

IRO Express Inc.

An Independent Review Organization

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DATE OF REVIEW:

MAY 31, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Are eight outpatient Botox chemodenervation injections to the quadratus lumborum, gluteus maximus, gluteus medius related to low back

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

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Office notes, Dr., 04/25/01 and 06/13/01

Lumbar spine MRI, 06/13/01

Discogram, 08/03/04

Second surgical opinion, Dr., 10/24/01

Office notes, Dr., 11/01/01, 12/06/01, 02/21/03, 05/11/02, 05/23/02, 10/31/02, 05/22/03, 10/02/03, 02/26/04, 07/30/04, 08/05/04, 09/04/04, 09/16/04 and 10/07/04

Note, 01/10/02 and 03/19/02

Chest x-ray report, 02/04/02

Dual lead spinal stimulator trial report by Dr., 02/13/02

Review of medical records, Dr., 07/02/03

Letter, Dr., 08/12/03 and 11/20/03
Phone message, Dr, 03/04/04
Office note, Dr., 02/08/05, 03/09/05 and 03/15/05
Operative report, 02/09/05, 09/07/05 and 02/19/06
Lumbosacral spine x-ray report, 03/10/05
Lumbar spine note, 05/05/05
Office note, Dr., 05/18/05
Thoracic spine x-ray report, 05/23/05
Lumbar spine x-ray report, 05/23/05
Letters, Dr., 05/25/05 and 01/24/06, 03/07/06, 08/01/06, 04/03/07 and 04/19/07
Independent Medical Evaluation, Dr., 07./11/05
Office note, Dr., 09/13/05 and 03/07/06
Operative report, Dr., 06/01/06
Denial noted, 04/25/07 and 05/09/07
Request for reconsideration, Dr., 05/02/07

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male who slipped and fell on xx/xx/xx culminating in a xxxx lumbar laminectomy. The records suggest that the claimant treated with Dr. who performed two surgical procedures with the most recent surgical procedure being a xx/xx/xx removal of posterior unilateral segmental pedicle screw instrumentation, removal of bone growth stimulator, revision L3 through S1 laminectomy with left sided partial medial facetectomies and foraminotomies.

On 04/25/01, Dr. placed the claimant at maximum medical improvement. The 06/13/01 lumbar MRI showed laminectomy changes at L4-5 and L5-S1 level, no recurrent disc herniation, small disc protrusion at L3-4, and facet arthropathy at L3-4 level. Upon review of the 06/13/01 lumbar MRI, Dr. recommended a discogram which was performed on 08/03/04 and was abnormal at L3-4 and with a negative control level at L2-3.

The claimant saw Dr. on 10/24/01 for a second surgical opinion. Dr. was not convinced that the claimant was a surgical candidate and recommended that the L4-5 and L5-S1 disc be evaluated by a discogram. The claimant began treating with Dr. on 11/01/01. Dr. recommended spinal cord stimulator for the diagnosis of failed back syndrome. The permanent spinal cord stimulator was implanted on 02/27/02. On 05/23/02, Dr. noted that the claimant was using the spinal cord stimulator daily with some complaints of soreness. Dr. documented on 05/22/03 that the claimant was taking Celebrex and Effexor. Impression was status quo. Dr. performed a medical record review on 07/2/03 and opined that the claimant's present symptoms were causally related to the original injury of xx/xx/xx. Dr. recommended that if the spinal cord stimulator provided relief then no additional treatment would be needed.

The claimant continued to treat with Dr. through 10/03. At that time, the claimant reported a new complaint of pain arising from the lower back and ascending to the interscapular areas. Dr. felt the claimant's complaints were of myofascial in nature. On 02/26/04, Dr. changed his medications. The spinal cord stimulator was helping the claimant's pain. Dr. noted that the claimant was disabled and not a rehabilitation candidate. On 07/30/04, Dr. reviewed flexion extension films of the lumbar spine which showed severe transitional syndrome at L3-4 above the level of the fusion, and a mild

spondylolisthesis. There were sclerotic changes at both endplates and it looked like he had some minimal bone formation anteriorly as if he were trying to go not to an auto fuse. There was an air vacuum phenomenon in the disc. Dr. recommended a caudal epidural steroid injection.

