

SENT VIA EMAIL OR FAX ON
May/26/2009

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An Independent Review Organization

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DATE OF REVIEW:

May/24/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Two-Day inpatient stay and X-Stop, 0171T, interspinous process distractor at L4/5

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified in Orthopaedic Surgery

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Overturned (Disagree)

Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY SUMMARY

The patient has mechanical low back pain. MRI shows mild herniation at L4-5. There is no evidence of stenosis or radiculopathy.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION

The request is not medically reasonable and necessary. The X-Stop device is not indicated for mechanical low back pain. This device is not recommended in the ODG guidelines.

Interspinous decompression device (X-Stop®)

Not recommended due to the lack of sufficient literature evidence (absent long term studies,

potential risks), with initially encouraging results. While short-term results are promising, there are currently no long-term clinical trials for interspinous process decompression (IPD). The X-Stop® Interspinous Process Decompression System (Kyphon, Inc., Technologies, Inc.) is the only IPD system that has received clearance from the U.S. Food and Drug Administration (FDA), but there are several others in trials. FDA approval is as indicated below. A prospective, Phase IV, five-year, post approval study of the X-Stop called the Condition of Approval Study (COAST) is currently in progress. Interspinous process decompression with the X-Stop device offers an intermediate step in the continuum of care for patients with neurogenic intermittent claudication associated with lumbar spinal stenosis. With careful patient selection for this procedure, progression to more invasive surgical interventions, such as decompressive laminectomy, may be avoided or delayed. The X-Stop procedure is performed in under half an hour with only local anesthesia and the patient generally can go home after one day. This randomized controlled trial demonstrated that only approximately 5% of participants assigned to continuation of conservative treatment met the treatment success criteria for the study after 24 months of follow up, with approximately 28% requiring decompressive laminectomy due to unresolved symptoms. This contrasted sharply with the findings in patients treated with the X-Stop device, approximately 48% of whom satisfied the three success criteria, with 7% still requiring laminectomy. (Zucherman, 2005) This study concluded that, while the X-Stop does improve the clinical situation, a good outcome is achieved less often than previously reported, with 31% of the patients having a good outcome. A good outcome was not related to smoking, BMI, or number of implanted X-Stops; however, a good outcome was related to the absence of orthopaedic co-morbidity or male gender. (Brussee, 2007) The X-Stop interspinous distraction device has shown to be an attractive alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis; however, we do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis. (Verhoof, 2007) The X-Stop is appropriate for patients with moderately severe functional impairment whose symptoms are exacerbated in extension and relieved in flexion. Implanted between the spinous processes without disrupting the normal anatomical structures, the X-Stop limits narrowing of the spinal canal and neural foramina by reducing extension at the symptomatic level(s). (Laurysen , 2007) CMS has approved the new technology application for the X-Stop Interspinous Process Decompression System for Medicare coverage. (GAO, 2007) Although there is fair evidence that an interspinous spacer device is superior to nonsurgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) Kyphon Inc. acquired St. Francis Medical Technologies, Inc., a privately held, California-based company that manufactures the X-Stop System, the first FDA-approved interspinous process device for treating lumbar spinal stenosis. The transaction broadened Kyphon's focus in minimally invasive spine to its existing KyphX® Balloon Kyphoplasty technologies for repairing vertebral compression fractures and its recently launched Functional Anaesthetic Discography procedure for diagnosing the source of low back pain. Medtronic has recently acquired US-based Kyphon. The X-Stop consists of a titanium alloy cylindrical spacer (available in five different sizes) that fits in between the spinous processes of two adjacent vertebrae, with two wings on either end to secure the device in place. The device works by maintaining the space between the spinous processes when the patient is standing or flexing backwards. By keeping the spinous processes apart, the nerve impingement by the narrowing spinal canal is reduced, relieving the symptoms.

Indications for Surgery -- Interspinous decompression device (X-Stop®) -

The X-Stop Procedure is indicated for patients aged 50 or older who are suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis, who would otherwise be candidates for laminectomy

- Confirmation should be based on x-ray film, MR imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing

- It is indicated for patients with moderately impaired physical function who experience relief

in flexion (bending forward) from their symptoms of leg/buttock/groin pain, with or without back pain, and who have undergone a regimen of at least 6 months of non-surgical treatment

- The X-Stop may be implanted at one or two lumbar levels in patients in whom surgical treatment is indicated at no more than two levels

- The following conditions are contraindications for this procedure: (1) an allergy to titanium or titanium alloy; (2) spinal anatomy or disease that would prevent implantation of the device or cause it to be unstable in situ (this includes significant instability of the lumbar spine [for example, isthmic spondylolisthesis greater than Grade I]; an ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis; and significant scoliosis [Cobb angle $\geq 25^\circ$]); (3) cauda equina syndrome, defined as neural compression causing neurogenic bowel or bladder dysfunction; (4) diagnosis of severe osteoporosis, defined as bone mineral density (based on dual-energy x-ray absorptiometry scan or some comparable study) in the spine or hip that is more than 2.5 standard deviations below the mean of adult normal individuals in the presence of one or more fragility fractures; & (5) active systemic infection or infection localized to the site of implantation.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

AHCPR-AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

DWC-DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

INTERQUAL CRITERIA

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

MILLIMAN CARE GUIDELINES

ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

TEXAS TACADA GUIDELINES

TMF SCREENING CRITERIA MANUAL

PEER ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)