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Notice of Independent Review Decision

DATE OF REVIEW: 6/6/12

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the retrospective medical necessity of 30 tablets of Topiramate 200 mg between 2/9/12 and 2/9/12.

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

The reviewer is a Medical Doctor who is board certified in Anesthesiology. The reviewer has been practicing for greater than 7 years.

REVIEW OUTCOME

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

- Upheld (Agree)
 Overturned (Disagree)
 Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the retrospective medical necessity of 30 tablets of Topiramate 200 mg between 2/9/12 and 2/9/12.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties: The patient, MD and.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from: 1/27/12 operative report, 2/9/12 EOR report, 12/12/11 history and physical report by Dr., 11/14/06 and 4/29/10 reports by MD, HICFA 1500 forms of various dates, 5/2/12 denial letter, 5/2/12 peer report, 4/22/12 letter by patient, 4/16/12 denial letter, 10/24/02 follow up consult, 11/2/10 report by MD, 5/24/06 diagnostic report, 6/2/06 report by Dr., 4/16/12 peer report

by Dr., form DWC066 dated 3/28/12 with W9, and ODG for review 119392 and 120627.

Patient: undated handwritten letter indicating summary of patient history, and prescription notes.

Dr.: 4/5/12 follow up notes.

A copy of the ODG was provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

This claimant is a female that was injured xx/xx/xx when she fell at work. Patient developed moderate low back pain radiating to the legs. She was diagnosed with herniated nucleus pulposus at L5-S1. Surgical intervention was not recommended for this patient. She was treated with oral medications, physical therapy and periodic ESIs with very good results. Spinal cord stimulator was implanted and then subsequently removed. Per medical report dated 12/12/2011, patient complained of weakness and numbness. On examination of the lumbar spine, patient has a mildly antalgic gait. Muscle spasms are noted. She has decreased flexion, extension, lateral flexion and rotation. She has tenderness of the facet joints on palpation. Left ankle jerk and knee jerk deep tendon reflexes are 1+. She has 4/5 muscle strength on left plantar flexor. She has positive straight leg test on the left at 40 degrees. Lumbar spine CT in 2004 demonstrated moderate compression of the sac at L4-L5, posterolateral herniations at T9-10, T10-11, T11-12 and degenerative facet disease from L1-2 to L3-4. Per medical reported dated 12/12/2011, the claimant's prescription medications at the time include Topamax and tramadol.

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

Official Disability Guidelines Treatment in Worker's Compensation, Online Edition Chapter: Pain: Topiramate (Topamax®) See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Topiramate listing. Anti-epilepsy drugs (AEDs) for pain. Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain).

There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy.

Specifically studied disease states: (also see below for specific drugs)
Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example).

The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine).

Chronic non-specific axial low back pain: A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. (Chou, 2007) There is one randomized controlled study that has investigated topiramate for chronic low back pain. This study specifically stated that there were no other studies to evaluate the use of this medication for this condition. Patients in this study were excluded if they were taking opioids. No patient had undergone back surgery. In terms of the Oswestry low back pain questionnaire scale, the differences in the placebo group and treatment group were significant, although the mean score in both groups remained ³ 34. Reduction in pain rating index appeared to be correlated with weight reduction.

See Topiramate below. The authors felt additional research was required to see if the results could be replicated and how long-lasting benefits were. There are no other articles available that evaluate the use of other anti-epilepsy drugs in the treatment of chronic non-specific, non-neuropathic axial low back pain. Topiramate (Topamax®, generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard.

Anti-epilepsy drugs (AEDs) for pain. Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. (Attal, 2006) The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin®); Pregabalin (Lyrica®); Lamotrigine (Lamictal®); Carbamazepine (Tegretol®); Oxcarbazepine (Trileptal®); Phenytoin (Dilantin®); Topiramate (Topamax®); Levetiracetam (Keppra®); Zonisamide (Zonegran®); & Tiagabine (Gabitril®)

SPECIFIC ANTI-EPILEPSY DRUGS:

Topiramate (Topamax®, generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard.

This is a retrospective request for topiramate 200mg for a patient with low back pain radiating to the lower extremities. The patient has had a long-standing history of low back pain that has been managed with a combination of oral drug therapy, physical therapy, epidural steroid injections and spinal cord stimulator

placement. The patient has also been on topiramate. ODG guidelines recommend topiramate for neuropathic pain, but not for acute nociceptive pain (including somatic pain). This patient does not have any evidence of neuropathic pain, pain arising from nerve injury. Additionally, this patient does not have any history of epilepsy or migraine headaches for which topiramate could be used. The patient is diabetic, but there is no evidence that the medication was prescribed for any associated complications of diabetes such as painful polyneuropathy. Therefore, based on evidence-based, peer-reviewed guidelines, this request is non-certified.

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
- 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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)