On 10/07/04, Dr. instructed the claimant to follow up with Dr. for his long term care. On 02/08/05, Dr. began to treat the claimant for his chronic back and lower extremity pain with medications. The claimant underwent a 02/09/05 right psoas compartment plexus block at L3 and L4 and myoneural injections. The claimant reported significant pain to Dr. on 03/09/05. X-rays of the lumbar spine were recommended. The 03/10/05 lumbar spine x-rays showed post surgical changes at L4-S1, moderate severe degenerative changes at L3-4 and grade 1 anterolisthesis L3 on L4. The 05/05/05 lumbar spine x-rays showed essentially the same findings as the previous x-rays.

The claimant began treating with Dr. of pain management on 05/18/05. The claimant reported low back pain and bilateral lower extremity pain. Exam findings revealed pain with flexion and extension of the lumbar spine, strength of 5/5, left patella reflex was 2+ and the right was 1+. Right straight leg raise was slightly positive at 40 degrees. There were complaints of myofascial tenderness at the quadratus lumborum, gluteus maximus and gluteus medius. A positive psoas maneuver was noted. A right and left psoas compartment block was recommended by was denied by the insurance carrier.

Trigger point injections were performed on 09/07/05. A follow up visit with Dr. on 09/13/05 noted no significant long term relief. The claimant reported problems with depression. Exam findings revealed area of trigger point tenderness. Ultram and a left psoas block with trigger point injections were recommended. On 02/19/06, the claimant underwent replacement of the spinal cord stimulator battery. On 06/01/06, the claimant underwent a right psoas compartment block with Botox chemodenervation at L3 and L4.

Dr. saw the claimant for persistent low back pain on 08/01/06. The spinal cord stimulator was reprogrammed. On 04/19/07, Dr. saw the claimant. Exam findings revealed trigger point areas to the lumbar spine and limited range of motion of the lumbar spine secondary to pain. The Botox injections were denied on 04/25/07 and on 05/09/07. Dr. requested reconsideration on 05/20/07. Dr. documented that the use of the Botox chemodenervation was used in an effort to provide relief of myofascial spasm.

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

Botox is a toxin derived from the bacterium clostridium botulism whose mechanism of action is to block neuromuscular function with inhibition of acetylcholine release from the nerve terminals without causing death of the neurons. The neurons can, therefore, produce a new synapse at the neuromuscular junction within months. Botox A is marketed as Botox and Botox B is marketed as Myobock in the United States. Botox is usually kept frozen then reconstituted with saline and requires usage within a couple hours. It has been studied and used in multiple treatment protocols and there are numerous papers describing its results. The effects appear to last from weeks to months and there does not appear to be permanent loss of function with the usual non-toxic dosage. Botox has been approved by the FDA for a number of different conditions and has been described in the literature as being used for the treatment of spastic

muscle disorders, congenital defects, headaches, chronic neck and back pain, strabismus and other eye disorders, generalized post-stroke muscle spasticity, treatment of movement disorders and eating disorders. Numerous studies reveal either neutral or positive effects for the use of Botox with minimal side effects. Botox is not recommended as medically necessary for treatment of the diagnoses of chronic back or myofascial pain. This claimant has failed back syndrome with primarily myofascial complaints. Therefore, the eight outpatient Botox chemodenervation injections to the quadratus lumborum and gluteus maximum is not recommended as medically necessary.

2007 Official Disability Guidelines, 12 edition, Integrated with Treatment Guidelines (ODG Treatment in Workers Comp, 5th edition). Low back lumbar and thoracic, Botulinum toxin (Botox)

Not recommended. Paravertebral administration of botulinum toxin A in patients with chronic low back pain may relieve pain and improve function. Initial data from small trials suggest that botulinum toxin is effective, alleviating back pain in selected patients. On the basis of these promising results, additional study in larger trials is warranted. If approved, the number of injections should be limited to one, followed by exercise. A number of studies have evaluated the effectiveness of botulinum toxin type A in the treatment of back and neck pain, and the manufacturer is planning on pursuing FDA approval of botulinum toxin for this indication, but there is currently insufficient scientific evidence of the effectiveness of botulinum toxin in the treatment of back pain.

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**
 - 2007 Official Disability Guidelines, 12 edition, Integrated with Treatment Guidelines (ODG Treatment in Workers Comp, 5th edition). Low back lumbar and thoracic, Botulinum toxin (Botox)
- 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)**