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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Pain Medications Tramadol 50 mg #180 and Oxycodone 30 mg #120

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

Physician 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)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who was injured on XX/XX/XX, while performing his duties as a XX. The patient was moving a X and the X got stuck and he had to push it. While doing this he injured his lumbar spine and felt a pop in his left shoulder.

On XX/XX/XX, XX evaluated the patient for pain with burning in the left lower extremity. The patient stated he had extensive injections including lumbar epidural injection, lower facet injections and piriformis injections all of which provided temporarily for anywhere from three to six months. Examination showed the patient was distressed chronically related to his lumbar spine and left shoulder and he was able to heel and toe walk bilaterally. There was tenderness noted diffusely at the lumbar paraspinal muscles. He had a positive left straight leg raising test in the sitting position. Shoulder examination showed he had a full range of motion of the left shoulder with minimal pain. There was decreased sensation noted to light touch and pinprick at the left lateral lower extremity. The impression was L4-L5 fusion and L5-S1 prosthesis and chronic lumbar radiculitis affecting the left lower extremity. Treatment included Mobic, Opana and Nucynta. The plan was to discontinue Dilaudid and Soma.

On XX/XX/XX, XX evaluated the patient. The patient stated Mobic was not helping and would like to discontinue that secondary to his stomach side effects. Physical examination and the diagnoses remained the same. The treatment plan was to continue with the Opana 30 mg, ER and Nucynta and discontinue Mobic.

On XX/XX/XX, XX evaluated the patient and stated the plan was to continue with OxyContin 30 mg ER and Oxycodone 15 mg, IR and discontinue the Nucynta.

On XX/XX/XX, XX noted the patient felt that the Nucynta was not helpful and Oxycodone had been helpful. Examination remained unchanged. The plan was to discontinue Opana and continue with MS-Contin 30 mg and Oxycodone 15 mg IR.

On XX/XX/XX, XX evaluated the patient for his ongoing chronic issues related to his lumbar spine. The patient was on narcotic contract and there had been no issues with the medications. Examination showed the patient was able to heel and toe walk but with significant difficulty. The ROM of the lumbar spine was 35 degrees of flexion and 20 degrees of extension. He had a positive left straight leg raising in the sitting position and a negative Patrick-Fabere's test bilaterally. The deep tendon reflexes were +2/4 in the lower extremities and sensation was decreased to the left lateral lower extremity. The medications were MS-Contin, 30 mg and Oxycodone 15 mg IR.

On XX/XX/XX, an x-ray of the lumbar spine was performed at XX which showed posterolateral fusions at L4-L5 and disc prosthesis t L5-S1.

On XX/XX/XX, XX evaluated the patient who was injured at work on XX/XX/XX. The patient was injured at his low back and left shoulder. He had a fusion at L4-L5 and prosthesis at L5-S1 in XX. He had ongoing symptoms in the left lower extremity. He stated his left shoulder was treated conservatively. The patient stated his pain was worse with prolonged sitting, heavy lifting and straining on a daily basis. His pain was better with hydration, stretching and medications. Examination showed he was able to stand on his heels and his toes but he was unable to heel and toe walk. The lumbar ROM was decreased with 28 degrees of flexion and 16 degrees of extension. He had tenderness centrally at the lumbar paraspinal muscles with tenderness to palpation at the left lumbar paraspinal muscles. He had a positive left straight leg raising test in the sitting and the supine positions. He had tenderness noted at the left sacroiliac joint with a positive left Patrick-Fabere's test. He also had tenderness to palpation at the left sacroiliac joint and at the left PSIS. Neurological examination showed there was decreased sensation noted at the left L5-S1 distribution. There was a difference of one centimeter in the lower extremities. The impressions were lumbar spine and left shoulder injury related to Worker's Compensation claim on XX/XX/XX, status post L4-L5 fusion and L5-S1 disc prosthesis, ongoing chronic lumbar radiculopathy affecting the left lower extremity, and left shoulder strain which was treated conservatively at his initial injury. The patient stated he had not been taking narcotics and it had caused a severe dysfunction in his life. The plan was to start Oxycodone 15 mg, IR.

On XX/XX/XX, XX documented a pain medication agreement.

On XX/XX/XX, a urine drug screening report showed inconsistent result for tramadol.

On XX/XX/XX, XX evaluated the patient for his ongoing chronic issues with his left shoulder and lumbar spine. Physical examination showed he was able to stand on his heels and toes but was not able to heel and toe walk. The ROM of the lumbar spine continued to decrease with both flexion and extension. He had a positive left straight leg raising test in the sitting and supine positions. He also had a left Patrick-Fabere's test. There was tenderness to palpation noted in the lumbar paraspinal muscles. The deep tendon reflexes were +2/4 in the upper and lower extremities. The manual muscle testing showed some slight difference with measurements of one or two centimeter differences. The diagnoses remained unchanged. The plan was to start Embeda 30 mg ER, Oxycodone 15 mg, IR and discontinue Ultram.

On XX/XX/XX, XX noted the patient was using Embeda once a day rather than twice a day and Oxycodone twice a day for immediate release. The plan was to continue usage of Embeda once a day, Oxycodone 15 mg IR #60 and start Movantik 25 mg #30.

