Claims Eval

Notice of Independent Review Decision

[Date notice sent to all parties]: 9-12-12

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Cymbalta 60 mg; Lyrica 100 mg; Hydrocodo/Acetam 5-500; Diclofenac Sod 75 mg.

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

American Boards of Physical Medicine and Rehabilitation and Pain Management

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)

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:

- 3-19-12 MD., performed a Peer Review.
- 4-19-12 MD., provided a letter regarding Dr. Peer Review.
- 4-25-12 MD., office visit.
- 5-9-12 MD., provided a Peer Review.
- 7-27-12 Receipt for $505.75.
- Undated - Prescription for medications.
- 8-13-12 Hand written letter from the claimant.
- 8-21-12 Letter from.

PATIENT CLINICAL HISTORY [SUMMARY]:

3-19-12, MD., performed a Peer Review. He saw no indication for the diagnostic testing that has been done. The confusing thing in this file is that this claimant's initial treatment with Dr. was clearly focused on the claimant's chronic cervical pain. In the latter part of 2000, Dr. reports that the claimant's back is better. Then it appears that in 2001, her neck was not problematic, and since that time treatment has been only to the lower back. There is no evidence in this file indicating that the claimant had a significant back or neck injury on the date of injury in question. She had degenerative disease in the cervical and lumbar spine, which is disease of life, not a work-related condition.
Certainly there is no indication for additional diagnostic testing here. This claimant has a widespread, nonspecific chronic pain problem. The most appropriate diagnosis here would be fibromyalgia, which is a form of a somatoform disorder with prominent pain features. This is not a work-related condition, nor is it a condition which can be helped with diagnostic testing. Diagnostic testing in cases such as this misleads the ordering practitioner and typically results in persons receiving surgical treatment that is not helpful and not necessary. There is no indication, then, for any additional diagnostics here. This claimant's treatment has been excessive, unreasonable, and unnecessary. This claimant has been in the medical treatment system an excessively long period of time without result. Despite extensive treatment, this claimant is functioning at what appears to be a very low level. Treatment, then, has been a failure. Certainly anyone can see that continuing with failed treatment strategic benefits no one, especially not the claimant. He saw no indication, then, for any ongoing treatment here other than a home exercise program and over-the-counter medication. That sort of a program does not require formal medical supervision. He noted that medications are not promoting functioning here. As such, then the claimant is only being exposed to

possible side effects of these medications. It is not appropriate to continue in this fashion. He found no evidence in the file that this medication regimen is promoting functioning. As such then, there is no indication for the use of opioid analgesics, and ODG does not approve of them without clear evidence of benefit. The side effects of Diclofenac outweigh any benefit that is being seen here. That medication can be stopped without weaning. As far as Lyrica and Cymbalta, he found no evidence indicating that this claimant has neuropathic pain. As such then, those medications are not appropriately used, nor is there evidence that they have promoted function or are benefitting the claimant in any way. All of these medications are exposing the claimant to potential side effects without any objective evidence of benefit. It is not medically reasonable to continue in this fashion. He did not know the current dose of Lyrica, Cymbalta, or Hydrocodone. No matter what the dose, the claimant could be weaned off of all of these medications in four to six weeks. He could not provide an exact weaning protocol, as that is outside the purview of his specialty. He saw no indication for a pain pump, muscle stimulator, spinal cord stimulator, or bone growth simulator.

4-19-12 MD., provided a letter regarding Dr. Peer Review. He disagreed with Dr. assertions. Dr discusses in question number two that the more appropriate diagnosis would be fibromyalgia. Dr. has never interviewed this patient, nor has he ever examined the patient. It is inappropriate and dangerous to make medical diagnostic conclusions without examining a patient. This would be considered malpractice. Dr. likes to comment that the patient appears to be at a very low functional level. Again, Dr. has never evaluated the patient. He has not taken a history from her nor examined the patient. The patient is actually functioning at a fairly high level because of her appropriate medication management, which allows her to maintain function and improve her quality of life. He further states that she has been a "treatment failure." This is his opinion, and he is welcome to it, but the patient has stated and it has been documented that her pain levels are improved with the medication management and the medications do allow her to function. The patient has been maintained with the judicious use of medication management consistent with the ODG Guidelines for several years. She occasionally has flare-ups of radicular pain and most recently had a flare-up of greater trochanteric bursitis which is possibly related to her altered gait pattern due to her chronic back pain. The patient is followed in his office on a quarterly basis. She is 100% compliant with her treatment and shows no signs of aberrant drug-related behaviors. The medications improve her quality of life and allow her to function in her activities of daily living. The medications prescribed include Cymbalta for chronic pain, neuropathic and low back; Lyrica for neuropathic pain; Diclofenac non-steroidal anti-inflammatory medication for pain and inflammation; and Vicodin 5/500 for PRN breakthrough pain, with judicious use of two tablets daily as needed. Additionally, she has recently had insomnia, for which she was prescribed Lunesta to assist with improvement in her sleep pattern.

