mcmc
managing care. managing claims.
88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

Notice of Independent Review Decision

DATE OF REVIEW:
10/04/2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Botox Injections

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Doctor of Osteopathy, Boarded in Anesthesiology, and Specializing in Pain Management.

REVIEW OUTCOME
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.
Botox is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
- MCMC: Case Report dated 09/25/07
- MCMC Referral dated 09/25/07
- DWC: Notice To MCMC, LLC of Case Assignment dated 09/25/07 from
- DWC: Notice To Utilization Review Agent of Assignment dated 09/25/07 from
- DWC: Confirmation of Receipt of a Request For a Review dated 09/21/07
- LHL009: Request For a Review By An Independent Review Organization dated 09/17/07
- Letters dated 09/04/07, 08/24/07
- RN: Office notes dated 08/29/07, 08/17/06
- Note from claimant (handwritten) dated 08/28/07
- Family Practice: Precert forms dated 08/28/07, 08/15/06, 05/02/06
- D.O.: Handwritten notes dated 08/28/07, 08/14/06, 05/01/06
- Dr.: Patient Questionnaire dated 08/28/07
- Notification of Appeal Outcome dated 08/22/06
- D.O.: Letter dated 08/14/06
- Lab report dated 08/07/06
- Letter dated 08/04/06 from, M.D.
- Undated article entitled, “Procedures for Administering Botulinum Toxin Type A for Migraine and Tension-type Headache”
- Undated article entitled, “Find an Osteopathic Physician”
- Official Disability Guidelines not included from the carrier.

88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

PATIENT CLINICAL HISTORY [SUMMARY]:
The injured individual is a male with chronic neck or shoulder pain and headache. The injured individual received Botox in the past with relief of his headache but it was short lived. The injured individual has a diagnosis of cervical radiculopathy also.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.
This injured individual has neck and shoulder pain and headache. He received Botox in xx/xx/xx, which reportedly helped his headache. He also has myofascial pain and cervical radiculopathy. Botox is not FDA approved for the treatment of these diagnoses nor is it proven effective per the literature. It has a palliative, short-term benefit at most as well. Therefore, it is not medically necessary in this situation.

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

- **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
  Botox for low back pain: Not recommended. Paravertebral administration of botulinum toxin A in patients with chronic low back pain may relieve pain and improve function. Initial data from small trials suggest that botulinum toxin is effective, alleviating back pain in selected patients. On the basis of these promising results, additional study in larger trials is warranted. If approved, the number of injections should be limited to one, followed by exercise. (Foster, 2001) (Difazio, 2002) (Lang, 2004) A number of studies have evaluated the effectiveness of botulinum toxin type A in the treatment of back and neck pain, and the manufacturer is planning on pursuing FDA approval of botulinum toxin for this indication, but there is currently insufficient scientific evidence of the effectiveness of botulinum toxin in the treatment of back pain. (Aetna, 2005)? (Blue Cross Blue Shield, 2005)

  Botox for neck pain: Recommended for cervical dystonia, but not recommended for mechanical neck disorders, including whiplash. See more details below.
  Not recommended for the following: 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 the treatment of cervical or upper back pain, including the following:
  - 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) There is one 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 taking an opioid. (Gobel, 2006) Botulinum toxin A (e.g., Botox) remains under study for treatment of chronic whiplash associated disorders and no

88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

statistical difference has been found when compared to treatment with placebo at this time. (Freund, 2000) (Aetna, 2005) (Blue Cross Blue Shield, 2005) (Juan, 2004)
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. In recent years, botulinum toxin type A has become first line therapy for cervical dystonia. 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. (Costa-*Cochrane*, 2005) (Costa2-*Cochrane*, 2005) (Costa3-*Cochrane*, 2005) (Jankovic, 2006) (Lew, 1997) (Trosch, 2001) (Balash, 2004) (Sycha, 2004) .

PER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

- Neurology 2006 Jul;67(2):241-5 Qerama E. This reference concluded: "The results (of their double blind, randomized, placebo controlled, parallel clinical trial on Botox) do not support a specific antinociceptive and analgesic effect of botox A."

- Clin J Pain 2006 Jan;22(1):90-6 Ojala T. This states in their double blind, randomized, controlled crossover trial that: "there was no difference between the effect of botox A and physiologic saline in the treatment of myofascial pain."

- Pain 2005 Nov;118(1-2):170-5 Graboski CL. This double blind, randomized crossover trial stated: "there was no significant difference between the botox A group and the bupivicaine injectate group in duration or magnitude of pain relief, function, satisfaction."

- Anesthesiology 2005 Aug;103(2):377-83 Ferrante FM. This noted the injection of botox into trigger points did nothing to improve cervicothoracic myofascial pain.