Subject: Interspinous Process Fixation Devices for Spinal Fusion		Original Effective Date: 3/11/2019
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DISCLAIMER

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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [2 16 17 18]

This MCP addresses interspinous, non-pedicle fixation devices attached to the spinous process to achieve rigid spinal fixation and accommodate bone graft material for spinal fusion.

The most common surgery for chronic nonspecific low back pain with lumbar disc degenerative changes is spinal fusion, a procedure that fuses two or more vertebral bodies together. The goal is to restrict spinal motion and remove the degenerated disc (the presumed cause of pain) in order to relieve symptoms. A variety of fusion techniques are used. All involve the placement of a bone graft between the vertebrae. Fusion can be performed with or without supplemental hardware (instrumentation), such as pedicle rods, plates, screws, or cages that function as an internal splint while the bone graft heals. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments. The standard spinal fusion procedure for rigid spinal fixation involves the use of pedicle screws, rods, cages and plates. Non-pedicle interspinous process fixation devices were developed as a minimally invasive rigid fixation alternative to standard rigid fixation instrumentation to aid in the stabilization of the spine. It is proposed that interspinous fixation systems are less invasive and present fewer risks than standard instrumentation and are being evaluated as alternatives to pedicle screw, rod, cages, and plates in combination with interbody fusion. Interspinous fixation devices are also being evaluated for stand-alone use in patients with spinal stenosis.

A number of interspinous process fixation devices have been approved by the U.S. Food and Drug Administration (FDA) 510(k) clearance process and are used an adjunct to interbody fusion. The use of one of

these devices for a stand-alone procedure would be considered an off-label use. Examples of devices include but are not limited to the following:

- Affix™ II and Affix II Mini Spinous Process Plate System (Nuvasive®), Aileron® Posterior Fusion System (Life Spine®) Surgery M-SUR172 3, Aspen® Spinous Process Fixation System (BioMet) , Axle™ Interspinous Fusion System (X-Spine), BacFus® Spinous Process Fusion Plate (RTI Surgical™, BridgePoint™ Spinous Process Fixation System (Alphatec Spine®), coflex-F® Implant Systems (Paradigm Spine), Inspan™ Spinous Process Plate System (SpineFrontier®), InterBRIDGE Interspinous Posterior Fixation System (LDR Spine), Minuteman® Interspinous Interlaminar Fusion Device (percutaneous spinal fusion) (Spinal Simplicity), Octave™ Posterior Fusion System (Life Spine®), PrimaLOK™ SP Interspinous Fusion System (OsteoMed Spine), SP-Fix™ Spinous Process Fixation System (Globus Medical), Spire™ Stabilization System (Medtronic Sofamor Danek), ZIP™ MIS Interspinous Fusion System (Aurora Spine) [2]

Note: Interspinous process fixation devices for spinal fusion in this MCP differ from interspinous decompression devices for Spinal Stenosis. Please see the following related MCP for additional information concerning these devices: Interspinous Decompression Devices for Spinal Stenosis (X Stop, non-fusion Coflex) MCP-222.

RECOMMENDATION

Interspinous Process Fixation Devices for Spinal Fusion are considered experimental, investigational and/or unproven for any indication, due to insufficient clinical evidence of safety and efficacy in published peer-reviewed medical literature.

SUMMARY OF MEDICAL EVIDENCE [3-15]

Overall, there is a paucity of evidence in the peer-reviewed published medical literature to support the long-term safety and effectiveness of interspinous process fixation devices when used in combination with interbody fusion or as a stand-alone procedure. Large well designed randomized controlled trials are needed to demonstrate the clinical utility of interspinous process fixation devices compared with established standard surgical approaches involving pedicle screw-rod-cage-plate fixation with lumbar fusion procedures.

A recent systematic review and meta-analysis (Poetscher et al, 2018) was conducted to provide complete and reliable information regarding benefits and harms of interspinous process devices (IPDs) when compared to conservative treatment or decompression surgery and suggest directions for forthcoming RCTs. Overall quality of evidence was low. One trial compared IPDs to conservative treatment: IPDs presented better pain, functional status, quality of life outcomes, and higher complication risk. Five trials compared IPDs to decompressive surgery: pain, functional status, and quality of life had similar outcomes. IPD implant presented a significantly higher risk of reoperation. We found low-quality evidence that IPDs resulted in similar outcomes when compared to standard decompression surgery. Primary and secondary outcomes were not measured in all studies and were often published in incomplete form. Subgroup analysis was not feasible. Difficulty in contacting authors may have prevented us from including data in quantitative analysis. The review concluded that patients submitted to IPD implants had significantly higher rates of reoperation, with lower cost-effectiveness. Future trials should improve in design quality and data reporting, with longer follow-up periods. [11]

The results of a Cochrane review (Machado et al, 2016) show a paucity of evidence on the efficacy of surgery for lumbar spinal stenosis. Twenty four randomised controlled trials included 2352 participants with lumbar spinal stenosis with symptoms of neurogenic claudication. Three trials investigated the effects of interspinous process spacer devices compared with conventional bony decompression. These spacer devices resulted in similar reductions in pain and disability but the spacer devices required longer operation time and were associated with higher risk of reoperation. Two trials compared interspinous spacer devices with decompression plus fusion. The data found no difference in pain relief the spacer devices revealed a small but significant effect in disability reduction and were also superior to decompression plus fusion in terms of operation time and perioperative blood loss however, there was no difference in rate of reoperation. Overall there were no differences for the primary or secondary outcomes when different types of surgical decompression techniques were compared among each other. The quality of evidence varied from 'very low quality' to 'high quality'. Placebo-controlled trials in surgery are feasible and needed in the field of lumbar spinal stenosis. The results demonstrate that at present, decompression plus fusion and interspinous process spacers have not been shown to be superior to conventional decompression alone. More methodologically rigorous studies are needed in this field to confirm our results. [9]

Another systematic review (Lopez et al, 2017) evaluated the literature on lumbar spinous process fixation and fusion devices (excluding dynamic fixation and spinous process spacer devices). A total of 15 articles met the inclusion and exclusion criteria, two of the nonrandomized studies compared interspinous process fixation devices to pedicle screws in individuals undergoing interbody fusion and two other studies included interspinous process fixation devices alone or pedicle screws plus an interspinous process fixation device in individuals undergoing interbody fusion. Use of an interspinous process fixation device decreased surgical time and blood loss compared to pedicle screw implantation procedures, however, study designs were methodologically flawed and biased when reporting outcomes of reduced spinal instability at 1 year, rates of device failure, bony fracture, and complications. No comparative studies exist that report either complication rates of interspinous process fixation devices to other treatment modalities or length of hospital stay for interspinous process fixation devices compared to pedicle screw implantation procedures. [8]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
22899	Unlisted procedure, spine [when specified as insertion of a non-pedicle interspinous process fixation device]

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