Dynamic Spinal Stabilization Devices

INDEPENDENT CARE HEALTH PLAN

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Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

There are no NCDs and/or LCDs for Dynamic Spinal Stabilization Devices

Description

Dynamic spinal stabilization devices are proposed as a way to immobilize and stabilize spinal segments in a skeletally mature individual as an adjunct to fusion in the treatment of chronic instabilities or deformities of the thoracic, lumbar and sacral spine including, but not limited to, degenerative spondylolisthesis (with objective evidence of neurologic impairment) or previous failed spinal fusion. These devices are also approved by the US Food & Drug Administration (FDA) for spinal fusion with autogenous graft only, when the device fixed or attached to the lumbar or sacral spine and for when the device removed after the development of a solid fusion mass.

These devices attach to the spine via the implantation of two titanium alloy screws per vertebra. The protruding ends of the screws, which have been implanted into two or three adjacent vertebrae, are attached to polyethylene-terephthalate cords. These cords are surrounded by a set of solid polycarbonate urethane spacers. The system is designed to stabilize the spine by the cords pulling against the spinal motions that separate the vertebrae. At the same time, the spacers push against the spinal motions that compress the vertebrae. These devices differ from traditional instrumentation used during spinal fusion, as they are nonrigid and allow some movement of the spine segments. An example of dynamic spinal stabilization devices includes, but may not be limited to, the **Dynesys Stabilization System**.

The Dynesys Stabilization System has also been proposed for immobilization and stabilization of spinal segments *without* a spinal fusion procedure; at this time, the FDA has not approved this application.

The **Zimmer DTO Implant**, considered a hybrid device, combines the Dynesys Dynamic Stabilization System with the rigid stabilization of the **OPTIMA ZS Spinal System**. This device is an attempt to offer a new segmental solution for treating degenerative lumbar spine pathologies with different stages of degeneration at contiguous levels.

Dynamic spinal stabilization devices may also be semi-rigid in design. These devices purportedly allow less spinal movement than the nonrigid, but more than traditional spinal fusion instrumentation.

The FDA granted its Breakthrough Device Designation for the **LimiFlex Dynamic Sagittal Tether** (also referred to as the **Paraspinous Tension Band**). It consists of two titanium coil springs attached to each other by polyethylene straps, which form a loop; the loop is wrapped around the spinal processes and applies force to maintain lordosis and stabilize the spine. The LimiFlex is implanted in conjunction with a decompression procedure via a minimally invasive approach and has been proposed as an alternative to spinal fusion.

The **coflex Interlaminar Stabilization Device**, while it does provide dynamic spinal stabilization, differs somewhat from the other devices in that it does not use cords to help with motion preservation. The coflex device is positioned between two adjacent spinous processes after a decompression of spinal stenosis has been performed (during the same surgical procedure). It purportedly provides stability while also still allowing some functional spinal motion and is proposed as an alternative to spinal fusion.

Vertebral body tethering, similar to dynamic spinal stabilization, has been proposed as a treatment for scoliosis. In this procedure, as in dynamic spinal stabilization, the screws are implanted into each side of the vertebra, which are then attached to polyethylene-terephthalate cords. Where the procedures differ, however is the theory of growth modulation – partially restraining one side of the spine (pulling one cord tighter than the other) to purportedly allow growth on the other side, to reverse the abnormal scoliosis

growth pattern in the anterior thoracic (upper) spine. Examples of devices used for this procedure include, but may not be limited to, the **MIScoli System** and **The Tether Vertebral Body Tethering System**. A variation of these devices is the **Auctus VBT system**, which was granted an FDA Breakthrough Device Designation; it utilizes an external magnet controller for nonsurgical adjustment of the spinal curvature over time.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

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The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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	

22849	Reinsertion of spinal fixation device	
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)	
22899	Unlisted procedure, spine	
CPT® Category III Code(s)	**Description**	**Comments**
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	
0657T	Vertebral body tethering, anterior; 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	
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

Change Summary

- 01/01/2024 New Policy.
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