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Notice of Independent Review Decision

Date notice sent to all parties: 09/24/13

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

OxyContin 80 mg. two tablets every 12 hours #120 with no refills

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

Board Certified in Anesthesiology
Fellowship Trained in Pain Management
Added Qualification in Pain Medicine

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.

OxyContin 80 mg. two tablets every 12 hours #120 with no refills - Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Reports and other providers dated 10/23/06, 11/06/06, 12/06/06, 01/09/07, 02/05/07, 02/28/07, 03/07/07, 03/21/07, 04/04/07, 04/05/07, 05/10/07, 06/06/07, 08/08/07, 09/05/07, 10/08/07, 11/07/07, 11/12/07, 11/26/07, 12/10/07, 01/03/08,

02/25/08, 03/04/08, 03/24/08, 04/02/08, 05/05/08, 06/04/08, 07/03/08, 07/14/08, 07/31/08, 08/28/08, 09/29/08, 10/30/08, 11/24/08, 12/23/08, 01/29/09, 02/26/09, 03/26/09, 03/31/09, 04/29/09, 05/27/09, 06/24/09, 07/23/09, 08/19/09, 09/17/09, 10/15/09, 11/19/09, 12/17/09, 01/11/10, 01/18/10, 02/17/10, 03/17/10, 04/14/10, 05/17/10, 06/16/10, 07/15/10, 08/16/10, 09/15/10, 10/14/10, 11/16/10, 12/15/10, 01/13/11, 02/10/11, 03/14/11, 04/14/11, 05/12/11, 06/13/11, 07/11/11, 08/11/11, 09/08/11, 10/11/11, 11/10/11, 12/09/11, 01/11/12, 02/09/12, 03/09/12, 04/11/12, 05/11/12, 06/08/12, 07/11/12, 08/10/12, 09/07/12, 10/04/12, 11/02/12, 12/04/12, 01/04/13, 02/05/13, 03/08/13, 04/05/13, 05/03/13, 06/04/13, 07/03/13, 08/02/13, 09/03/13, and 09/12/13

Toxicology screens dated 11/06/06, 01/09/07, 05/05/08, 12/23/08, 03/26/09, 04/29/09, 05/27/09, 07/23/09, 08/19/09, 12/17/09, 02/17/10, 04/14/10, 01/13/11, 02/10/11, 03/14/11, 04/14/11, 05/12/11, 06/13/11, 08/11/11, 09/08/11, 11/10/11, 12/09/11, 01/11/12, 02/09/12, 03/09/12, 04/11/12, 07/11/12, 09/07/12, 12/04/12, 02/05/13, 03/08/13, 05/03/13, 06/04/13, 07/03/13, 08/02/13, and 09/03/13

Electrodiagnostic studies dated 01/03/07 and 09/06/07

Operative reports dated 02/28/07, 11/12/07, 11/26/07, 12/10/07, 08/19/10, 12/14/10, 05/16/11, 01/10/12, 03/27/12, 05/31/12, 09/06/12, 09/27/12, 06/18/13, and 07/09/13

Lumbar MRI dated 07/23/07

MRIs of the cervical, lumbar, and thoracic spines dated 06/08/10

Lumbar myelogram with post myelogram CT scan dated 10/28/11

Left knee MRI dated 06/06/12

Preauthorization notice from Mutual dated 09/09/13

Undated Provider List

Undated treatment history

The Official Disability Guidelines (ODG), Pain (Chronic) Chapter, along with a formulary list of medications was provided by the carrier

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient was injured on xx/xx/xx, a complex left humerus fracture, left scapula fracture, pneumothorax, closed head injury, and pelvic fractures. The patient had a history of preexisting complex regional pain syndrome due to a work injury in the early xxxx with continued neuralgic left upper extremity pain prior to the work injury herein under discussion. The patient has been maintained on various doses of OxyContin and Hydrocodone since at least October 2006, as well as other medications, including Duragesic and Morphine. On 10/23/06, was prescribing the patient OxyContin 60 mg. three times a day, Duragesic 50 mcg. patch every three days, and Hydrocodone 10-20 mg four to six times daily. The patient's pain level was said to be 4/10 and the listed diagnosis was reflex sympathetic dystrophy (RSD) of the left arm. The patient's chief complaint was left arm pain. Since that time, the patient has also complained variously of low back pain and left leg pain. increased the patient's OxyContin to 80 mg. three times a day and discontinued the Duragesic patch, then continuing Hydrocodone unchanged. On 02/28/07, a left stellate ganglion block was performed. A lumbar MRI dated 07/23/07 revealed findings consistent with an old healed fracture of the

left sacral ala. There was no abnormality in the left lumbosacral plexus or proximal sciatic nerve. There was denervation atrophy in both gluteus maximum muscles, on the left greater than the right, and probable old atrophic change in the left piriformis muscle. There was a decreased conspicuity since 2004 of an annular tear at the posterior disc margin at L5-S1. An electrodiagnostic evaluation on 09/06/07 revealed previous left L4 and/or L5 and/or S1 radiculopathy, as well as possible previous left lumbosacral plexopathy sustained at the time of injury. He continued to have electrodiagnostic evidence of a mild right peroneal nerve injury. On 11/12/07 and 12/10/07, performed bilateral SI joint injections. On 05/05/08, the patient returned, now complaining of buttock and left leg pain. He was taking OxyContin 80 mg. three times daily and Hydrocodone 10 mg. six times daily. The patient's diagnosis was now listed as sacroiliitis and lumbar disc displacement. A urine drug screen on that date was consistent with the medications being prescribed. On 03/25/09, the patient followed-up, who documented that the medication provided "50-75%" relief. These medications were OxyContin 80 mg. every eight hours and Hydrocodone 10 mg. six times daily. On 01/18/10, the patient again followed-up, now complaining of low back pain and no pain score was documented. The patient was still taking OxyContin and Hydrocodone as before. discussed a spinal cord stimulator trial with the patient, who indicated that he had one done 15 or 20 years before without benefit.

On 06/08/10, a lumbar MRI scan was performed. It showed only focal left L3-L4 disc protrusion, which did not impinge the left L3 root, as well as annular L5-S1 bulge contained by epidural fat with no mass effect on any nerve roots. Thoracic MRI scan demonstrated mild T7-T8 through T9-T10 disc bulges without canal or foraminal stenosis. then performed a left L3 and L4 transforaminal ESI on 08/19/10. On 11/16/10, noted the claimant had numbness in the top of the foot that now felt like it was in the entire foot. An EMG study was recommended and Hydrocodone would be increased to eight tablets a day and Oxycodone and Lidoderm patches were refilled. On 12/14/10, performed left L3-L4 transforaminal ESI. On 06/13/11, no pain score was documented on the note. By this time, the patient was taking OxyContin 160 mg. every twelve hours, as well as Hydrocodone 10 mg. four to six times daily. Medications were said to allow the patient to "do some physical activity at home." A lumbar myelogram with post myelographic CT scan was obtained on 10/28/11. There was minor annular disc bulging at L3-L4 and L5-S1 that did not change with weight loading or flexion/extension. There was no compression of the descending or exiting nerve roots and the nerve roots filled normally at all levels. On 01/10/12, the first of five left lumbar sympathetic blocks were performed. Additional blocks were performed on 03/27/12, 05/31/12, 09/06/12, and 09/27/12. On 02/09/12, noted the claimant received excellent relief from the left lumbar sympathetic block and a second and third were recommended. Toxicology screening that day revealed opiates. A left knee MRI on 06/06/12 revealed a limited examination due to metallic artifact. There was complete absence of the medial meniscus with truncation of the body of the lateral meniscus and absence of its anterior horn. There was degenerative thinning of the cartilage of the medial and lateral knee. Follow-up on 12/04/12 did not document any pain level, but stated that the patient had "decreased" left leg

pain following the five lumbar sympathetic blocks. However, the patient continued to take OxyContin and Hydrocodone at the same doses and frequency, confirmed by urine drug screens.

On 03/08/13, the patient returned. Again, no pain level was documented. noted now the patient's major complaint as being left knee and low back pain and the failure of the L3-L4 transforaminal ESI to provide any relief. OxyContin and Hydrocodone were continued at the same doses. Two months later, on 05/03/13, however, the patient's medications were listed as being OxyContin 160 mg. every twelve hours, Hydrocodone 10 mg. four to six times daily, and now Morphine 15 mg. every four to six hours, up to five times daily. The patient was said to have failed the spinal cord stimulator trial. The patient stated that medications allowed him to function regarding activities of daily living, work on home exercises, and obtain sleep. Again, no pain level was documented. Bilateral L5-S1 transforaminal ESIs were then performed on 06/18/13. On 07/03/13, followed-up with the patient, who stated he had "70% pain reduction" following the injections. Medications now were documented as being OxyContin 160 mg every. twelve hours and Hydrocodone 10 mg. six times daily. No pain level was documented. On 07/09/13, repeated bilateral L5 and S1 transforaminal ESIs.

