855	Removal of anterior instrumentation	\$1,138.89
22899	Unlisted procedure, spine (use for revision)	Carrier Priced

MEDICARE BILLING AND PAYMENT

For hospital inpatient and outpatient procedures, device category HCPCS codes (i.e., C-codes) for implantable devices, along with the associated charge for the device may be reported. Complete and accurate reporting of implantable devices and the associated HCPCS codes assures accurate payment and provides necessary data for the reimbursement system.

MEDICARE HOSPITAL OUTPATIENT/ASC CODING AND 2022 MEDICARE PAYMENT

CPT CODE	DESCRIPTION	SI	APC	2022 MEDICARE NATIONAL AVERAGE PAYMENT HOPD ⁱⁱⁱ	SI	PI	2022 MEDICARE NATIONAL AVERAGE PAYMENT ASC ^{iv}
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	C	N/A	Inpatient only procedure for Medicare	N/A	C5	Inpatient only procedure for Medicare
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	C	N/A	Inpatient only procedure for Medicare	N/A	C5	Inpatient only procedure for Medicare

Private Payers may allow for this procedure to be done in the HOPD/ASC settings of care

HOSPITAL INPATIENT CODING AND 2022 MEDICARE PAYMENT

The ICD-PCS (procedure) code and possible MS-DRG assignments are provided below along with the 2022 Medicare national average payment rates.

CLINICAL DIAGNOSIS NAME	ICD-10-CM CODE	ICD-10-PCS CODE	MS-DRG ^v	ICD-10-PCS DESCRIPTION	2022 MEDICARE PAYMENT
<i>Insertion (Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part.)</i>					
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PS403Z	518 519 520	Reposition Thoracic Vertebra with Spinal Stabilization Device, Vertebral Body Tether, Open Approach	\$23,652.88 \$12,924.71 \$9,352.61
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PS443Z	518 519 520	Reposition Thoracic Vertebra with Spinal Stabilization Device, Vertebral Body Tether, Percutaneous Endoscopic Approach	\$23,652.88 \$12,924.71 \$9,352.61
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0QS003Z	518 519 520	Reposition Lumbar Vertebra with Spinal Stabilization Device, Vertebral Body Tether, Open Approach	\$23,652.88 \$12,924.71 \$9,352.61
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0QS043Z	581 519 520	Reposition Lumbar Vertebra with Spinal Stabilization Device, Vertebral Body Tether, Percutaneous Endoscopic Approach	\$23,652.88 \$12,924.71 \$9,352.61
<i>Removal (Taking out or off a device from a body part. If a device is taken out and a similar device put in without cutting or puncturing the skin or mucous membrane, the procedure is coded to the root operation CHANGE. Otherwise, the procedure for taking out the device is coded to the root operation REMOVAL.)</i>					
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PP404Z	495 496 497	Removal of Internal Fixation Device from Thoracic Vertebra, Open Approach	\$24,015.56 \$13,098.80 \$9,571.54
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PP444Z	495 496 497	Removal of Internal Fixation Device from Thoracic Vertebra, Percutaneous Endoscopic Approach	\$24,015.56 \$13,098.80 \$9,571.54
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0QP004Z	495 496 497	Removal of Internal Fixation Device from Lumbar Vertebra, Open Approach	\$24,015.56 \$13,098.80 \$9,571.54

Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0QP044Z	495 496 497	Removal of Internal Fixation Device from Lumbar Vertebra, Percutaneous Endoscopic Approach	\$24,015.56 \$13,098.80 \$9,571.54
Revision <i>(Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device)</i>					
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PW404Z	495 496 497	Revision of Internal Fixation Device in Thoracic Vertebra, Open Approach	\$24,015.56 \$13,098.80 \$9,571.54
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0PW444Z	495 496 497	Revision of Internal Fixation Device in Thoracic Vertebra, Percutaneous Endoscopic Approach	\$24,015.56 \$13,098.80 \$9,571.54
Juvenile & Adolescent Idiopathic Scoliosis	See List of codes below	0QW004Z	495 496 497	Revision of Internal Fixation Device in Lumbar Vertebra, Open Approach	\$24,015.56 \$13,098.80 \$9,571.54
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HCPCS CODES

