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Notice of Independent Review Decision

DATE OF REVIEW: 09/03/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Botox Injection-Lumbar

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by a Texas licensed DO, specializing in Preventive Medicine/Occupational Medicine, Family Medicine. The physician advisor has the following additional qualifications, if applicable:

ABMS, AOA Family Medicine, Preventive Medicine: Occupational Medicine

REVIEW OUTCOME:

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overturned

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
Botox Injection-Lumbar	64614	-	Overturned

PATIENT CLINICAL HISTORY (SUMMARY):

The claimant was reportedly injured on xx/xx/xx. He reportedly experienced low back pain. Treatment has included injections of Botox. Following this, the progress notes indicated that the claimant had 70 to 75% relief of pain. It was reported that he received an injection on 04/17/08. The injection was now wearing off and he has had to decrease his working hours. It was reported that he hardly took any medications in the last 90-days until the Botox wore off. The treatment note of 07/28/08 indicated that the claimant had increased his work load to 25 hours a week, but had now decreased his hours to 14. He was reporting that Flexeril was not working any longer. A letter from the claimant dated 07/10/08, indicated that he went from

zero hours per week to 20 hours per week and was taking over-the-counter medications.

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

The treatment guideline (ODG) indicates that botulinum toxin for low back pain is under study. As such, the ODG does not give a recommendation or specific non-recommendation. The ODG does however reference the small studies that indicate that the studies have shown promising results. As a result, additional study in larger trials is warranted. It reports that a number of studies have evaluated the effectiveness in back and neck pain and the manufacturer is planning to pursue FDA approval of the botulinum toxin for this indication. It reports however that there is current insufficient evidence of the effectiveness in the treatment of back pain, but there has been approval in the neck. The ODG references studies that report yields of 60% experienced significant pain relief with chronic refractory low back pain. As such, we are faced with a situation where the requested treatment is not necessarily recommended. At this point there is still not enough clinical evidence to make a recommendation. However, this treatment has been tried on this individual and he reports significant results. It was stated that prior to the injection he was not working and he was now working up to 20-25 hours a week. It was reported that he had been able to decrease his medication use and according to the patient, was utilizing only over-the-counter medications. As such, it would appear that there is some objective evidence that for this individual the treatment has been beneficial. This would seem to be in line with the clinical studies referenced by the ODG. Viewing the fact that the ODG does reference clinical studies that have provided benefit, and it appears that the reservation in the ODG is because large studies have not been accomplished, I feel that in this particular case the treatment should be approved viewing the fact that there is evidence that this treatment is beneficial and most importantly for this individual, there has been evidence of benefit. I would consider return to work and decrease medication usage as sufficient evidence that the treatment is successful for this individual. As such, I would recommend overturning the carrier's denial of this treatment.

Under study. 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. 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. ([Foster, 2001](#)) ([Difazio, 2002](#)) ([Lang, 2004](#)) Group health insurers do not generally cover this treatment for back pain. ([Aetna, 2005](#)) ([Blue Cross Blue Shield, 2005](#)) Some additional new data suggests that it may be effective for low back pain. ([Jabbari, 2006](#)) ([Ney, 2006](#)) In a recent double-blind, randomized, placebo-controlled study, administration of botulinum toxin A into paraspinal muscles using a novel technique produced significant pain relief in 60% of patients with chronic, refractory low back pain. A similar yield of 53% was noted in another prospective, randomized, open-label study of 75 patients, with 14 months of follow-up. In this study, an early response predicted later responsiveness, with 91% of the responders continuing to respond to repeat injections. The technique of treatment for both studies included covering the whole length of the lumbar erector spinae with one injection given at each lumbar level regardless of pain, tenderness, or trigger point location(s). The dose per injection site was 50 U (Botox), with the total dose per session not to exceed 500 U. ([Jabbari, 2007](#)) Interventional strategies, such as prolotherapy, botulinum toxin injections, radiofrequency denervation, and intradiskal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. ([Chou, 2008](#))

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