



Specialty Independent Review Organization

## Notice of Independent Review Decision

**DATE OF REVIEW:** 4/7/2008

**IRO CASE #:**

### **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

The item in dispute is the prospective medical necessity of one visit of Botox Chemodenervation injection with EMG Guidance.

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

The reviewer is a board certified physical medicine and rehabilitation physician with greater than 10 years of experience in this field.

### **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 agrees with the previous adverse determination regarding the prospective medical necessity of one visit of Botox Chemodenervation injection with EMG Guidance at the level of cervical spine. The reviewer disagrees with the previous adverse determination regarding the prospective medical necessity of one visit of Botox Chemodenervation injection with EMG Guidance at the lumbar level at multiple levels.

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties:  
MD and Utilization Review.

These records consist of the following (duplicate records are only listed from one source): : follow up examinations from 8/16/07 to 2/19/08, consult script by Dr. of 11/8/07 and work status report 9/20/07.

: denial letters undated by DO and MD, preauth request 2/25/08, letter by Dr. of 2/25/08 and appeal preauth request (undated).

We did not receive a copy of the ODG Guidelines from Carrier/URA; however, it was cited in the denial letters.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient was injured when at work. She has cervical and lumbar spine pain. Recent documentation by Dr. indicates that that patient has multiple trigger points (TrPs) in the quadratus lumborum, gluteal trapezeii, rhomboids, splenius capitus and cervicis, infraspinati, and levators. He proposes Botox chemodenervation via EMG guidance into the noted muscles. He documents that this was provided one year ago, and this resulted in diminished analgesic use and maintenance of her vocation.

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

Per ODG (13<sup>th</sup> Ed, 2008), administration of Botox/Botulinum Toxin for cervical spine pain (723.1) is “Not recommended for the following: headache; fibromyositis; chronic neck pain; myofascial pain syndrome; & trigger point injections.

Per the ODG (13<sup>th</sup> Ed, 2008), administration of Botox/Botulinum for lumbar spine pain (724.2) is “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. Group health insurers do not generally cover this treatment for back pain. Some additional new data suggests that it may be effective for low back pain. 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.

The updated version of the ODG 13<sup>th</sup> Ed. 2008 suggests that the Botox will be beneficial for management of lumbar spine based on Jabari's report in 2007. The evidence of administration via EMG guidance is neither supported nor disputed by the ODG. Therefore the Botox Chemodenervation injection with EMG Guidance at the level of cervical spine is not medically necessary. However, the Botox Chemodenervation injection with EMG Guidance at the lumbar level at multiple levels is medically necessary. The dose per injection site is not to exceed 50-U and the total dose is not to exceed 500U.

**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)