



Notice of Independent Review Decision

DATE OF REVIEW: 9/8/2008

IRO CASE #: **NAME:**

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Determine the appropriateness of the previously denied request for X-Stop intervertebral distraction device at L2-3 and L3-4 and a 2-day inpatient length of stay.

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

A Texas licensed Neurological surgeon.

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The previously denied request for X-Stop intervertebral distraction device at L2-3 and L3-4 is medically necessary and the 2-day inpatient length of stay is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Fax Cover Sheet dated 9/2/08.
- Notice to CompPartners, Inc. of Case Assignment dated.

- Notice to Utilization Review Agent of Assignment of Independent Review Organization dated 9/2/08.
- Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 8/29/08.
- Company Request for Independent Review Organization dated 8/27/08.
- Request Form Request for a Review by an Independent Review Organization dated 8/27/08.
- Letter dated 8/20/08, 8/13/08.
- Notice of Utilization Review Findings dated 8/20/08, 8/13/08.
- Fax Cover Sheet/Note/Comment/Message dated 8/13/08, 8/7/08.
- Behavioral Medicine Evaluation/Pre-Surgical Screening dated 7/22/08.
- Follow-Up Visit Note dated 7/15/08, 6/23/08, 5/12/08, 4/23/08, 4/15/08, 1/15/08, 10/16/07, 7/17/07, 4/13/07, 1/12/08, 11/16/06, 10/11/06.
- Surgery Scheduling Slip/Checklist dated 6/23/08.
- Electrodiagnostic Study Report dated 6/12/08.
- Procedure Report dated 5/28/08.
- Lumbar Spine CT Scan dated 5/12/08, 10/4/06.
- Radiology Report dated 5/12/08, 10/4/06.
- Consultation Report dated 1/12/07.
- Cervical Spine MRI dated 1/5/98.

There were no guidelines provided by the URA for this referral

PATIENT CLINICAL HISTORY (SUMMARY):

Age: xx years old.
Gender: Male
Date of Injury: xx/xx/xx
Mechanism of Injury: Strain during lifting.

Diagnosis: Complex regional pain syndrome (CPRS) to the left upper extremity.

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

This is a xx-year-old male with a date of injury on xx/xx/xx. He was fused from L4 to the sacrum. He had several months of increasing left leg pain. He did get relief from leaning forward. He had some transient relief with Lyrica. He was on Methadone and Lyrica. A pre-surgical psychological evaluation revealed heightened pain sensitivity, insomnia, reactive depression, and limited pain coping skills. He had been cleared for surgery, however. He had multiple back surgeries and had been diagnosed with CRPS to the left upper extremity. He used a spinal cord stimulator (SCS). The stimulator was at L1-L2. An electromyogram / nerve conduction velocity (EMG/NCV) dated 06/12/2008 failed to indicate conclusive evidence of a radiculopathy in the lower extremities. His neurological examination reveals absent reflexes in the lower extremities. A

lumbar myelogram dated 05/12/2008 showed severe central canal narrowing at L3-4. This had increased significantly since a myelogram performed in 10/2006. There was minimal spondylolisthesis seen here and no movement on flexion and extension. There was a disc bulge and ligamentum hypertrophy seen at L2-3 causing canal stenosis, as well. The provider is requesting an X-Stop intervertebral distraction device at L2-3 and L3-4 with a 2-day length of stay. The X-Stop procedure at L3-4 is medically necessary. This patient had symptoms of neurogenic claudication. He meets the ODG criteria listed below for placement of an X-Stop procedure Particularly because of his history of multiple spinal surgeries and a SCS, a less invasive procedure to give him some pain alleviation would be preferable to a larger decompression. The amount of spondylolisthesis that he had (described as minimal, without significant movement in flexion and extension) should not be a contraindication to this procedure. However, this procedure can be done, in some cases, as an outpatient, and often with a one-day hospital stay. There does not appear to be a medically necessary reason, as to why this procedure would require a one-day hospital stay. Occupational and Disability Guidelines, "Low Back" chapter: 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.* This procedure can be done at two levels with a 1 day hospital stay.

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

- ACOEM – AMERICAN COLLEGE OF OCCUPATIONAL AND 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.
- X** ODG – OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES.

The Official Disability Guidelines (ODG), Treatment Index, 6th Edition (Web), 2008-Low back--Interspinous decompression device (X-Stop).

- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR.
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE AND PRACTICE PARAMETERS.
- TEXAS TACADA GUIDELINES.
- TMF SCREENING CRITERIA MANUAL.
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION).
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION).