

I-Resolutions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW: DECEMBER 19, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of two day inpatient stay and lumbar L3-4 decompression and arthrodesis and transforaminal posterolateral with instrumentation case spacer, iliac crest autograft, allograft with Dynesys.

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

MD, Board Certified Orthopedic 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 reviewer finds that medical necessity does not exist for two day inpatient stay and lumbar L3-4 decompression and arthrodesis and transforaminal posterolateral with instrumentation case spacer, iliac crest autograft, allograft with Dynesys.

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx year old male claimant who reportedly is status post L4- S1 decompression and fusion with instrumentation performed on 06/13/07. The records indicated that the claimant was noted to have persistent low back pain and stiffness despite post – operative physical therapy and hardware block injections. Lumbar x-rays done in April 2008 showed implants to be intact and the spine above to be reasonably well maintained along with what appeared to be slight retrolisthesis of L3 on L4. Ongoing lumbar pain with mild residual left foot numbness post lumbar fusion was noted. The claimant was diagnosed with lumbar spondylosis. A bilateral facet injection was performed on

04/30/08 followed by bilateral L3-4 medial branch blocks on 07/02/08 which reportedly provided minimal relief. A physician visit dated 08/12/08 for an impairment status rating noted the claimant with marked tenderness over the lower lumbar with bilateral spasm. There was decreased range of motion noted along with marked weakness to dorsiflexion of the left great toe and weakness of extension. Repeat facet blocks L3-4 were recommended and additional fusion C3-4 was discussed. A lumbar CT done 08/12/08 showed the posterior fusion at L4-5 – S1 levels and a right L5 pars defect. An additional facet injection L3-4 was performed on 09/10/08 with reported eighty percent relief for four days. The claimant was diagnosed with adjacent facet syndrome. The treating physician has requested a lumbar L3-4 decompression and arthrodesis posterolateral and transforaminal with instrumentation cage spacer, iliac crest autograft, allograft with Dynesys.

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

Two day in patient stay for a lumbar L3-4 decompression, arthrodesis and transforaminal posterolateral with instrumentation case based on iliac crest autograft/allograft with Dynesys is not medically indicated and appropriate in this xx-year-old male who has previously undergone L4 through S1 decompression fusion and TLIF. There has been adjacent facet syndrome, however, a recent CT scan report reviewed on 08/15/08 by Dr. noted that the posterolateral graft looks organized and the L3-4 facet does not look that bad without significant arthritic changes. The CT scan was performed on 08/12/08. Conservative measures have included injections, but have not been exhausted. There is no evidence of instability. All pain generators have not been appropriately identified. Based upon the medical records available for review, fusion is not indicated and appropriate as per the ODG Guidelines. The reviewer finds that medical necessity does not exist for two day inpatient stay and lumbar L3-4 decompression and arthrodesis and transforaminal posterolateral with instrumentation case spacer, iliac crest autograft, allograft with Dynesys.

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates, Low Back

Dynamic neutralization system (Dynesys®)

Not recommended for non-specific LBP. Under study for spondylolisthesis as an option to fusion. A dynamic neutralization system for the spine, the Dynesys® Spinal System (Zimmer USA), is an investigational device currently limited by Federal law to investigational use in the US. The Dynesys is a nonfusion pedicle screw stabilization system that uses flexible materials to stabilize the affected lumbar region while preserving the natural anatomy of the spine, and it was developed in an attempt to overcome the inherent disadvantages of rigid instrumentation and fusion. The results of studies indicate that both back and leg pain are, on average, still moderately high 2 years after instrumentation with the Dynesys system. Only half of the patients declared that the operation had helped and had improved their overall quality of life; less than half reported improvements in functional capacity. The reoperation rate after Dynesys was relatively high. There is limited support for the notion that semirigid fixation of the lumbar spine results in better patient-oriented outcomes than those typical of fusion. ([Grob, 2005](#)) ([Schwarzenbach, 2005](#)) The manufacturer study for FDA approval concluded that Dynesys may be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain while avoiding the relatively greater tissue destruction and the morbidity of donor site problems encountered in fusion. However, long-term follow-up care is still recommended. ([Welch, 2007](#)) Numerous new posterior dynamic stabilization (PDS) devices have been developed for the treatment of disorders of the lumbar spine. Devices include: Interspinous Spacer Devices; The Wallis System; The X STOP Device; The DIAM

System; The Coflex, ExtendSure, and CoRoent Devices; Pedicle Screw/Rod-Based Stabilization Devices; The Graf System; The Dynesys System; The AccuFlex, PEEK, and Isobar Rods; Total Facet Replacement Systems; The TFAS Implant; The TOPS Implant; The Stabilimax NZ Implant. ([Khoeir, 2007](#)) See also [DIAM](#) (device for intervertebral assisted motion).

Milliman Care Guidelines. Inpatient and Surgical Care 12th Edition.
Lumbar fusion: Goal Length of Stay: 3 days postoperative:

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

- ACOEM- AMERICAN 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 REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)