

US Resolutions Inc.

An Independent Review Organization

71 Court Street

Belfast, Maine 04915

Notice of Independent Review Decision

DATE OF REVIEW: AUGUST 11, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

64614 – DESTROY, NERVE, EXTREM MUSC; Botox Injection to the Lumbar Area

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 64614 – DESTROY, NERVE, EXTREM MUSC; Botox Injection to the Lumbar Area.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Peer reviews 07/09/08, 07/17/08

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

Employer's First report of Injury or Illness xx/xx/xx

Lumbar myelogram/CT scan 10/08/99

Dr. office notes 11/18/99, 11/29/99, 12/16/99, 01/20/00, 02/22/00, 03/23/00, 04/20/00, 05/18/00, 06/15/00, 07/13/00, 08/10/00, 09/07/00, 10/05/00, 11/02/00, 01/24/01, 04/25/01, 05/16/01, 08/08/01, 11/01/01, 11/19/01, 11/29/01, 01/24/02, 02/21/02, 05/15/02, 08/07/02, 10/01/02, 10/25/02, 11/27/02, 10/29/02, 11/27/02, 12/30/02, 02/12/03, 05/08/03, 07/23/03, 08/20/03, 09/24/03, 12/17/03, 01/14/04, 02/16/04, 05/10/04, 09/01/04, 12/29/04, 06/28/05, 10/06/05, 10/28/05, 11/28/05, 12/29/05,

01/18/06, 02/23/06, 03/23/06, 04/19/06, 05/18/06, 06/29/06, 07/19/06, 08/16/06,
10/05/06, 01/25/07, 05/30/07, 12/07/07, 01/09/08, 04/07/08, 06/30/08
Dr. medical report 12/09/99, 12/21/99, 04/17/00,
Dr. office note 12/23/99, 05/12/00, 01/25/01
Dr. medical report 05/30/00
Chest x-ray 01/18/00, 01/30/01, 02/07/01, 02/08/01, 02/09/01, 02/11/01, 02/12/01,
02/13/01, 02/17/01, 02/24/01, 07/03/03, 07/01/04, 07/06/04, 07/18/04
Dr. History and Physical 03/15/00
Dr. office notes 01/17/01, 05/24/01, 11/11/01, 12/11/01
Heart Center records 02/02/01
Dr. history and physical 02/05/01
Neurophysiologic monitoring report 02/05/01
X-ray lumbar spine 02/05/01, 05/24/01, 10/25/05
Operative report 02/05/01
Dr. consultation report 02/05/01
Dr. consultation report 02/05/01
Discharge summary 02/16/01
Venous Doppler report 02/19/01, 07/31/01, 10/02/01,
CT scan chest 02/19/01, 02/26/01, 07/06/04
Physician's statement of medical necessity 03/08/01
Angiography records 04/17/01
Functional Capacity Evaluation 11/13/01
Dr. procedure report 10/10/02, 06/17/03, 11/09/04, 09/07/06
Letter of medical necessity Dr. 10/18/02,
Dr. letter 11/12/02
Dr. letter 12/06/02, 07/08/04, 06/28/05
Records sleep disorder specialist 01/27/03, 02/27/03, 09/22/03
Dr. peer review 02/25/03
Dr. pulmonary consultation 05/20/04
Dr. office note 06/30/04
Dr. pulmonary consultation 07/01/04, 07/18/04
Bronchoscopy report 07/01/04
Dr. infectious disease consultation
Echocardiogram report 07/02/04, 07/18/04
Pathology report 07/08/04
Emergency room record 07/18/04
Dr. history and physical 07/18/04
Dr. consultation 07/18/04
Dr. consultation 07/18/04
Cardiac cath report 07/18/04
Dr. consultation 07/19/04
Dr. consultation 07/20/04
Dr. letter 11/01/04, 01/10/05,
Dr. letter 01/11/05, 03/29/05, 06/30/06
Dr. work status report 01/18/05, 03/15/05, 11/28/05
D.C. RME exam 02/21/05
Dr. evaluation 04/06/06

PATIENT CLINICAL HISTORY [SUMMARY]:

This xx year old male injured his low back on xx/xx/xx when he was lifting a pipe. On 02/05/01 Dr. performed an L4-5, L5-S1 laminectomy/fusion. The claimant continued to treat with Dr. for low back pain and spasms. He was treated with aquatic therapy and

medications. On 10/10/02 lumbar paravertebral trigger point injections were given with some benefit. It was felt the claimant would benefit from Botox injections to treat refractory myofascial pain and muscle spasm in the lumbar area. On 06/17/03 Botox injections of bilateral multifidus muscles and bilateral longissimus muscles from L3 to L5 were given. The diagnosis was lumbar dystonia and post laminectomy syndrome. The claimant had 60-65% improvement that lasted until May 2004 when he had increased lumbar spasms. Repeat injections were given on 11/09/04 with dramatic improvement in the spasms.

As of 12/29/04, there was no tenderness or myofascial pain. He was to wean down reliance on muscle relaxants and on Norco. Repeat Botox injections were recommended in December 2005 for increased back pain but were delayed to due cardiology problems and anticoagulation therapy. The injections were given on 09/07/06 and as of 01/25/07 were felt to be working well. The claimant had less spasm and was not taking muscle relaxers. He continued to take Elavil and around nine Norco a day. Muscle spasms were noted to be worsening at the 12/07/07 visit. Repeat Botox injection were recommended but denied on peer review.

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

The claimant is a xx-year-old with apparent chronic back pain. Date of injury was listed as xx/xx/xx. The claimant appears to have received trigger point injections and botulism toxin injections in the past. Records indicate that injections were most recently performed on 09/07/06 following the injection, minimal difference in pain was noted one month later. The claimant was then not evaluated for several months, at which time he still reported seven out of ten pain. The claimant reportedly has muscle spasm and hypertonicity diffusely over the lumbar spine and repeat botulism toxin injections have been requested.

Botulism toxin injections cannot be justified as medically necessary. The most recent injection showed no improvement at one month after the injections and Botox injections are not supported by ODG for reports of pain or lumbar muscle spasm. For these reasons the request cannot be justified based on the information provided and ODG criteria. The reviewer finds that medical necessity does not exist for 64614 – DESTROY, NERVE, EXTREM MUSC; Botox Injection to the Lumbar Area.

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates, Low Back: Botox Under study. 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. (Foster, 2001) (Difazio, 2002) (Lang, 2004) Group health insurers do not generally cover this treatment for back pain. (Aetna, 2005) (Blue Cross Blue Shield, 2005) Some additional new data suggests that it may be effective for low back pain. (Jabbari, 2006) (Ney, 2006) In a recent double-blind, randomized, placebo-controlled study, administration of botulinum toxin A into paraspinal muscles using a novel technique produced significant pain relief in 60% of patients with chronic, refractory low back pain. A similar yield of 53% was noted in another prospective, randomized, open-label study of 75 patients, with 14 months of follow-up. In this study, an early response predicted later responsiveness, with 91% of the responders continuing to respond to repeat injections. The technique of treatment for both studies included covering the whole length of the lumbar erector

spinae with one injection given at each lumbar level regardless of pain, tenderness, or trigger point location(s). The dose per injection site was 50 U (Botox), with the total dose per session not to exceed 500 U. (Jabbari, 2007) Interventional strategies, such as prolotherapy, botulinum toxin injections, radiofrequency denervation, and intradiskal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. (Chou, 2008)

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)