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Notice of Independent Medical Review Decision

Reviewer's Report

DATE OF REVIEW: April 10, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Botox injections 200 units to the bilateral corrugators, procerus, frontalis, temporalis, occipitals, cervical paraspinals, and trapezius, as an outpatient.

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:

- Upheld (Agree)
- Overturned (Disagree)**
- Partially Overturned (Agree in part/Disagree in part)

I have determined that the requested Botox injections 200 units to the bilateral corrugators, procerus, frontalis, temporalis, occipitals, cervical paraspinals, and trapezius, as an outpatient, are medically necessary for the treatment of this patient.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Request for a Review by an Independent Review Organization dated 3/19/13.
2. Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 3/20/13.
3. Notice of Assignment of Independent Review Organization dated 3/21/13.
4. Denial documentation.

5. Letter dated 1/17/13.
6. Medical records dated 9/04/12, 12/04/12 and 1/15/13.
7. Medical records dated 7/17/12.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who has a history of chronic pain and neuralgia beginning on xx/xx/xx after she was hit in the head by an elevator door. Per the submitted medical records, she has developed severe headaches which are described as migraine headaches. The patient has received Botox injections, with good relief of her pain. The documentation indicates that oral medications have not provided symptom relief. The patient has requested coverage for Botox injections 200 units to the bilateral corrugators, procerus, frontalis, temporalis, occipitals, cervical paraspinals, and trapezius, as an outpatient.

The URA indicated that the patient does not meet Official Disability Guidelines (ODG) criteria for the requested services. Specifically, the URA's initial denial indicated that Botox is not indicated for the patient's medical condition, as there is no indication of cervical dystonia or spasmodic torticollis. On appeal, the URA indicated that despite prior injections, there was no specific improvement of functional gain or decreased use of opioid medication. The URA noted that the peer-reviewed guidelines indicate Botox injections are not recommended for chronic pain disorder but are recommended for cervical dystonia.

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

The medical records from the provider document the diagnosis of chronic migraine. The Official Disability Guidelines (ODG) note that Botox injections are under study for prevention of headache in patients with chronic migraine. ODG cites studies with mixed results. However, the US Food and Drug Administration has approved Botox for prophylaxis of chronic migraine. Additionally, studies by Aurora, et al. and Dodick, et al. demonstrate there is significant peer-reviewed evidence in support of the use of onabotulinum toxin for the treatment of migraine headaches. As such, the current medical literature supports the medical necessity of the requested Botox injections to the bilateral corrugators, procerus, frontalis, temporalis, occipitals, cervical paraspinals, and trapezius. This patient has failed to respond to oral medications, and the requested Botox injections are a reasonable alternative in this clinical setting.

Therefore, I have determined the requested Botox injections 200 units to the bilateral corrugators, procerus, frontalis, temporalis, occipitals, cervical paraspinals, and trapezius, as an outpatient, are medically necessary for treatment of the patient's medical condition.

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 JUDGMENT, 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)**
 1. Aurora, S., et al. OnabotulinumtoxinA for treatment of chronic migraine: Pooled analyses of the 56-week PREEMPT clinical program. *Headache*, 2011 Oct;51(9):1358-73.
 2. Dodick, D., et al. OnabotulinumtoxinA for treatment of chronic migraine: Pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. *Headache*, 2010 Jun;50(6):921-36.
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**