4-25-12 MD., notes the claimant is in for follow up with a history of chronic low back pain status post lumbar laminectomy, discectomy and fusion. The patient states currently she is stable on her current medication regimen. She is having no

side-effects and displaying no aberrant behaviors. Her pain level is approximately 4-5/10 with her medicine. They help increase her functioning and decrease her pain. She is using Lunesta for sleep and finds it to be very effective. It helps her maintain her sleep at night without having a hangover effect the next morning, and it makes her more functional and have decreased pain the next day. Current medications: Lunesta 2 mg Os, Lyrica 100 mg tid, Cymbalta 60 mg qd, Voltaren 75 mg with food bid, and Vicodin 5/500 bid prn. Physical Examination: Her back excision is well healed. She has functional thoracolumbar range of motion and palpable spasm, and her pelvis is symmetric. Straight leg raising is negative. Lower extremities are without peripheral edema, skin lesions or rashes. Neurologic exam is without motor or sensory deficits. Diagnostic Data: Urine drug testing was reviewed from her previous visit on February 1, 2012 and found to be positive and consistent for Hydrocodone and its metabolite norhydrocodone and Hydromorphone. No illicit substances were detected. Impression: Chronic intractable low back pain status post lumbar laminectomy, discectomy and subsequent lumbar fusion at L5-S1. Plan: The claimant will continue with medication management. Her medications are helping her with the pain and increasing her function. Medications refill: Lunesta 2 mg 1 po qhs prn insomnia, Lyrica 100 mg tid, Cymbalta 60 mg 1 po qd, Voltaren 75 mg po bid with food, Vicodin 5/100 1 po bid prn pain, two refills of each.

5-9-12, MD., provided a Peer Review. He noted that MD, has written a letter in response to his review. He was asked if his letter causes him to change his previously stated opinion in any way. Previously in his review dated March 19 2012, he had some disclaimers and listed his qualifications. There is also a listing of records reviewed at the time of that prior review. He did not plan to repeat that material here as this is an addendum to that prior report and that information is included in the prior report. Please pull that report to obtain that information. At the time of his prior review, he noted that the claimant was apparently injured on March 16, 2000, when her chair broke and she fell to the floor. He found no evidence in the file of a serious work-related injury which would have required anything more than a couple of months of treatment, yet the claimant has been in the medical treatment system consistently since March 16, 2000. He believed that during that time the claimant has become habituated to the medical treatment system, which has ensured that she will have ongoing complaints and higher than expected levels of disability. The claimant did have some surgical procedures of questionable indication. These did not help her. Information that he received seemed to suggest that this claimant had not worked in many years by the latter part of the file. When he referred to function, he was referring to work. He found no evidence in this file to suggest that this claimant is functioning at the expected functional level, which would include working. As such, Dr. contention that the medications he is prescribing allow her to function is not supported despite his suggestion that this is the case. Dr. does not discuss in his letter dated April 19, 2012, what he means by "allow her to function." If he means that the claimant is not bedridden, he would certainly agree with that and certainly that is a low standard of term function. Again, there is no reason that he could find related to the claimant's alleged compensable injury that she should not be working and if

she is not working, then she is not functioning. If this claimant is not working, then this is a treatment failure. He continued to see little connection between this claimant's global body pain and the alleged compensable injuries. It is his suggestion that she suffers from fibromyalgia, which should be a disease of life not a work-related condition.

7-27-12 Receipt for $505.75.

Undated - Prescription for Lyrica 100 mg po tid, Voltaren 75 mg po bid, Vicodin 5.500 mg po bid prn, Lunesta 2 mg po prn with two refills each.

8-13-12 Hand written letter from the claimant requesting reimbursement for her out of pocket expenses for her prescribed medications. Total amount due is $505.75.

8-21-12 Letter from: It was noted that the medications she was seeking reimbursement were filled under and the amounts she was requesting were her co payments, totalling $505.75.

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

I have reviewed the records provided in this case. ODG does not support the use of Diclofenac for long term use. The claimant was injured in xx/xx/. Therefore, the ongoing use of this medication is not recommended or considered medically necessary twelve years after the date of injury.

The Lyrica 100 mg is too low to even have any beneficial effect and the records provided for review do not indicate or document a neuropathic process. Therefore, it is not considered medically necessary.

Hydrocodo/Acetam 5-500 (Vicodin) and Cymbalta are specifically for chronic pain. Records indicate the claimant has been provided these medications for chronic intractable low back pain status post lumbar laminectomy, discectomy and subsequent lumbar fusion at L5-S1 as a result of the work injury. Therefore, these medications are appropriate and considered medically necessary.

ODG 2012 CRITERIA FOR USE OF OPIOIDS

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 dairy 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)
5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):
(a) Every 2 weeks for the first 2 to 4 months
(b) Then at approximate 1 ½ to 2-month intervals
Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)

Per ODG 2012 regarding NSAID's: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection

is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008)

Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)

Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications.

Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006)

See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) Revised AGS practice guidelines on the management of persistent pain (including noncancer-related pain) in the elderly recommend that patients avoid NSAIDs and consider the use of low-dose opioid therapy instead, because the risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, usually outweigh the benefits.

(AGS, 2009)

Per ODG 2012 regarding anti-depressants: Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-*Cochrane*, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. (Perrot, 2006) (Schnitzer, 2004) (Lin-*JAMA*, 2003) (Salerno, 2002) (Moulin, 2001) (Fishbain, 2000) (Taylor, 2004) (Gijsman, 2004) (Jick-*JAMA*, 2004) (Barbui, 2004) (Asnis, 2004) (Stein, 2003) (Pollack, 2003) (Ticknor, 2004) (Staiger, 2003) Long-term effectiveness of anti-depressants has not been established. (Wong, 2007) The effect of this class of medication in combination with other classes of drugs has not been well researched. (Finnerup, 2005) The "number needed to treat" (NNT) methodology (calculated as the reciprocal value of the response rate on active and placebo) has been used to calculate efficacy of the different classes of antidepressants. (Sindrup, 2005) See also the Stress/Mental Chapter: Antidepressants for the treatment of depression. Also see Comorbid psychiatric disorders.

Per ODG 2012 regarding anti-epileptic medication: 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)

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)