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Notice of Independent Review Decision

DATE OF REVIEW: 6/18/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month.

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 Physical Medicine and Rehab.

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 medical necessity of Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source):

Records reviewed:

A copy of the ODG was not provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The records that were provided to me for this review begin in the year xxxx and there is little information in the medical record regarding this worker's original injury and treatment. There is a mention in other record reviewers' notes that the worker was injured while carrying a hand rail. Apparently, there were injuries to his right knee and possibly his lumbar spine although this is not clear from available medical records. The records do indicate that the worker developed a complex regional pain syndrome related to his right knee injury. Records indicate that the worker was employed in the construction industry and has not been able to work regularly because of pain. Notes also suggest that the worker has had problems with situational dysthymia and family interpersonal relationships due to his pain.

In recent years, records indicate that signs and symptoms of autonomic dysfunction due to complex regional pain syndrome have spread from the right lower extremity to involve the left lower extremity and both upper extremities. The worker has been treated with a number of medications. He was on Opana ER 10 mg every 12 hours at the time of the first note that was provided to me. This was dated xxxxx. There is no indication of what analgesic medications might have been tried prior to this, but he was on Opana, hydrocodone/acetaminophen 10/325 1 two to three times a day, and Lunesta 3 mg at bedtime for insomnia. As his pain progressed, he was started on other medications mentioned in the medical record including a Lidoderm 5% patch for the right knee, Lyrica 50 mg two times a day, and Soma 350 mg by mouth, three times a day as needed. The dosage of Opana ER has over the past five years been increased from 10 mg q12h to 40 mg q12h. The injured worker's pain level is recorded at each of his physician visits and has varied from 6 to 10 on a scale of 0 to 10.

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

Medical records presented for my review begin in the year xxxxx and this injured worker sustained an injury prior to the time that records were provided to me. It appears that he had serious injuries to the right knee and possibly the spine. In any event, he developed a complex regional pain syndrome which began in the region of the right knee and has subsequently spread to involve, to some degree, all four extremities. I do not have any way of knowing what drugs were initially tried to control this injured worker's pain, but he was taking Opana ER 10 mg q12h at the beginning of the records that were provided to me in November, 2009. In addition, he was taking hydrocodone/acetaminophen 10/325 1 up to twice a day for break through pain and Lunesta 3 mg at bedtime as needed for sleep.

As his pain syndrome spread to involve other extremities, his dosage of Opana was increased and other medications were added to his treatment regime including a Lidoderm patch and Lyrica. He was offered a spinal cord stimulator and what sounds like a morphine pump, but declined those procedures.

According to ODG Treatment Guidelines, oxymorphone is not recommended due to issues of abuse and black box FDA warnings. Oxymorphone is recommended as a second

line of therapy for long-acting opioids. Oxymorphone products do not appear to have any clear benefits over other agents and have disadvantages related to dose timing and potential for serious adverse effects. ODG Treatment Guidelines indicate that if opioids are used, dosing should not exceed 120 mg of oral morphine equivalents per day and it appears that this patient's established treatment regime exceeds that guideline. In terms of criteria for long-term use of opioids such as oxymorphone, there must be clear documentation of pain and functional improvement if a worker is given these medications. The pain level in this patient's case is recorded at each visit, but there is no evidence in available medical records to indicate that function is measured at six-month intervals using a numeric scale or validated instrument as required by ODG guidelines. Although not required, ODG Treatment Guidelines recommend that there be a pain agreement for chronic use of opioids and I did not see this referenced in the available medical records. ODG Treatment Guidelines also recommend, but do not require, consideration of urine drug screens to assess for the presence of illegal drugs. The treating physician has indicated that there is no reason to suspect that illegal drugs would be used, but there is no indication in the record that a drug screen has been performed. ODG Treatment Guidelines further recommend that a pain diary be kept by the patient to assist in determining elements of pain assessment including current pain, least reported pain, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. I did not see any reference to those issues in available medical records.

Opana may be the only drug that can be used to provide this injured worker relief from what is apparently severe, incapacitating progressive pain, but if a reviewer is to determine the prospective medical necessity of this drug, the medical record should provide more objective documentation including what other drugs have been given trials and failed, more objective documentation of the pain and its characteristics, and more objective documentation of the physical and functional response of the injured worker to the Opana. Opana is not recommended by ODG, and if it is used, it should be used at acceptable dosage and documentation should be careful, detailed, and complete.

VI. Reference:

ODG Treatment Guidelines

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)