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Notice of Independent Review Decision

[Date notice sent to all parties]:

09/27/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Chemodenervation botox of gluteus medius muscle (64612 J0585)

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)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Designated doctor evaluation dated 02/19/13
Clinical report dated 01/08/13
Clinical report dated 05/06/13
Letter of medical necessity dated 05/10/13
Clinical report dated 05/13/13
MRI of the pelvis dated 05/14/13
MRI of the lumbar spine dated 05/17/13
Clinical report dated 06/03/13
Clinical report dated 06/24/13
Clinical report dated 07/02/13
Prior reviews dated 07/12/13 & 07/29/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who sustained an injury on xx/xx/xx when she was involved in a motor vehicle accident. The patient sustained lacerations and contusions in the forehead as well as chest contusions and contusions to the left upper extremity. The patient reported ongoing constant headaches as well as hip and gluteal musculature pain. The patient is noted to have undergone prior PRP injections and received physical therapy including aquatic therapy with no significant changes in her pain complaints. The designated doctor evaluation from 02/19/13 did show some tenderness in the right gluteal musculature with midline tenderness to palpation in the sacral region. There was also tenderness of the right trochanteric region. No findings for sacroiliac joint dysfunction were noted. The patient was not felt to have been at maximum medical improvement for the mid back and the patient was recommended to have additional injections performed at the gluteal medial area to avoid any surgical intervention. clinical report from 01/08/13 indicated the patient had no improvement with additional PRP injections. The patient was noted to be utilizing a Fentanyl patch for chronic pain as of May of 2013. The patient continued to report an exacerbation of right gluteal pain with driving. recommended possible Botox injections on 05/13/13. MRI studies of the pelvis completed on 05/14/13 showed improvement in the insertional tendinopathy at the right gluteal medius and minimus. The findings do appear to be symmetric to the left hip. Follow up on 06/24/13 indicated the patient did have increased amounts of pain in the gluteal region with a lower dose of Fentanyl. The patient was compliant with dry land and aquatic therapy in regards to her low back pain. Physical examination at this visit demonstrated significant tenderness to palpation over the gluteal regions, right worse than left as well as the posterior lateral hip area. The patient was again referred for potential Botox injections. The patient was seen on 07/03/13 with ongoing complaints of pain in the right buttock area that was rated as severe. Physical examination showed significant tenderness to palpation at the right hip area. Negative signs for sacroiliac joint dysfunction were noted. The patient was recommended for Botox injections at the right gluteus medius muscle.

This request was denied by utilization review on 07/12/13. Per the analysis, Botox was an unproven treatment for long term pain relief and guidelines did not support its use for the requested gluteus medius muscle.

The request was again denied by utilization review on 07/29/13 as it was unclear what prior treatment was provided for the gluteus medius tendinopathy and Botox injections were unproven as an alternative for long term pain relief or improvement in function.

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

Based on review of the documentation submitted, the patient has had ongoing chronic pain in the gluteus medius and minimus areas to the right. The patient

reported no benefits from prior PRP injections. Other than PRP injections and therapy which appears to have been performed for the mid back area, there was no other documentation regarding treatment for the patient's gluteus medius and minimus pain. Of note, MRI studies of the pelvis showed resolution of the tendinopathy at the gluteus medius and minimus muscles and essentially showed normal findings. Given the resolution of the tendinopathy on imaging, the patient's pain is of unknown etiology per the reports. Therefore, based on clinical literature findings, it is unclear what if any benefit the patient would reasonably have with Botox injections at this point in time. As such, it is this reviewer's opinion that the use of Botox in this case would be investigational and unfounded.

IRO REVIEWER REPORT TEMPLATE -WC

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines, Online Version, Pain Chapter

Botulinum toxin (Botox®; Myobloc®)

Not generally recommended for chronic pain disorders, but recommended for cervical dystonia. See more details below.

Not recommended for the following: tension-type headache; fibromyositis; chronic neck pain; myofascial pain syndrome; & trigger point injections.

Several recent studies have found no statistical support for the use of Botulinum toxin A (BTX-A) for any of the following (note, most reference links go to [Neck Chapter](#)):

- Myofascial analgesic pain relief as compared to saline. ([Qerama, 2006](#))
- Use as a specific treatment for myofascial cervical pain as compared to saline. ([Ojala, 2006](#)) ([Ferrante, 2005](#)) ([Wheeler, 1998](#))
- Injection in myofascial trigger points as compared to dry needling or local anesthetic injections. ([Kamanli, 2005](#)) ([Graboski, 2005](#)).

Recent systematic reviews have stated that current evidence does not support the use of BTX-A trigger point injections for myofascial pain. ([Ho, 2006](#)) Or for mechanical neck disease (as compared to saline). ([Peloso-Cochrane, 2006](#)) A recent study found statistical improvement with the use of BTX-A compared to saline. Study patients had at least 10 trigger points and no patient in the study was allowed to take an opioid in the 4 weeks prior to treatment. ([Gobel, 2006](#))

Recommended: cervical dystonia, a condition that is not generally related to workers' compensation injuries (also known as spasmodic torticollis), and is characterized as a movement disorder of the nuchal muscles, characterized by tremor or by tonic posturing of the head in a rotated, twisted, or abnormally flexed or extended position or some combination of these positions. When treated with BTX-B, high antigenicity limits long-term efficacy. Botulinum toxin A injections provide more objective and subjective benefit than trihexyphenidyl or

other anticholinergic drugs to patients with cervical dystonia. See the [Neck Chapter](#) for cervical dystonia references.

Recommended: urinary incontinence following spinal cord injury. Botox significantly reduced urinary incontinence and improved urodynamics and quality of life in spinal cord injury and multiple sclerosis patients with neurogenic detrusor overactivity. ([Cruz, 2011](#)) Botulinum toxin is well tolerated and provides clinically beneficial improvement for urinary incontinence and neurogenic detrusor overactivity secondary to spinal cord injury or multiple sclerosis. ([Herschorn, 2011](#)) There are other potential roles in spinal cord injury with spasticity. ([Marciniak, 2008](#))

Recommended: spasticity following TBI. See the [Head Chapter](#).

Under study: chronic low back pain, if a favorable initial response predicts subsequent responsiveness, as an option in conjunction with a functional restoration program. Some additional new data suggests that it may be effective for low back pain. ([Jabbari, 2006](#)) ([Ney, 2006](#)) Botulinum neurotoxin may be considered for low back pain (Level C). ([Naumann, 2008](#)) See also the [Low Back Chapter](#).

Under study: migraine headache. The evidence is mixed for migraine headaches. This RCT found that both botulinum toxin type A (BoNTA) and divalproex sodium (DVPX) significantly reduced disability associated with migraine, and BoNTA had a favorable tolerability profile compared with DVPX. ([Blumenfeld, 2008](#)) In this RCT of episodic migraine patients, low-dose injections of BoNTA into the frontal, temporal, and/or glabellar muscle regions were not more effective than placebo. ([Saper, 2007](#)) Botulinum neurotoxin is probably ineffective in episodic migraine and chronic tension-type headache (Level B). ([Naumann, 2008](#)) The FDA approved Botox injection (onabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine. Chronic migraine is defined as having a history of migraine and experiencing a headache on most days of the month. ([FDA, 2010](#)) It is recommended as a second line therapy (since other acute therapies should have been attempted).