On 09/03/13, again followed-up with the patient, stating that the initial set of transforaminal ESIs in June provided about two weeks of relief and that the subsequent set provided about four weeks of the same "70%" relief. No pain level was listed and the patient was still taking the same amount of OxyContin and Hydrocodone. Medications were now documented as providing "25 to 50%" pain relief and improved functioning. No pain level was documented. On 09/09/13, a physician advisor, after having a peer-to-peer discussion regarding OxyContin, recommended non-certification of the request to refill OxyContin 80 mg. two tablets every twelve hours. The physician advisor cited the ODG in his discussion with the nurse practitioner. The nurse practitioner acknowledged her awareness of OxyContin being on the "N" formulary list and also acknowledged that the documentation submitted in support of the request for continued OxyContin did not delineate functional improvement or pain relief beyond general references. The physician advisor noted that the current OxyContin dose was "four times" the suggested maximum Morphine equivalent dose and recommended non-authorization for the refill. The patient returned on 09/12/13, who again documented no pain level. noted the patient had been weaned successfully off OxyContin, substituting Fentanyl patch 100 mcg. in its place, and was continuing Oxycodone 15 mg. six times a day instead of Hydrocodone. noted the patient's denial of any chills, night sweats, fever, nausea, or vomiting in review of systems. Because of the patient's ongoing pain, the Fentanyl patch dose was increased to 150 mcg. every 72 hours with plans to further increase to a total of 200 mcg. every 72 hours if necessary. Additionally, Oxycodone 15 mg. six times daily was also continued.

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

As pointed out by the previous physician advisor and acknowledged by the nurse practitioner requesting refill of OxyContin, OxyContin is on the "N" list of the Division of Workers' Compensation (DWC) formulary. Therefore, its use is not allowed except for extenuating circumstances. Moreover, despite the patient taking increasing doses of OxyContin over the last six or seven years, increasing from 60 mg. three times a day to 160 mg. three times a day (almost a 300% increase), there has never been any documentation of a decreased pain level or significantly improved functional status. In fact, the most recent documentation indicated that the patient was obtaining only 25-50% pain relief while on OxyContin. Given the amount of time that the patient has been on OxyContin and the excessive dose he has been taking as compared to recommended Morphine equivalents, it is highly likely that the patient has developed significant tolerance to OxyContin and/or opioid hyperalgesia, both of which, if present, would be significant barriers to OxyContin providing significant relief and, more importantly, significant indications for its discontinuation. Absent significant pain relief and documented objective evidence of functional improvement (not just diffuse non-specific references to activities of daily living), there is no medical reason or necessity for the continuation of any opioid nor any support for such continuation in the ODG treatment guidelines. Additionally, if OxyContin were providing significant relief, there would have been no reason to request and subsequently perform multiple invasive procedures to treat the patient's ongoing pain, and, despite those injections, increase the OxyContin dose to its current level. If medication is providing significant relief, justifying its continuation, then repeated injections to treat pain would not have been medically reasonable or necessary and would, in my opinion, illustrate that the opiate was not providing significant relief. Therefore, according to the ODG treatment guidelines and accepted medical standards of care regarding chronic opioid therapy, as delineated by the Texas Medical Board (which requires objective evidence of both improved pain relief and improved functional status), there is no medical reason or necessity for the renewal of OxyContin 80 mg. two tablets every twelve hours. Since the patient has recently been successfully weaned from OxyContin, according to the 09/12/13 office note, and a Fentanyl patch was substituted for OxyContin, there is, moreover, no medical reason, necessity, or indication to restart the use of OxyContin both because of the clear lack of any objective evidence of its efficacy while it was being used, as well as its status of being an "N" drug on the DWC system formulary. Finally, according to the ODG treatment guidelines, opioids should be discontinued when there is "continuing pain with lack of significant benefit (persistent pain and lack of improving functioning despite high doses of opioids greater than 120 mg. per day Morphine equivalent)." Since this patient clearly illustrates that situation, there is no ODG support for the continuation or resumption of OxyContin use in this case. Therefore, the previous adverse determinations should be upheld at this time for the requested OxyContin 80 mg. two tablets every twelve hours #120 with no refills.

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)**