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Notice of Independent Review Decision

August 7, 2018

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
XX patch 50 mg #15, 30 days and three refills

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

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:
X Upheld (Agree)
Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a XX who was injured on XX, while grabbing an object. XX developed low back pain and then underwent lumbar fusion.

On XX, the patient was seen by XX PA, for back and right leg pain. It was noted the patient was injured on XX, while trying to prevent a heavy object from falling on a coworker. This caused severe low back injury. XX exhausted conservative treatment and went on to surgery with L4-L5 fusion and had been in chronic pain since the accident. Since the last office visit, the patient was concerned about the recent recommendation to wean XX XX. XX pain increased that month which further fueled anxiety. The present pain level was 7/10. The worse pain level was 10/10 and the best pain level was 5.10. The patient reported the back and right leg pain were the same. The pain radiated down the right side. The associated symptoms included restlessness and change in sleep pattern. The current medications were XX and XX. The past surgical history was notable for L4-L5 spinal fusion, right hip replacement/extensive revision and left total hip replacement. On exam, the patient used a walker or a cane. XX had antalgic, limping gait with substantial difficulty rising from a chair. The lumbar spine showed a well-healed surgical scar, paravertebral spasms, tenderness of the paraspinal musculature and tenderness over the facets. The lumbar range of motion (ROM) was

limited and painful. The bilateral straight leg raising (SLR) had no pain below the knee at 60 degrees. The diagnoses were chronic pain syndrome related to a work injury of XX to the lumbar spine, chronic pain syndrome, post-laminectomy syndrome, lumbar radiculopathy and pain in the right hip. XX reviewed the 4A's and noted no abnormal findings. The plan was to continue medications and HEP. A prescription for XX 75 mcg/XX and XX10-325 mg was given.

On XX, a urine drug screen was consistent with the medication regimen. The study was positive for XX, XX XX XX and XX.

From XX, through XX XX performed periodic follow-up evaluation. The patient continued to have back and right leg pain. The pain level was rated at 5/10. XX had tried XX 100 mg three times daily with no effect. XX continued to have difficulty ambulating. The examination and diagnoses were essentially unchanged. The patient was continued on XX 75 mcg/hour and XX 10-325 mg.

On XX the patient was seen by XX in a follow-up visit. It was noted on XX the patient had decreased XX from 75 mcg to 50 mcg for XX equivalent dose of 240 mg/day. The patient had increased pain, since decrease in medication. XX reported lower quality of life. XX was worried XX would not be able to function with lower doses. The present pain level was 6-7/10. XX assessed the patient had not done well with decrease in XX medication. The plan was to watch XX function over the next few months and discuss possible decreases. XX 50 mcg/hour and XX XX

Per Utilization Review dated XX, the request for XX 50 mg #15, 30 days three refills was denied based on the following rationale: "*The records submitted for review would not support the requested XX mg as reasonable or necessary. The request does not match the recommendations noted in the records. Further, the specific efficacy of XX is unclear as there are no clear functional improvements noted in the recent clinical reports as a result of the ongoing use of this medication. No substantial pain relief was evident. The records also did not include any recent risk assessments or urine drug screen testing for compliance measures as recommended by guidelines for long term use of narcotic medications. This would be indicated given that the claimant's current MED exceeds the maximum recommended by current evidence-based guidelines. Given these issues which do not meet guideline recommendations, this reviewer cannot recommend certification for the request. While the requested medication does not meet medical necessity based on information presented it is expected that the ordering provider will follow recommended medication guidelines for safe discontinuation.*"

On XX, XX wrote a letter documenting the following: "The patient has failed back surgery and is left with debilitating pain with the only option for treatment being chronic XX medication. XX has been stable for years with much higher doses than XX is currently prescribed. While we continue to seek the "lowest effective dose", at present we essentially are at that dose. Further decreases are going to likely render this patient bedbound. We continue to monitor this patient every other month (the Carrier will not allow our usual monthly monitoring). We continue to do urine drug screens every six months as allowed by the Carrier. The patient is always dependable and prudent but never appears overmedicated or under the influence. XX pain is moderated but not fully relieved by the

medications prescribed. Certainly, XX ability to be in any sense active hinges on the moderate relief offered by these medications."

On XX XX performed a follow-up evaluation. The patient's current pain level was 5-6/10. The worst pain level was 10/10. Since the last visit, XX back and right leg pain was same. The pain radiated down the right side. Associated symptoms included restlessness and change in sleep pattern. XX current pain medications were XX, XX and XX. On exam, the patient walked with an antalgic, limping gait with substantial difficulty rising from a chair. The lumbar spine showed well-healed surgical scar, paravertebral spasms, tenderness of the paraspinal musculature and tenderness over the facets. The lumbar ROM was limited and painful. The bilateral SLR had no pain below the knee at 60 degrees. The diagnoses were chronic pain syndrome related to a work injury of XX, to the lumbar spine, chronic pain syndrome, postlaminectomy syndrome, lumbar radiculopathy and right hip pain. The plan was to further decrease the dose of fentanyl next month from 50 mcg to 37.5 mcg. The recommendations were to continue the medications at the current strength and dose, refill as scheduled and continue HEP. A prescription for XX 50 mcg/hour XX 72 hour, 30 days, dispense #15 and XX 10-325 mg oral tablet was given.

Per Reconsideration review dated XX, the denial for XX 50 mcg/hour #15 for 30 days x3 months was upheld on the basis of following rationale: "*According to the Official Disability Guidelines, ongoing use of XX must be monitored by the direction of the 4 A's. The 4 A's for ongoing monitoring include analgesia, ADLs, adverse side effects, and aberrant drug-taking behavior. The request was previously denied as there was no documentation noting efficacy with the use of this medication nor compliance. The clinical documentation submitted for review indicated this patient had pain to the low back. However, there was no documentation noting pain and activities of daily living with and without the use of this medication. Further, a recent urine drug screen was not provided to determine medication compliance. I discussed the case with Richard Todd, PA; XX was unable to provide specific documentation of functional improvement from the medication regimen. Given the information obtained in this successful peer to peer conversation, the request is not supported. As such, the requested XX 50 mcg/hr #15 for 30 days x3 months remains non-certified.*"

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

Appendix A, ODG Workers' Compensation Drug Formulary (As of XX)

XX transdermal is a "N" status drug on the Formulary. The most recent review, XX stated there was no documentation noting pain and activities of daily living with and without the use of this medication. Further, a recent urine drug screen was not provided to determine medication compliance and specific documentation of functional improvement from this medication was provided. No new evidence is available to certify a pre-authorization on this "N" status medication. The medication should be weaned as it is not certified.

When discontinuing XX and not converting to another XX, use a gradual downward titration, such as a 50% dosage reduction every 6 days, while monitoring carefully for signs and symptoms of withdrawal. If the patient develops these signs or symptoms, raise the dose to the previous level and taper more slowly, either by increasing the interval between decreases, decreasing the amount of change in dose, or both. Do not abruptly discontinue XX. It is not known at what dose level XX may be discontinued without producing the signs and symptoms of XX withdrawal.

Significant amounts of XX continue to be absorbed from the skin for 24 hours or more after the XX is removed. To convert patients to another XX remove XX and titrate the dose of the new analgesic based upon the patient's report of pain until adequate analgesia has been attained. Upon system removal, 17 hours or more are required for a 50% decrease in XX concentrations. Withdrawal symptoms are possible in some patients after conversion or dose adjustment.
☐ Medically Necessary

X Not Medically Necessary

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES