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Notice of Independent Review Decision

DATE OF REVIEW: 07-21-08

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Botox injections for back pain

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o October 4, 2007 Office Note from Dr.
- o June 19, 2008 – April 24, 2008 Eight Follow-up reports from Dr.
- o February 31, 2008 Response to Letter of Clarification from Designated Doctor
- o May 22, 2008 Consultation report from Dr.
- o May 26, 2008 Referral form for Botox injections from Dr.
- o May 30, 2008 Letter of non-certification for Botox injections
- o June 23, 2008 Letter of non-certification for reconsideration for Botox injections
- o July 8, 2008 Request for IRO
- o July 19, 2008 Information and Consent form for Botox injection signed by the claimant

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records provided for my review, the patient is a xx-year-old male who sustained an industrial injury to the low back on xx/xx/xx. The patient's medical history includes a laminectomy/decompression in December of 2003 and a 360 degree fusion at a later unspecified date. The patient has been followed with pain management for failed back syndrome and chronic pain.

On October 4, 2007, the provider responds to a reviewer's opinions that treatment should be discontinued and medications weaned as the patient has merely a strain injury not related to prior surgeries. The provider notes that at the time of his initial surgery in 2003 the patient had conjoined nerves and since the surgery has had increased leg symptoms. The patient may have gotten irritation of nerve roots from the hardware or he got overstretching of the nerve roots from the fusion. The patient has improved to the extent that he no longer uses a cane and is able to mow his lawn. Per functional testing, he has increased his functioning level and ADLs. In addition, his pain level has been reduced from 8-9/10 to 6/10. He has had recent Botox injections which have been helpful as well. It was recommended by the reviewer for the patient to wean medications of Duragesic, Fentora and Norco and the provider concurs that a slow tapering is reasonable.

Per follow-up notes of the provider, in November of 2007 the patient was provided MS Contin for pain as he was weaning off medications that were no longer approved. The patient reacted to the morphine and was provided treatment in a hospital for renal failure, generalized cardiovascular collapse and narcotic withdrawal. Over the following months, the provider's follow-up notes indicate that various medications were attempted for sleep, pain, depression and leg symptoms.

On May 22, 2008 the claimant was provided a consultation for an episode of cognitive dysfunction in November of 2007 related to an ischemic event related to a reaction from morphine (MS Contin) provided when his regular medications were denied. It is reported that following the patient's initial surgery there was found to be a controlling nerve under the disc protrusion and a second surgery with hardware was performed to fuse the back posteriorly. The pedicle screw was subsequently found to impinge on the nerve and damaging it. The current provider put in a spinal cord stimulator which provided some relief but his chronic pain continues. Medications of Duragesic patch and Fentora were discontinued (weaned) per carrier instructions. The patient reacted to morphine (MS Contin) provided to prevent withdrawal of medications being weaned and the patient reacted with generalized cardiovascular collapse and was attended to in a hospital. He ultimately was allowed the prior medications but never realized full cognitive function and was sent for the instant consultation. He has chronic headaches, elevated blood pressure and impairment of short-term memory. He is back to using a cane and reports some bladder problems. Testing revealed some cognitive dysfunction and short-term memory impairment. Recommendation was for neuropsych testing and head MRI.

On May 26, 2008 request was made for Botox injections for sciatica (CPT code 724.3). According to the information and consent form Botox or botulinum toxin A is a purified protein derivative made by the bacterium Clostridium botulinum that is FDA approved for use in treating eye twitching, lazy eye and cervical dystonia.

Request for Botox injections were not certified in review on May 30, 2008 with rationale that The Official Disability Guidelines do not support Botox as medically necessary as there is currently insufficient scientific evidence of the effectiveness of botulinum toxin in the treatment of back pain. The reviewer noted that there was mention in the records of Botox injection in 2007 with some benefit but the majority of the medical records pertained to the patient's medication management.

Request for reconsideration of Botox injections was not certified in review on June 23, 2008 with rationale that, although there are some anecdotal reports in the medical literature that Botox can help patients with chronic low back pain, there is no scientific evidence documenting the efficiency of Botox injections in patients with back pain. ODG for Texas indicates that additional studies and larger trials are warranted, and the use of Botox injections for back pain is, therefore, not medically reasonable or necessary.

On July 8, 2008 request was made for an IRO.

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

The medical records document a patient with chronic low back pain that is associated with prior surgeries that is treated with medications and an implanted spinal cord stimulator. Since an ischemic incident related to use of morphine while weaning opiate medications, the patient is also reported to have impairment of short-term memory, chronic headaches and elevated blood pressure.

Per an information and consent form for Botox injection submitted by the provider, Botox remains an unapproved ("off label") use for treatment of myofascial pain of the neck and back, chronic tension headaches and migraine headaches, by the FDA. It is noted that the provider has requested Botox for back pain which per the submitted medical records is described as nerve root pain not myofascial pain.

ODG states, Botox injections are not generally recommended for chronic pain disorders, but recommended for cervical dystonia, a condition that is not generally related to workers' compensation injuries. Botox is not recommended for the following: headache; fibromyositis; chronic neck pain; myofascial pain syndrome; & trigger point injections. Under study for chronic low back pain. Lacking support in the evidence based literature for Botox injections for back pain, a positive response can not be provided to the request. Therefore, my recommendation is to agree with the previous non-certification of the request for Botox injections.

The IRO's decision is consistent with the following guidelines:

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

____ ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

____ AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

____ DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

____ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

____ INTERQUAL CRITERIA

____ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

____ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

____ MILLIMAN CARE GUIDELINES

____X__ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

____PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

____ TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

____ TEXAS TACADA GUIDELINES

____ TMF SCREENING CRITERIA MANUAL

____ PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

____ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

The Official Disability Guidelines – Pain Chapter – Botulinum Injections – 7-14-08

Not generally recommended for chronic pain disorders, but recommended for cervical dystonia. See more details below. Not recommended for the following: headache; fibromyositis; chronic neck pain; myofascial pain syndrome; & trigger point injections. Under study for chronic low back pain. Several recent studies have found no statistical support for the use of Botulinum toxin A (BTX-A) for any of the following (note, most reference links go to Neck Chapter):

- 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) (W heeler, 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 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) And some additional new data also suggests that it may be effective for low back pain. (Jabbari, 2006) (Ney, 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 A injections provide more objective and subjective benefit than trihexyphenidyl or other anticholinergic drugs to patients with cervical dystonia. See the Neck Chapter for cervical dystonia references. See also the Low Back Chapter.

