MAXIMUS Federal Services

Case Number:	CM14-0034116		
Date Assigned:	06/20/2014	Date of Injury:	06/02/1999
Decision Date:	07/18/2014	UR Denial Date:	02/28/2014
Priority:	Standard	Application Received:	03/18/2014

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 Internal Medicine and is licensed to practice in Arizona. 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 patients is a 46-year-old female with a diagnosis of Chronic Regional PainSyndrome (CRPS) involving both upper extremities. This patient's injury occurred in1999, when she hit her arm on the corner of a desk. She has had multiple surgeries and procedures which include right lateral epicondylectomy, neurolysis of the radial and posterior interosseous nerves, lengthening of the supinator tendon, carpal tunnel release, flexor tenosynovectomy, de Quervain's release, multiple cervical epidural sympathetic blocks and sub scapular nerve blocks. In 2004 she underwent a surgery for an Intrathecal Implant which delivers Baclofen, clonidine, and hydromorphone. This is supplemented with oral opiates. The patient did undergo a Spinal Cord Stimulator trial that gave her partial (35- 40%) relief.This patient additionally has chronic migraine, related to her CRPS. The patient has conveyed that she can have 3-5 headaches a week; and that some of these headaches persist 3-5 days at a time. Elsewhere, it was noted that she has more than 16 headaches a month that last more than four hours at a time. The medications that have been tried are Imipramine, Topamax and Gabapentin, Imitrex and Frova. These did not help sufficiently or were not tolerated. Recently, she did undergo a trial of Botox 100 Units at the seven areas as instructed by the manufacturer of Botox. An in-office ultrasound was used by the physician to help locate the trapezius muscles. The patient reported a dramatic response from the Botox, but claimed the headaches had started to return at about two months after the procedure.

IMR ISSUES, DECISIONS AND RATIONALES

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

Botox Injection 200 Units: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 26. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Procedure Summary, Pain, Summary of Medical Evidence, Botox; Other Medical Treatment Guideline or Medical Evidence: UpToDate, Chronic Migraine, Ivan Garza, MD & Todd J. Schwedt, MD; www.allergan.com/assets/pdf/botox_pi.pdf. pages 1, 6, 7.

Decision rationale: The MTUS references two papers from 2007 and 2008 stating Botox is probably ineffective in episodic migraine and chronic tension-type headaches. The MTUS does not address chronic migraine nor does it reference any more current studies. The ODG, however, indicates that the FDA approved Botox to prevent headaches in adult patients with chronic migraine. It cited the FDA, 2010 and indicated Botox should be used as a second line therapy. The manufacturer of Botox, Allergan, has updated the recommendations as of February 2014. It defines chronic migraine as a frequency of headaches equal to or greater than 15 days per month with the headaches lasting four hours a day or longer. This patient exceeds this minimum criterion. UpToDate gives further detail on the management of Chronic Migraine with Botox. Because of the expense, it views Botox as a second line of treatment. It is suggested that a trial of one of the first-line prophylactic medications (Topamax, Amitriptyline or in men- Valproic Acid) be used prior to trying a second line. This patient did not benefit from the Topamax. Alternative or second line agents include Botox, verapamil, other beta blockers, gabapentin, and other tricyclic antidepressants. This patient was tried on the less expensive (relative to Botox) treatments with Imipramine and gabapentin with ineffective benefit and/or intolerable side effects. Then the Botox was tried and the patient reported "dramatic" benefit, but with a return of symptoms at two months. There are two remaining issues. 1) Should 200 Units be approved?Allergan's instruction for chronic migraines is to use a dose of 155 Units, to be injected at 7 specific head/neck muscle areas. There are three different sized vials containing 50, 100 and 200 Units each. To obtain 155 Units, a 200 Unit vial would be mixed up thus it makes sense that this authorization request is for 200 Units of Botox. 2) Is Ultrasound necessary? Most clinicians who are knowledgeable in giving Botox for migraine management inject the medication directly into the muscle using palpation alone. The manufacturer, however, has suggested that localization of the involved muscles with electromyographic (EMG) guidance may be useful. Using EMG would generally mean getting the assistance of someone specifically trained in EMG, such as a neurologist. One could argue this could mean utilizing more resources. I would propose that the manufacturer's intent in mentioning EMG was to ensure that the proper muscles be injected. If the doctor is not readily able to sort out the proper muscles with palpation, then another means of doing this could be to use an in-office ultrasound. This patient's managing physician is an anesthesiologist who is not likely trained in EMG. He does, however, have access to an in-office ultrasound which he did use for the localization of the trapezius muscles. It is for these reasons that Botox 200 units with ultrasound, is found to be medically necessary.