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| Case Number: | CM14-0027619 | | |
| Date Assigned: | 06/13/2014 | Date of Injury: | 03/15/2012 |
| Decision Date: | 07/21/2014 | UR Denial Date: | 02/12/2014 |
| Priority: | Standard | Application Received: | 03/04/2014 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

Patient is an injured worker with lumbago, lumbosacral disc degeneration, right L4 radiculitis, and right L4-S1 lumbar facet syndrome. Date of injury was 03-15-2012. Utilization review dated February 12, 2014 provided a case summary: The patient is a 34-year-old female who sustained her injuries on 03/15/2012. Assessments include chronic pain syndrome, lumbago, lumbosacral disc degeneration, right L4 radiculitis, and right L4-S1 lumbar facet syndrome. MRI on 4/29/13 revealed mild lower lumbar spondylosis with facet arthropathy at L3-4, L4-5 and L5-S1 without nerve root compression. The patient had five PT visits on 1/30/13 with some improved mobility. She was certified for additional PT in 9/2013. She also received acupuncture treatments. She underwent L3-4, L4-5 and L5-S1 facet injection on 7/10/13 with relief of back pain for one day. Bilateral L4 and L3 transforaminal epidural steroid injection was performed on 8/28/13 with 100% relief. She likewise improved with the second epidural steroid injection. She attended six pain management counseling sessions without significant changes. As per the latest progress report dated 2/4/14, the patient has new pain in the left lower limb. She stated that following her repeat ESI, a nerve was hit. The effects of the steroid have worn off. She is complaining of worsening pain described as constant and radiating down the left leg into the anterior thigh, anterior leg, and into the 2nd and 3rd digit of the left foot. Strength was at least 4/5 for hip flexor, knee extensor / flexor, ankle dorsiflexor / invertor / evertor / plantar flexor and hallucis longus muscle strength bilaterally. Light touch is intact in the lower limbs but sensation to pinprick is diminished in the left L3-S1 dermatomal distribution. Reflexes were normal. Current medications are Relafen 750 mg twice daily, Ativan 1 mg daily, Opana ER 5 mg every 8 hours, and Gralise 30 day pack. She is to continue Pamelor. The drug screen on 10/29/13 did not detect Ativan or Pamelor. The current prescription, is for Opana 10 mg to be taken twice daily. It is unclear in the records how long the patient has been on Opana. According to the 9/30/13

examination, the patient began weaning from Opana a week before the examination but noted significant recurrence of radicular pain when she did that. There was "some improvement in symptoms" with her medications but pain is usually rated 8-9/10. There was "good benefit" from Opana without side effects based on the 5/31/13 and 11/12/13 reports. UR Determination: The prospective request for 60 Tablets of Opana Extended Release 10 mg between 2/7/2014 and 3/24/2014 was not medically necessary. Date of UR was 02-12-2014.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

60 TABLETS OF OPANA EXTENDED RELEASE 10 MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308.

Decision rationale: Medical treatment utilization schedule (MTUS) American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 12 Low Back Complaints presents a Summary of Recommendations for Evaluating and Managing Low Back Complaints (Table 12-8) states that using opioids for more than 2 weeks is not recommended. Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines states that regarding chronic back pain and opioids: Long-term efficacy is unclear (>16 weeks), but also appears limited. Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. Regarding treatment of chronic lumbar root pain: A limitation of current studies is that there are virtually no repeated dose analgesic trials for neuropathy secondary to lumbar radiculopathy. A recent study that addressed this problem found that chronic lumbar radicular pain did not respond to either a tricyclic antidepressant or opioid in doses that have been effective for painful diabetic neuropathy or postherpetic neuralgia. FDA Prescribing Information for OPANA ER presents warnings: addiction, abuse, and misuse; life-threatening respiratory depression; and interaction with alcohol. OPANA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Serious, life-threatening, or fatal respiratory depression may occur with use of OPANA ER. OPANA ER is contraindicated in patients with moderate or severe hepatic impairment. Patients with renal impairment require monitoring. OPANA ER contains oxymorphone, a Schedule II controlled substance. Patients must not consume alcoholic beverages or prescription or non-prescription products containing alcohol while on OPANA ER therapy. Hypotension, profound sedation, coma, respiratory depression, and death may result if OPANA ER is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). OPANA ER may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant

drugs. Monitor these patients for signs of hypotension after initiating or titrating the dose of OPANA ER. Patient is an injured worker with lumbago, lumbosacral disc degeneration, right L4 radiculitis, and right L4-S1 lumbar facet syndrome. Date of injury was 03-15-2012. MRI on 4/29/13 revealed mild lower lumbar spondylosis with facet arthropathy at L3-4, L4-5 and L5-S1 without nerve root compression. Bilateral L4 and L3 transforaminal epidural steroid injection was performed on 8/28/13 with 100% relief. She likewise improved with the second epidural steroid injection. As per the latest progress report dated 2/4/14, the patient has new pain in the left lower limb. She is complaining of worsening pain described as constant and radiating down the left leg into the anterior thigh, anterior leg, and into the 2nd and 3rd digit of the left foot. Current medications are Relafen 750 mg twice daily, Ativan 1 mg daily, Opana ER 5 mg every 8 hours, Gralise 30 day pack, Pamelor. Medical records did not document laboratory tests to evaluate hepatic and renal function. Patient was also prescribed Ativan which is a CNS depressant. Blood pressure measurements were not documented. Alcohol consumption history was not documented. MTUS and ACOEM guidelines do not support the long term use of opioids for chronic back pain. Medical records do not address the risks of Opana ER. MTUS and ACOEM guidelines and medical records do not support the medical necessity of Opana ER 10 mg. Therefore, the request for 60 TABLETS OF OPANA EXTENDED RELEASE 10 MG is Not medically necessary.