MAXIMUS Federal Services

Case Number:	CM14-0192489		
Date Assigned:	11/26/2014	Date of Injury:	04/19/2013
Decision Date:	01/14/2015	UR Denial Date:	11/17/2014
Priority:	Standard	Application Received:	11/18/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

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

This 38-year old school psychologist reported a head injury after a student threw a rock or rocks at her on 4/19/13. She was struck in the head but did not lose consciousness. She apparently reported subsequent injuries due to falling because of the dizziness caused by her head injury. Current diagnoses include concussion, post concussive syndrome, retrograde amnesia, Wernicke's aphasia, headache, knee contusion, vertigo, sensory problems with limbs, contusion of upper limb, left leg spasticity versus contracture, and insomnia. Past medical history is notable for asthma, marked obesity, high blood pressure, ADHD and hyperthyroidism. Treatment has included medications, physical therapy, occupational therapy and speech therapy. She has been restricted to sedentary work and has remained at work with some difficulty since the injury. An urgent care physician follows her on a weekly basis. Her exams document speech slowing and gait difficulties, with spasm of the left calf. She documents that the patient is taking multiple medications including baclofen and dantrolene, which are presumably being prescribed for spasm. A physiatrist also follows this patient. On 5/30/14 he documents her gait as left antalgic with plantar flexion contracture of the left ankle, hip hike and spastic gait with hyperextension of the left leg. He documents that the patient is unwilling to try Botox injections and recommends that she increase her dantrolene. Findings are essentially unchanged on 7/31/14. The patient remains unwilling to try Botox injections, and the physiatrist recommends that she increase her Depakote dose. On 10/31/14 the physiatrist reports that the patient continues to have difficulty with speech and walking. Her left calf is still tight. Exam findings include a left antalgic gain with plantar flexion contracture of the left ankle and hip hike. The modified Ashworth scale of spasticity is 2+ in the quads and gastrocs. The physiatrist documents that he watched a video of the patient waking, and that she circumducts the left leg and has plantar flexion and decreased knee flexion. The physiatrist states that the patient is now willing

to undergo Botox injections, and requests authorization to inject 50 units of Botox into the quads, 25 units to the VMO, 50 units to the gastrocs and 25 units to the soleus (total of 150 units). A request for authorization for Botox injection 200 units for "spasms of muscle" was generated the same day (10/31/14). This request was denied in UR on 11/17/14 on the basis that there was no information about where the Botox was to be injected, and that MTUS does not support the use of Botox for trigger point injections, headaches, or other chronic pain disorders besides cervical dystonia. Note that the reviewing physician does not appear to have had access to the physiatrist's 10/31/14 progress note.

IMR ISSUES, DECISIONS AND RATIONALES

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

Botox 200 units, per 10/31/14 form quantity 1.00: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Botulinum toxin (Botox; myobloc) Page(s): 25-26.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Botulinum toxin (Botox; Myobloc) Page(s): 25-26. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for practitioners, (www.uptodate.com), OnabotulinumA (botulinum toxin type A, Botox): Drug information; and Symptom management of multiple sclerosis in adults

Decision rationale: The MTUS reference cited above states that Botox injections are not recommended for tension-type headaches, migraine headaches, fibromyositis, chronic neck pain, myofascial pain syndrome, or for trigger point injections, because performance of these injections is not supported by the evidence. Botox injections are recommended for cervical dystonia, which is usually not work-related, and for chronic low back pain in conjunction with a functional restoration program, if a favorable initial response predicts subsequent responsiveness. The UptoDate references state that Botox is indicated for focal spasticity. In clinical trials used to support the FDA-approved labeling, total doses of up to 360 units Botox were administered as separate injections typically divided among selected muscles. Safety and efficacy of doses over 500 units has not been evaluated. All of the studies used to support the FDA-approved labeling involved the upper limbs. However single site doses of less than or equal to 400 units in a lower limb have been reported. The UptoDate Multiple Sclerosis reference states that limb spasticity occurs in patients with MS and is usually more severe in the lower limbs. First line drugs for spasticity include baclofen, tizanidine or dantrolene. An evidence-based review published by the American Academy of Neurology in 2008 concluded that botulinum toxin is effective for reducing muscle tone and improving passive range of motion in adults with arm and leg spasticity, and that it is probably effective for improving active limb function.The clinical documentation in this case supports the administration of Botox injections to this patient. Gait difficulty, calf spasm and ankle contracture are reported throughout the notes by both of her physicians despite the use of both baclofen and dantrolene. A trial of Botox would therefore be indicated. The amount of Botox requested is not excessive, and the injections sites appear to be appropriate, although there is a discrepancy between the total amount of toxin requested and the sum of the amounts to be injected into various muscles. Since the total amount requested is still

well below the maximum used for the FDA labeling studies cited above, it is reasonable to allow the requesting physician to proceed with an injection trial, rather than delaying further because of the dose discrepancy. Based on the evidence-based citations above and on the clinical information provided for my review, Botox 200 units IS medically necessary because this patient appears to have genuine spasm and gait difficulties that have not responded to first line oral agents and which may respond to Botox injections.Again, please note: Although I am reversing the UR decision of 11/17/14, it appears that the UR physician did not have access to the requesting physician's 10/31/14 progress note, on which much of my decision to reverse the determination was based.