

IRO REVIEWER REPORT TEMPLATE -WC

INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

[Date notice sent to all parties]:

12/13/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Gabapentin and hydrocodone

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: Board Certified PM&R; Board Certified Pain Medicine

REVIEW OUTCOME:

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

Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Patient chart report 11/26/13

Patient prescription history report 06/25/12-06/25/13

Toxicology report 11/16/12-11/16/13

Clinical records 10/26/12-11/13/13

Prior utilization reports 10/20/13 and 11/12/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who originally sustained an injury on xx/xx/xx. No specific mechanism of injury was noted. The patient was followed for chronic pain syndrome in the low back left buttock and left lower extremity. The patient had prior dorsal column stimulator; however, this was removed due to an infection. The

patient had been managed with multiple medications including amitriptyline gabapentin omeprazole and Norco in 2012 and 2013. The patient was being followed since 10/12 per the records. On toxicology results from 11/06/12 showed positive findings for hydrocodone. Toxicology results from 06/03/13 showed positive findings for methadone and opiates. The most recent urine drug screen from 11/16/13 again showed positive findings for opiates including hydrocodone and hydromorphone; however, this was considered a metabolite of hydrocodone. As of 09/17/13 the patient reported an acceptable level of pain control. The patient performed normal activities of daily living but continued to describe low back pain radiating to the left lower extremity with associated weakness and muscular spasms. The patient described that his current medications improved function and his activities of daily living. The patient reported his pain score as 3/10 on the VAS. Physical examination demonstrated positive straight leg raise to the left side. The patient could perform normal heel and toe walking. Medications were continued at this visit. Follow up on 10/16/13 reported continuing benefits for medications. No side effects were reported and the patient did not exhibit any aberrant drug taking behaviors. Physical examination continued to show tenderness to palpation in the left paraspinal regions with negative straight leg raise findings at this evaluation. The patient was seen on 11/13/13 with continuing complaints of low back pain radiating to the left lower extremity. The patient reported acceptable levels of pain control 3/10 on the VAS. The patient was requesting an attempt to reduce the amount of hydrocodone taken daily. The patient was able to perform activities of daily living and denied any side effects. No aberrant medication use was noted. Physical examination reported positive straight leg raise at this evaluation with tenderness to palpation in the bilateral paraspinal regions of the lumbar spine. The patient was instructed to reduce hydrocodone to a maximum of three per day and gabapentin was continued. Utilization report from 10/28/13 recommended certifying gabapentin for 600mg and hydrocodone 10/325mg for an additional one month. Utilization report from 11/12/13 indicated that the requested dosage and frequency for hydrocodone and gabapentin were not documented.

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

The patient has been followed for ongoing chronic low back and radicular pain that was being well managed with gabapentin and hydrocodone. The patient had compliant toxicology results in regards to hydrocodone and reported controlled pain 3/10 on the VAS. The patient indicated that he was able to perform activities of daily living and was functional with this medication. The patient exhibited narrow positive straight leg raise findings on physical examination and no aberrant medication use was identified in the clinical records. Given the positive effects of continued use of hydrocodone and gabapentin in the treatment of chronic low back and radicular pain and as gabapentin is a recommended first line medication for the treatment of neuropathic pain it is the opinion of this reviewer that medical necessity has been established for both medications.

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

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines, Pain Chapter, online version

Opioids, Criteria for Use

4) On-Going Management. Actions Should Include:

(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.

(b) The lowest possible dose should be prescribed to improve pain and function.

(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of [function](#), or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. *The 4 A's for Ongoing Monitoring*: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. ([Passik, 2000](#))

(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. ([Webster, 2008](#))

(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).

(g) Continuing review of overall situation with regard to nonopioid means of pain control.

(h) Consideration of a consultation with a [multidisciplinary pain clinic](#) if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. ([Sullivan, 2006](#)) ([Sullivan, 2005](#)) ([Wilsey, 2008](#)) ([Savage, 2008](#)) ([Ballyantyne, 2007](#))

Anti-epilepsy drugs (AEDs) for pain

Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants.

Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). ([Gilron, 2006](#)) ([Wolfe, 2004](#)) ([Washington, 2005](#)) ([ICSI, 2005](#)) ([Wiffen-Cochrane, 2005](#)) ([Attal, 2006](#)) ([Wiffen-Cochrane, 2007](#)) ([Gilron, 2007](#)) ([ICSI, 2007](#)) ([Finnerup, 2007](#)) 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®)

Outcomes: A “good” response to the use of AEDs has been defined as a 50% reduction in pain and a “moderate” response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the “trigger” for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. ([Eisenberg, 2007](#)) ([Jensen, 2006](#)) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills). ([Clinical Pharmacology, 2008](#)) Manufacturers of antiepileptic drugs will need to add a warning to their labeling indicating that use of the drugs increases risk for suicidal thoughts and behaviors, according to an FDA Alert issued December 16. ([FDA MedWatch, 2008](#))

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). ([Attal, 2006](#)) ([Jensen, 2006](#))

Postherpetic neuralgia: Gabapentin and pregabalin are recommended. ([Attal, 2006](#)) ([Backonja, 2004](#))

Central pain: There are so few trials (with such small sample size) that treatment is generally based on that recommended for peripheral neuropathy, with gabapentin and pregabalin recommended. Lamotrigine has been found to be effective for central post-stroke pain (see below for specific drugs), and gabapentin has also been found to be effective. ([Backonja, 2004](#))

Acute pain: Not indicated due to lack of evidence.

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. ([Muehlbacher, 2006](#)) 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 ≥ 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.

Treatment of pain associated with osteoarthritis of the hip: Not indicated

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Spinal cord injury: Gabapentin is recommended for chronic neuropathic pain. ([Levendoglu, 2004](#))

CRPS: Gabapentin has been recommended ([Serpell, 2002](#))

Fibromyalgia: Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. ([Arnold, 2007](#)) ([Crofford, 2005](#)) Pregabalin is FDA approved for fibromyalgia.

Lumbar spinal stenosis: Gabapentin produced statistically significant improvement in walking distance, decrease in pain with movement and sensory deficit in a pilot study. ([Yaksi, 2007](#))

Myofascial pain: Not recommended. There is a lack of evidence to demonstrate that AEDs significantly reduce the level of myofascial or acute musculoskeletal pain, or other sources of somatic pain. ([Wiffen-Cochrane, 2005](#)) ([Washington, 2005](#))

Postop pain: AEDs may also be an option for postoperative pain, resulting in decreased opioid consumption. ([Peng, 2007](#)) ([Buvanendran, 2007](#))

SPECIFIC ANTI-EPILEPSY DRUGS:

Gabapentin (Neurontin®, Gabarone™, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. ([Backonja, 2002](#)) ([ICSI, 2007](#)) ([Knotkova, 2007](#)) ([Eisenberg, 2007](#)) ([Attal, 2006](#)) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. ([Backonja, 1998](#)) It has been given FDA approval for treatment of post-herpetic neuralgia. The **number needed to treat** (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. ([Wiffen2-Cochrane, 2005](#)) ([Zaremba, 2006](#)) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. ([Gilron-NEJM, 2005](#)) Recommendations involving combination therapy require further study.

Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. ([Arnold, 2007](#))

Specific pain states:

Acute pain: There is limited evidence to show that this medication is effective for acute pain, and for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. ([Peng, 2007](#)) ([Buvanendran, 2007](#)) ([Menigaux, 2005](#)) ([Pandey, 2005](#))

Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. ([Levendoglu, 2004](#))

CRPS: Recommended as a trial. ([Serpell, 2002](#))

Fibromyalgia: Recommended as a trial. ([Arnold, 2007](#))

Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. ([Yaksi, 2007](#))

Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. ([Eisenberg, 2007](#)) ([Attal, 2006](#)) Weight gain is also an adverse effect.

Dosing Information:

Postherpetic neuralgia – Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert)

Diabetic neuropathy (off-label indication) – Gabapentin dosages range from 900 mg to 3600 mg in three divided doses ([Backonja, 2002](#)) ([Eisenberg, 2007](#)). Gabapentin is 100% renally excreted.

Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. ([Dworkin, 2003](#)) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). ([Jensen, 2006](#)) ([Eisenberg, 2007](#))

Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) *When to switch to pregabalin:* If there is evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trials of the two drugs.