HCPCS Code(s)^{vi}	HCPCS Code Description
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)
C1889	Implantable/insertable device, not otherwise classified

POSSIBLE ICD-10-CM (DIAGNOSIS) CODES (This is not a complete list)

M41.1	Juvenile and adolescent idiopathic scoliosis
M41.11	Juvenile idiopathic scoliosis
M41.114	Juvenile idiopathic scoliosis, thoracic region
M41.115	Juvenile idiopathic scoliosis, thoracolumbar region
M41.119	Juvenile idiopathic scoliosis, site unspecified
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.129	Adolescent idiopathic scoliosis, site unspecified
M41.20	Other idiopathic scoliosis, site unspecified
T84.296A	Other mechanical complication of internal fixation device of vertebrae, initial encounter

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Frequently Asked Questions

The new CPT codes became effective on July 1, 2021, at which time providers and facilities must utilize the code(s) when performing anterior vertebral body tethering.

What is the coding and reimbursement breakdown of CPT codes 0656T & 0657T?

Professional component: Category III codes do not have any established RVU's for the Physician, therefore it will be carrier determined.

Setting of care - Inpatient Hospital: Under the Inpatient Prospective Payment System (IPPS), each case or “discharge” is categorized into a Medicare Severity – Diagnosis Related Group (MS-DRG) depending on the patient’s diagnosis, the procedures performed (using ICD-10 procedure and diagnosis codes), complicating conditions, age, and discharge status. Each MS-DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that MS-DRG compared to the cost of cases in other MS-DRGs.

Setting of care - Hospital Outpatient and ASC: 0656T & 0657T are inpatient only codes and cannot be performed in the outpatient & ASC settings of care.

What codes can Physicians use as Crosswalks or Proxy codes for Comparison?

- To request the appropriate reimbursement amount, physicians may use a comparator CPT code that reflects similar physician work as Anterior Vertebral Body Tethering.
- The following codes may be used as a crosswalk, or proxy, to code 0692T in order to compare physician work performed:
- The provider is ultimately responsible for selecting the appropriate code based on the services they provided to their patient.

CPT code	Descriptor	Pre-eval time	Median Intra-Svc. Time	Immediate Post Svc. Time	Total time	2022 Total Facility RVUs
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	22.21	34.33	7.08	63.62	\$2,201.65
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	25.73	39.38	8.12	73.23	\$2,534.21

Comparator code summary used by the physician:

- The physician work involved requires complex decision making due to the nature of the patient's illness and their comorbidities and complications. The skill involved in Anterior Vertebral Body Tethering, is similar to that required by CPT [Comparator Code]. The total physician work time is estimated at XX minutes, which is greater than [Comparator Code]. My fee for [Comparator Code] is \$[Dollar Amount].

Based on the Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments information included in this letter, I believe the relative values for the Anterior Vertebral Body Tethering, procedure should be [RVU Amounts], which is [Percent]% greater than [Comparator Code]. Therefore, I am submitting my charge for \$[Dollar Amount] for this service.

Will payers cover this treatment in pediatric patients?

- Coverage & payment of The Tether Vertebral Body Tethering System and procedure is not guaranteed by any Payer. We highly recommend that you contact your Payers before surgery to see if the procedure requires prior authorization.

Payment Systems Overview

Provider	Setting of Care	Payment Method	Categorization	Coding Methods
Physician	Inpatient	Physician Fee Schedule (PFS)	Based on RVUs	CPT
Facility	Inpatient	IPPS	DRG	ICD-10 dx and ICD-10 procedure (pcs)

REFERENCES

ⁱ CPT 2022 Professional Edition, ©2021 American Medical Association (AMA); CPT is a trademark of the AMA.

ⁱⁱ <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1751-f>

ⁱⁱⁱ <https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/cms-1753-fc> Addenda A&B

^{iv} <https://www.cms.gov/medicare/medicare-fee-service-payment/ascpaymentasc-regulations-and-notices/cms-1753-fc> ASC Addendum AA, BB, DD1, DD2, EE, and FF

^v <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ippf-final-rule-home-page>

Table 5 MS-DRGs, Relative Weighting Factors and Geometric and Arithmetic Mean Length of Stay 2022 MS-DRG IPPS Final Rule CF 6594.24

^{vi} <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>