On XX/XX/XX, XX evaluated the patient for his chronic issues of left shoulder and lumbar spine. XX noted the medication Embeda was used due to the fact that it was actually the current recommendation related to the medication abuse and medication diversion. The patient had problems with Opioid constipation. XX noted Movantik was actually the medication of choice for that issue when the other over the counter and other prescription medication had not worked. Physical examination remained unchanged. The plan as to start Ultram 50 mg and Oxycodone 15 mg.

On XX/XX/XX, XX noted the patient's complaints were unchanged. The patient continued to need medications which was agreed by the Peer Review doctor. The treatment plan was unchanged.

On XX/XX/XX, a urine drug screening report showed positive results for Oxycodone and tramadol.

On XX/XX/XX, XX noted the patient's drug screening was done on XX/XX/XX which showed no issues with the medications. The treatment remained the same.

On XX/XX/XX, XX evaluated the patient for his unchanged complaints of left shoulder and lumbar spine. The treatment plan was with Ultram 50 mg and Oxycodone 30 mg.

On XX/XX/XX, XX saw the patient and noted the trial of treatment was also done with other medication but they had not worked as well as the short acting Oxycodone and the Tramadol. Refill was given for Oxycodone and Ultram. The patient was advised to continue full duty with no restrictions.

On XX/XX/XX, XX evaluated the patient for ongoing chronic issues with his left shoulder and lumbar spine. The treatment plan remained the same.

On XX/XX/XX, a urine drug screening report was positive for Oxycodone and oxymorphone.

On XX/XX/XX, XX saw the patient in follow up. The patient continued to work full duty at XX and used medications related to his lumbar spine surgery. The patient was on a narcotic contract and was undergoing random urine screening. Examination showed ROM of the lumbar spine continued to decrease with both flexion and extension. He had a positive left straight leg raising test in the sitting and supine position and had a positive left Patrick-Faber's test. There was tenderness to palpation in the lumbar paraspinal muscles. Ultram and Oxycodone were prescribed. The patient was advised to work full duty with no restrictions as the medications were enabling the patient to do so.

On XX/XX/XX, XX evaluated the patient for ongoing chronic issues with his left shoulder and lumbar spine. He was able to stand on his heels and toes but was not able to heel and toe walk. The lumbar spine examination showed the range of motion (ROM) continued to decrease with both flexion and extension. He had a positive left straight leg raising testing in the sitting and supine position and had a positive left Patrick-Fabere's test. There was tenderness to palpation noted in the lumbar paraspinal muscles. The deep tendon reflexes were +2/4 in the upper and lower extremities. The manual muscle testing showed some slight difference with measurements of one to two centimeter differences. However, the manual testing was 5/5 in the lower extremity. The diagnoses were lumbar spine and left shoulder injury related to Worker's Compensation claim on XX/XX/XX, status post L5 fusion and an L5-S1 disc prosthesis, ongoing chronic lumbar radiculopathy affecting the left lower extremity, left shoulder strain treated conservatively. The treatment was with Oxycodone 30 mg, and Ultram 50 mg. XX noted the medications would allow the patient to continue to work full duty with no restrictions along with decreasing his pain level from a seven to three.

On XX/XX/XX, XX performed a utilization review and denied the services for Tramadol HCl 50 mg #180 and Oxycodone 30 mg #120 with the following rationale: *Regarding Tramadol HCl 50 mg #180, ODG-TWC Pain Procedure Summary Online version last updated XX/XX/XX stated that opioid analgesic was a class of drugs (e.g., morphine, codeine and methadone) that have a primary indication to relieve symptoms related to pain. There were considered the most powerful class of analgesic that may be used to manage both acute and chronic pain. In this case, the claimant was currently prescribed with Tramadol 50 mg, Oxycodone 15 mg, Embeda 30/1.2 mg and Movantik 25 mg. There was no indication of objective functional gain with prior use of this medication and no documentation of ODG opioid medication guideline, attempt at weaning/tapering and an updated and signed pain contract between the provider and claimant. There was no recent documentation submitted for review outlining the claimant's current condition that would warrant the continued use of opioid medications. Therefore, non-certification was recommended for Tramadol HCL 50 mg #180. Regarding Oxycodone 30 mg #120, ODG-TWC Pain Procedure Summary Online Version last updated XX/XX/XX stated that opioid analgesics were a class of drugs (e.g. morphine, codeine and methadone) that have a primary indication to relieve symptoms related to pain. They were considered the most powerful class of analgesics that might be used to manage both acute and chronic pain. In this case the claimant was currently prescribed with Tramadol 50 mg, Oxycodone 15 mg, Embeda 30/1.2 mg, and Movantik 25 mg. There was no indication of objective functional gain with prior use of this medication and no documentation of ODG opioid medication guideline compliance documentation, including documentation of current urine drug test, risk assessment profile, attempt at weaning/tapering and an updated and signed pain contract between the provider and claimant. There was no recent documentation submitted for review outlining the claimant's current condition that would warrant the continued use of opioid medications. Therefore, non-certification was recommended for Oxycodone 30 mg #120.*

