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Notice of Independent Review Decision

DATE OF REVIEW: JUNE 28, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of proposed medications: Neurontin 300MG 2TID; Methadone 10MG, one TID #90; Lidoderm Patches; Avitan 1 MG TID; Effexor XR 75MG Daily

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

This case was reviewed by a Medical Doctor licensed by the Texas State Board of Medical Examiners. The reviewer specializes in Physical medicine and Rehabilitation, and is engaged in the full time practice of medicine

REVIEW OUTCOME

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

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

Primary Diagnosis	Service being Denied	Billing Modifier	Type of Review	Units	Date(s) of Service	Amount Billed	Date of Injury	DWC Claim#	IRO Decision
722.73, 724.8, 724.4	Neurontin 300MG 2TID		Prosp	1					Upheld
722.73, 724.8, 724.4	Methadone 10MG, one TID #90		Prosp	1					Upheld
722.73, 724.8, 724.4	Lidoderm Patches		Prosp	1					Upheld
722.73, 724.8, 724.4	Avitan 1 MG TID		Prosp	1					Upheld
722.73, 724.8, 724.4	Effexor XR 75MG Daily		Prosp	1					Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

TDI-HWCN-Request for an IRO-21 pages

Respondent records-

PATIENT CLINICAL HISTORY [SUMMARY]:

The medical records presented for review begin with the letter of non-certification and the denial of the appeal. It was noted that the treatment (multiple medications) was not consistent with the review criteria. The clinical summary presented indicated that this was a lady with a xxx year history of low back pain. As of xxx there were multiple degenerative changes noted on imaging studies. Electrodiagnostic studies noted a nerve root irritation (radiculitis) on the left. Ms. was placed that maximum medical improvement and subsequent to that determination. A surgical procedure was undertaken. 81 level lumbar fusion procedure was noted. This lady developed a pseudoarthrosis in the second surgery was completed. The hardware was ultimately removed as well. Treatment included a spinal cord stimulator.

The notes reflect that. The only medications that this lady was on as of xxxx was Methadone and Ativan. It is indicated that as per the primary treating physician. This lady is only "fairly low dose" of the Mmethadone for her radiating leg pain. Additionally, there is no indication in the records that appropriate studies were done to ensure compliance with the established protocols.

Dr. noted on March 25, 2000 and that this lady limited to a low dose of Methadone, Neurontin and lidoderm patches. She is also on Ativan and Effexor.

A peer review from Dr. outlined from an evidence based on the medicine perspective why continuing these medications was not supported. The summary of treatment for the life of the claim was also noted.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. IF THERE WAS ANY DIVERGENCE FROM DWC'S POLICIES/GUIDLEINES OR THE NETWORK'S TREATMENT GUIDELINES, THEN INDICATE BELOW WITH EXPLANATION.

As noted in the Division mandated Official Disability Guidelines the indications for the following are:

- A. Neurontin Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which 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.
- B. Methadone: Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long and variable half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. It may take several days to weeks to obtain adequate pain control.
- C. Lidoderm patches - Not recommended until after a trial of a first-line therapy, according to the criteria below. Topical lidocaine may be recommended for localized neuropathic pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further

research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia.

Criteria for use of Lidoderm patches:

(a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica).

(c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points.

(d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale.

(e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day).

(f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks).

(g) It is generally recommended that no other medication changes be made during the trial period.

(h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued.

(i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued.

- D. Avitan - Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing.
- E. Effexor XR Recommended as an option in first-line treatment of neuropathic pain. Venlafaxine (Effexor®) is a member of the Selective serotonin and norepinephrine reuptake inhibitors (SNRIs) class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders. It is off-label recommended for treatment of neuropathic pain, diabetic neuropathy, fibromyalgia and headaches. The initial dose is generally 37.5 to 75 mg/day with a usual increase to a dose of 75 mg b.i.d or 150 mg/day of the ER formula. The maximum dose of the immediate release formulation is 375 mg/day and of the ER formula is 225 mg/day. It may have an advantage over tricyclic antidepressants due to lack of anticholinergic side effects. Dosage requirements are necessary in patients with hepatic and renal impairment. ([Namaka, 2004](#))

As one can see from the Official Disability Guidelines determination relative to the citation for Neurontin, this would not be indicated, as there is no objective evidence of a diabetic painful neuropathy or postherpetic neuralgia. Moreover, we are in a situation where this is not a first-line treatment for neuropathic pain and does the literature to support this medication does not support

issues for a chronic lumbar fusion situation. Based on the literature presented there is no clear clinical reason to support this medication.

While noting that methadone is recommended as a second line drug. There is no objective amelioration of symptomology or improvement of functionality or allows one to return to work. Based on the limited records presented. Therefore, the efficacy of this medication has not been identified or followed upon by the primary treating physician. Given the potential for abuse and other uses of this medication. Based on the lack of the documentation presented by the primary treating physician. There is no clear clinical reason to continue this medication.

In terms of the indications for the lidoderm patches, the specific requirements are established in the ODG. Based on the limited medical records presented, none of these requirements is met. Furthermore, the utility or efficacy of this delivery model had not been established or address any progress notes presented for review. That's the requirement than objectification of the efficacy of the medication has not been supported by the treating Dr. limits any approval for this medication.

The Ativan is specifically not recommended for long-term use. This is a benzodiazepine and the sequelae of the long-term use of this medication are generally not as one would hope for. Given the lack of noted efficacy or utility, given the noted side effects of this medication, and considering the age and body habitus of the way the injured. There is insufficient data presented to support this request.

While noting that the Effexor is indicated as a first line mediation, this injury is more then a decade old. There is no noted response to this medication and the lack of objective clinical data from the primary treating physician would be an argument against this mediation. With the standard of evidence based medicine and reasonably required to address the sequale of the compensable event as the baseline, it is the lack of any clinical data that requires this request to be non-certified. There is no noted utility or efficacy noted. There is no clinical basis for continuing these medications.

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

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

XX ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES