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Notice of Independent Medical Review Decision

Reviewer's Report

DATE OF REVIEW: March 18, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Eight (8) Botox injections (CPT 64614 x 8, 95874 x 8, J0585 x 100 units; 99144, 99145, A4550, A4649) with EMG guidance for needle localization (herein referred to as "Botox injections with EMG guidance")

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

M.D., Board Certified in Physical Medicine and Rehabilitation

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

[X] Upheld (Agree)

[ ] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

The requested service, eight (8) Botox injections with EMG guidance, is not medically necessary for treatment of this patient.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Request for a Review by an Independent Review Organization dated 2/25/11.

2. Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 2/28/11.
3. TDI Notice to IRO of Case Assignment dated 2/28/11.
4. Medical Records from Pain Institute dated 12/10/09, 11/9/10, 12/7/10 and 2/8/11.
5. Letter of Medical Necessity from Pain Institute dated 2/17/11.
6. Denial documentation.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who sustained a work-related injury to her lower back on xx/xx/xx, when she attempted to sit down on a stool and the stool came out from under her causing her to land on the ground. The patient is currently experiencing pain to the lower back and lower extremities. The provider indicates that the patient has been treated for this injury by his office since 1999. The provided noted that the patient is status post two lumbar surgeries. The patient had a spinal cord stimulator system implantation in 2000, which has managed her pain to the lower extremities. The provider also indicates that the patient has had occasional flare ups of pain which have been treated with Botox injections which tend to provide her with one to two years of relief and allows her to be much more functional and to take fewer medications. The provider indicates that on 11/9/10 and 12/7/10, the patient was experiencing an acute exacerbation with a return of pain and evidence of a slow guarded gait pattern, pain with range of motion of the lumbar spine in all directions, limited range of motion of the lumbar spine and some numbness and tingling and decreased sensation with light touch to the left lower extremity past the knee. On 2/8/11, the provider indicated that the patient has failed conservative treatments including medications, a home exercise and stretching program, and trigger point injections. The provider has requested authorization and coverage for eight Botox injections with EMG guidance for treatment of the patient's continued low back and low extremity pain. The URA has denied this request. Specifically, the URA states that the Official Disability Guidelines (ODG) does not recommend the use of Botox injections for low back pain, as this treatment remains under study. The URA additionally states the records indicate that Botox injections were requested approximately every six months for several years, and there is little evidence of significant functional gains documented for the patient.

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

The requested Botox injections are not medically necessary for treatment of this patient's medical condition. Review of the ODG demonstrates that the use of Botox injections is not supported in this situation. According to the ODG, the use of Botox injections for back pain has not been approved by the Food and Drug Administration. The scientific evidence of the effectiveness of Botox injections for treatment of back pain/lower extremity pain is considered insufficient at this time. Specifically, ODG states, "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." In addition, ODG states, "Interventional strategies such as

botulinum toxin injections are not supported by convincing, consistent evidence of benefit from randomized trials (Chou, 2008)." All told, there is inadequate scientific data demonstrating that Botox is a medically necessary modality for the treatment of back/lower extremity pain. Therefore, the denial of Botox should be upheld.

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

[X] 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)