

<b>Case Number:</b>	CM15-0028288		
<b>Date Assigned:</b>	02/20/2015	<b>Date of Injury:</b>	01/22/1998
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	02/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/16/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: District of Columbia, Virginia  
 Certification(s)/Specialty: Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 60-year-old female, who sustained an industrial injury reported on 1/22/1998. She reported severe, and mostly, daily migraine headaches. The diagnoses were noted to have included closed head injury resulting in multi-level cervical degenerative disc disease, chronic and intractable migraine headaches, without aura, left shoulder partial thickness rotator cuff tear and status-post arthroscopic decompression (2005); and revision in 2006; opioid type dependence continuous use; cervicgia; myofascial pain syndrome; and shoulder joint pain . Treatments to date have included consultations; diagnostic laboratory and imaging studies; a Botox injection 200 units (2/19/14); dietary management; and medication management. The work status classification for this injured worker (IW) was noted to be permanently partially disabled - psychiatric. The attending physician's PR-2, dated 11/7/2014, notes the IW being bed-bound with migraines x several days, and that she ended up in the Emergency Department with fevers; rule out serotonin syndrome after increasing Mg Salt and Sumatriptan in combination of Cymbalta. Complicating matters were a urinary tract infection and hypokalemia with abdominal pain and insomnia. The pain management re-evaluation notes for 12/14/2014 stated a migraine headache x 2 days, and that the IW had to go to the Emergency Department for migraines, on 10/24/2014. The 12/15/2014 Neurological office visit migraine notes state numerous meds without relief, Botox x 7 cycles in pas was very beneficial, and still with migraine headaches 5/7 days, on added Elavil. The 12/30/2014 letter of medical necessity for Botox injection therapy to treat chronic migraine headaches, stated that a failed, prior course of management with muscle relaxants, anti-depressants, and anti-seizure medications, and was clearly not cost-effective.

Also, that that she has had Botox treatment, some time ago, and continuation of this therapy is advised and is being requested per the Medical Treatment Utilization Schedule Guidelines. This letter states for at least 3 injections at 12 week intervals, to the frontal, temporal and cervical and occipital areas, since she has proven to be intractable to traditional therapy. Also noted is the appeal that this is clearly medically necessary, meets Medical Treatment Utilization Schedule. Some patients require 3 sets of injections to determine their degree of response; and that the physician's treatment protocols will be clearly documented, and will document her response to BOTOX, should this therapy cease to produce adequate outcomes, and he will discontinue the neurotoxin injections. The pain management re-evaluation notes, dated 1/7/2015, note that the constant and severe headaches, and all pain is constant, causes numbness, tingling and heaviness in the left arm, is made worse with prolonged movement and is made better with rest and medications. The Neurological progress notes, dated 1/13/2015, note that worker's comp. has denied her migraine medication refills. The treatment plan included: re-submit for authorization for Botox 200 units with worker's compensation, and follow-up in 6 weeks or sooner if Botox is approved. The pain management re-evaluation notes for 2/3/2015, state a > 80% decrease in headache pain, increases her function, with her medication regimen, affording her the ability to drive and take care for her grandchildren, and has had fewer headaches. The attending physician's PR-2 notes frustration that she cannot access her migraine medications and has been suffering more. The 2/25/2015 Neurological progress notes a history of Botox, x 7 cycles, in the past was very beneficial. On 2/3/2015, Utilization Review (UR) non-certified, for medical necessity, the request, made on 1/28/2015, for 4 units of Botox 400 units, J0585x4,64615, to help with severe migraine headache pain. The Medical Treatment Utilization Schedule, chronic pain medical treatment guidelines, Botulinum toxin (Botox: Myobloc), was cited. The UR stated that the IW's response to the 2/19/2014 Botox injection, for migraine headaches, was not specified in the documentation.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Botox, 400 units:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Botulinum Toxin Section.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 25-26.

**Decision rationale:** Per MTUS: 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; migraine 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 (BTXA) for any of the following: 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). 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 that has 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 an injection provide more objective and subjective benefit than trihexyphenidyl or other anticholinergic drugs to patients with cervical dystonia. Recommended: 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) Per guidelines cited, this intervention would not be indicated for migraine headache.