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Notice of Independent Review Decision

DATE OF REVIEW: 4/20/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity a TLSO Back Brace.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic 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)

The reviewer disagrees with the previous adverse determination regarding the prospective medical necessity a TLSO Back Brace.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source):

Records reviewed:

LHL009 – 4/4/13

Denial Letters – 2/13/13, 2/25/13

Pre-authorization Request Form – no date

Peer Review Reports – 2/11/13, 2/21/13
Independent Medical Evaluation – 5/24/12

Office Notes – 11/23/09, 10/11/12, 12/10/12, 1/7/13, 2/4/13
Letter of Medical Necessity – 8/9/12
Letters – 12/22/11, 1/16/12, 3/12/12, 4/12/12, 5/10/12, 6/14/12, 9/6/12
Pre-Authorization Request – 6/4/09

Operative Reports – 7/1/09, 5/4/12, 1/15/13
Lumbar Myelograms – 7/1/09, 1/15/13
CT Lumbar Spine – 1/15/13
MRI Lumbar Spine – 6/18/09, 3/30/12
Radiology report – 1/20/11
CT Lumbar Myelogram – 7/1/09

Outpatient Orders/Referrals – 6/8/09, 6/29/09, 1/18/11
Myelogram/Discogram Discharge Instructions – 7/1/09
Radiology Progress Notes – 7/1/09
Myelogram Physician Orders – 7/1/09
MRI Patient Screening Form – 6/18/09

Claim Return Letter – undated

Appeal Report – 10/31/12

Records reviewed:

Letter – 2/26/09, 3/5/09, 3/12/09, 3/19/09, 4/9/09, 4/29/09, 5/14/09, 6/22/09, 6/11/09, 4/8/10, 7/12/10, 9/23/10, 11/22/10, 1/20/11, 2/14/11, 4/21/11, 6/13/11, 6/29/11, 11/21/11, 10/10/11

Office Notes – 7/6/09, 8/6/09, 8/17/09, 9/21/09, 10/12/09, 3/7/13, 4/4/13

Radiology Reports – 7/14/09, 9/23/10, 4/21/11
Operative Reports – 4/15/09, 1/5/10, 4/13/11
Discharge Summary – 1/5/10
MRI Evaluation of Lumbar Spine – 5/16/11
History and Physical Reports – 1/5/10, 4/13/11

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant was injured on xx/xx/xx. This was associated with having missed a step while climbing down. The claimant has had persistent low back pain, stiffness, along with paresthesias and weakness. Exam findings have included positive straight leg raise, bilateral weakness in the feet and decreased L5 and S1 dermatomal sensation. A 3/30/12 dated

lumbar MRI revealed degenerative disease of the discs and facets, along with retrolisthesis of L4-L5, with contact of the exiting nerve roots.

A CT-myelogram report from 1/15/13 revealed degenerative disc and facet disease, along with neuroforaminal stenosis. There was also a history of a prior decompression and fusion at L5-S1. A denial letter noted the lack of documented trial and failure of non-operative treatment, surgical procedure denial and therefore the requested brace was also deemed to lack medical necessity. Another denial letter indicated that the surgical request was appropriate only with a non-custom/standard brace.

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

Guidelines do not support the use of a lumbar brace for back pain prevention. The literature is equivocal regarding treatment of nonspecific back pain with such any form of brace. In any event, any form of brace treatment is only at best supported by a standard brace. Even allowing for the possibility of approval of the surgical request itself; guidelines do not support other than a standard non-custom brace. Therefore the request is not medically necessary and based on applicable clinical guidelines.

ODG Low Back Chapter:

Lumbar Supports-Not recommended for prevention. Recommended as an option for treatment. See below for indications. Prevention: Not recommended for prevention. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. (Jellema-Cochrane, 2001) (van Poppel, 1997) (Linton, 2001) (Assendelft-Cochrane, 2004) (van Poppel, 2004) (Resnick, 2005) Lumbar supports do not prevent LBP. (Kinkade, 2007) A systematic review on preventing episodes of back problems found strong, consistent evidence that exercise interventions are effective, and other interventions not effective, including stress management, shoe inserts, back supports, ergonomic/back education, and reduced lifting programs. (Bigos, 2009) This systematic review concluded that there is moderate evidence that lumbar supports are no more effective than doing nothing in preventing low-back pain. (van Duijvenbode, 2008) Treatment: Recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific LBP (very low-quality evidence, but may be a conservative option). Under study for post-operative use; see Back brace, post operative (fusion). Among home care workers with previous low back pain, adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism. (Roelofs, 2007) Acute osteoporotic vertebral compression fracture management includes bracing, analgesics, and functional restoration. (Kim, 2006) An RCT to evaluate the effects of an elastic lumbar belt on functional capacity and pain intensity in low back pain treatment, found an improvement in physical restoration compared to control and decreased pharmacologic consumption. (Calmels, 2009) This RCT concluded that lumbar supports to treat workers with recurrent low back pain seems to be cost-effective, with on average 54 fewer days per year with LBP and 5 fewer days per year sick leave. (Roelofs, 2010) This systematic review concluded that lumbar supports may or may not be more effective than other interventions for the treatment of low-back pain. (van Duijvenbode, 2008) For treatment of nonspecific LBP, compared with no lumbar support, an elastic lumbar belt may be more effective than no belt at improving pain

(measured by visual analogue scale) and at improving functional capacity (measured by EIFEL score) at 30 and 90 days in people with subacute low back pain lasting 1 to 3 months. However, evidence was weak (very low-quality evidence). (McIntosh, 2011) See also Back brace, post operative (fusion); IntelliSkin posture garments; & SpineCor brace.

Back Brace, post-operative (Fusion)- Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable. (Resnick, 2005)

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)