Per Reconsideration review dated XX/XX/XX, XX, denied the services for Tramadol HCL 50 mg #180 and Oxycodone 30 mg #120 with the following rationale: *Regarding Tramadol HCL 50 mg #180, ODG states that ongoing review and documentation of pain relief, functional status, appropriate medication use, and the side effects should be included in ongoing management for opioid use. In this case, the claimant was able to work full duty without restriction while on medications. The claimant was being monitored for compliance by urine drug test every three to four months. However, there was no documentation of a pain contract, risk assessment profile and attempts at weaning and tapering in accordance to ODG guidelines for chronic opioid use. Initial physician report dated XX/XX/XX noted that the tramadol HCL 50 mg #180 was non certified, as there was no indication of objective functional gain with prior use of this medication and no documentation of ODG opioid medication guideline compliance documentation, including documentation of current urine drug test, risk assessment profile, attempt at weaning/tapering and an updated and signed pain contract between the provider and claimant. No such documentation has been submitted for this review, given that the necessary documentation to certify the request was delineated in the initial peer review. Therefore, medical necessity for Tramadol HCL 50 mg #180 was not established. Non certification was recommended. Regarding Oxycodone 30 mg #120, ODG states that ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects should be included in ongoing management for opioid use. In this case, the claimant was able to work full duty without restrictions while on medications. The claimant was being monitored for compliance by urine drug tests every three to four months. However, there was no documentation of a pain contract, risk assessment profile, and attempts at weaning and tapering in accordance to ODG guidelines for chronic opioid use. Initial peer physical report dated XX/XX/XX noted that the Oxycodone 30 mg #120 was non certified, as there was no indication of objective functional gain with prior use of this medication and no documentation of ODG opioid medication guideline compliance documentation, including documentation of current urine drug test, risk assessment profile, attempt at weaning/tapering and an updated and signed pain contract between the provider and claimant. No such documentation had been submitted for this review, given that the necessary documentation to certify the request was delineated in the initial peer review. Therefore, medical necessity for Oxycodone 30 mg #120 was not established. Non-certification was recommended.*

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

Regarding the oxycodone and tramadol for breakthrough pain, the patient has not been adequately assessed for hyperalgesia as well as lack of documentation regarding why patient requires risk of mixing medications (continuous breakthrough medication) rather than increase of original opioid (morphine). Thus, the medical necessity of these medications has not been established.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Opioid hyperalgesia

Recommend screening and treatment as indicated below.

Definition: Patients who receive opiate therapy sometimes develop unexpected changes in their response to opioids. This may include the development of abnormal pain (hyperalgesia), a change in pain pattern, or persistence in pain at higher levels than expected. These types of changes occur in spite of continued incremental dose increases of medication. Opioids in this case actually increase rather than decrease sensitivity to noxious stimuli. It is important therefore to note that a decrease in opioid efficacy should not always be treated by increasing the dose, but may actually require weaning. ([Chang, 2007](#))

Diagnosis: How to diagnose:

- (1) Attempt to determine if pain has increased over that, which was pre-existing (in the absence of apparent disease progression).
 - (2) Attempt to determine if the patient has previously responded to opioids but now has worsening pain.
 - (3) Attempt to determine if the patient has never had improved pain with opioids.
 - (4) If disease progression is ruled out, determine if there is evidence of possible opioid tolerance or opioid hyperalgesia.
 - (5) Evaluate pain: In cases of opioid hyperalgesia pain may spread and become more diffuse and less well-defined in quality, beyond what would be expected from the preexisting pain state. This is generally not an acute but is an insidious process.
 - (6) Psychological issues such as secondary gain, exacerbation of underlying depression or anxiety, and the development of addictive disease should also be ruled out. **Treatment:** Suggested treatment for patients with increasing pain (assumes that the patient has had improvement with opioids at some point):
 - (1) It is not unreasonable to give a trial of opioid dose escalation to see if pain and function improves. If pain improves, the diagnosis is probable tolerance. If pain does not improve or worsens, this may be evidence of opioid hyperalgesia and the opioid dose should be reduced or weaned.
 - (2) Another option to consider is opioid rotation.
 - (3) Use of adjuvant pain medications is recommended when there is evidence of either tolerance or hyperalgesia.
 - (4) When there is no evidence of pain improvement after opioid dosage is increased, further evaluation by a specialist with additional expertise in psychiatry, pain medicine, or addiction medicine should be considered.
- Recent research:** Clinicians should suspect opioid-induced hyperalgesia (OIH) when opioid treatment effect seems to wane in the absence of disease progression, particularly in the context of unexplained pain reports or diffuse allodynia unassociated with the original pain, and increased levels of pain with increasing dosages. The treatment involves reducing the opioid dosage, tapering them off, or supplementation with NMDA receptor modulators. ([Lee, 2011](#)) Office-based detoxification, reduction of opioid dose, opioid rotation, and the use of specific NMDA receptor antagonists are all viable treatment options for OIH. The role of sublingual buprenorphine appears to be an attractive, simple option for the treatment of OIH. ([Silverman, 2009](#))