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Notice of Independent Review Decision

DATE NOTICE SENT TO ALL PARTIES: 1/20/14

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of OxyContin 40 mg.

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 Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

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 disagrees with the previous adverse determination regarding the prospective medical necessity of OxyContin 40 mg.

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: notes 9/18/13 to 11/13/13, 11/23/13 office notes, 11/6/12 to 8/1/13 notes, 5/1/13 notes, 10/31/12 lumbar myelogram and postmyelogram CT reports, 12/1/10 to 1/21/13 notes, toxicology report 9/18/13 to 10/16/13, 11/16/12 closed formulary letter, 11/30/12 peer review letter, and a medication list.

all records submitted were submitted by the carrier.

Patient: 1/2/14 letter by patient, 12/6/13 letter by patient, 1/3/14 letter, 6/26/13 letter, 5/3/13 response letter, 11/2/09 letter, 5/30/12 through 12/12/13 denial letters, and 7/16/13 complaint letter. All other records submitted were submitted by a party above.

11/8/13 letter by patient, and 10/30/13 letter supporting OxyContin use. All other records submitted were submitted by a party above.

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

PATIENT CLINICAL HISTORY [SUMMARY]:

AP records regarding the male were reviewed, including the most recent. The mechanism of injury was not evident at this time. Treatment medications have most recently included narcotics and topical analgesics. Consideration for a spinal cord stimulation repeat trial was noted on 9/18/13. "Excellent" medication compliance was noted on 10/16/13. As of 11/13/13, there were ongoing complaints of "severe pain in lower back, hips and groin and second most severe pain in the knees and both legs." There was an antalgic gait. Positive radicular pain on straight leg raise, along with lumbar facet tenderness, a 4/5 EHL bilaterally along with decreased sensation to light touch in the L4-S1 distribution. Diagnoses included chronic pain and post-laminectomy syndrome, radiculitis, and muscle spasm and "failed spinal cord stimulator trial implant." Interventional and medication pain management was considered. Records indicate "We discussed that OxyContin is the only analgesic medication that improves the patient's ability to perform activities of daily living. The patient has demonstrated compliance with the treatment plan... states OxyContin is the only long acting pain medication that doesn't give him side effects." A "...repeat SCS trial now that he has unbearable neuropathic pain." was felt indicated by a neurosurgical consultant. "He has long been opiate dependent and his pain has been intensifying..." The claimant appeal letter dated 12/6/13 was reviewed. The CT-myelogram dated 10/31/12 revealed s/p solid L5-S1 fusion with nerve root compression at L4-5, and, L3 nerve root abutment. The 11/20/13 and 11/4/13 dated denial letters discussed the lack of apparent functionality benefit from the medication, along with lack of exhaustion of non-narcotics. The 3/10/09 dated electrical study revealed active paraspinal denervation with worsening of neuropathy, along with increased clinical edema and hypo-reflexia.

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

This claimant has chronic low back pain and radiculopathy attributable to multiple levels of the lumbar and lumbosacral spine. The claimant has well-documented failed laminectomy syndrome and is status post multiple surgical procedures of the lumbar spine, including fusion. The claimant has both abnormal subjective and objective findings which are corroborated on imaging and electrical studies. The claimant has been well documented to have failed multiple other forms of medications, including narcotic and non-narcotic analgesics. The claimant has a

very positive history of compliance with treatments including OxyContin and is currently being considered for another trial of a spinal stimulator. Reasonable alternatives for this severe multi-level nerve compression with painful nerve scarring have failed, with the exception of OxyContin. Functionality improvements have been well documented (despite the chronic condition) and are noted to be specifically attributable to the OxyContin. Therefore, the ODG criteria have been met and the request is reasonable and medically necessary as documented.

Reference: ODG-Pain Chapter

OxyContin® is the brand name of a time-release formula of the analgesic chemical oxycodone, produced by the pharmaceutical company Purdue Pharma. See Opioids for general guidelines, as well as specific Oxycodone controlled release (OxyContin®) listing for more information and references. This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System that are under FDA investigation. (FDA, 2008) On April 2, 2010, the FDA approved a new formulation of OxyContin designed to discourage abuse, but according to the manufacturer, there is no evidence that the reformulation is less subject to misuse, abuse, diversion, overdose or addiction. (FDA, 2010) Due to issues of abuse and Black Box FDA warnings, Oxycontin is recommended as second line therapy for long acting opioids. [Oxycontin ranked #1 in amount billed for WC in 2011. (Coventry, 2012)] Oxycodone immediate release (OxyIR® capsule; Roxicodone® tablets; generic available), Oxycodone controlled release (OxyContin®): [Boxed Warning]: Oxycontin® Tablets are a controlled release formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Oxycontin tablets are NOT intended for use as a prn analgesic. Side Effects: See opioid adverse effects. Analgesic dose: (Immediate release tablets) 5mg every 6 hours as needed. Controlled release: In opioid naive patients the starting dose is 10mg every 12 hours. Doses should be tailored for each individual patient, factoring in medical condition, the patient's prior opioid exposure, and other analgesics the patient may be taking. See full prescribing information to calculate conversions from other opioids. Note: See manufacturer's special instructions for prescribing doses of over 80mg and 160mg. Dietary caution: patients taking 160mg tablets should be advised to avoid high fat meals due to an increase in peak plasma concentration. (Product information, Purdue Pharma) There is no evidence that has been found to support extended-release opioids vs. immediate release.

CRITERIA FOR USE OF OPIOIDS

Long-term Users of Opioids (6-months or more)

1) Re-assess

(a) Has the diagnosis changed?

(b) What other medications is the patient taking? Are they effective, producing side effects?

(c) What treatments have been attempted since the use of opioids? Have they been effective? For how long?

(d) Document pain and functional improvement and compare to baseline. 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. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument.

(e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritus, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation.

(f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships.

(g) Is there indication for a screening instrument for abuse/addiction? See Substance Abuse Screening.

2) Strategy for maintenance

(a) Do not attempt to lower the dose if it is working

(b) Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication.

(c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain.

3) Visit Frequency

(a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months.

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)