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| Case Number: | CM14-0063824 | | |
| Date Assigned: | 07/11/2014 | Date of Injury: | 02/08/2011 |
| Decision Date: | 09/23/2014 | UR Denial Date: | 04/28/2014 |
| Priority: | Standard | Application Received: | 05/06/2014 |

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 Physical Medicine and Rehabilitation 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:

The injured worker is a 61-year-old male with a reported date of injury on 02/08/2011. The mechanism of injury was not submitted within the medical records. His diagnoses were noted to include chronic discogenic back pain, bilateral lower extremity radiculopathy with multilevel degenerative change and central canal stenosis to L4-5 and transitional lumbar segment with degenerative lumbar disc disease. His previous treatments were noted to include medications, a TENS unit, and exercise. The progress note dated 04/02/2014 revealed complaints of sleep deprivation due to chronic pain and depression. The injured worker complained of gastritis that interfered with intake of NSAIDs but responded to H2 blockers. The injured worker complained of muscle spasms and facet generated pain with the loss of full upright posture. The physical examination of the lumbar spine revealed forward hunching measured 5 degrees. There was tenderness noted to the L5 facet region and moderate right paravertebral spasm that measured 8 cm in width on the right compared with the spasm measuring 4 cm on the left. Extension produced pain the two left L5 region. The range of motion was diminished. There was muscle spasm that measured 2+ bilaterally in the lumbosacral region. The manual muscle testing revealed the left lower extremity was decreased and there was decreased sensation to the S1 dermatome. The Request for Authorization form was not submitted within the medical records. The request was for Nucynta 150 mg #30 for severe pain, Norco 10/325 mg #60 for severe pain, magnesium oxide 400 mg #30 for opioid induced constipation and leg cramps, metaxalone 800 mg #60 for increased muscle spasms, and Flector patches daily #30 for lower back pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta 150mg, #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Tapentadol (Nucynta).

Decision rationale: The injured worker has been utilizing this medication since at least 03/2014. The Guidelines recommend Nucynta as a second line therapy for patients who develop intolerable adverse effects with first line opioids. The recent large random controlled trials concluded that Tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis of the knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. Nucynta extended release is FDA approved for moderate to severe chronic pain. There is a lack of documentation regarding evidence of a significant pain relief with the use of medications, improved functional status, side effects, and whether the injured worker has had consistent urine drug screens and when the last test was performed. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Norco 10/325mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 76-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78.

Decision rationale: The injured worker has been utilizing this medication since at least 03/2014. According to the California Chronic Pain Medical Treatment Guidelines, the ongoing use of opioid medications may be supported with detailed documentation of pain relief, functional status, appropriate medication use, and side effects. The Guidelines also state that the 4 A's for ongoing monitoring including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors should be addressed. There is a lack of documentation regarding evidence of decreased pain on a numerical scale with the use of medications. There is a lack of documentation regarding improved functional status with activities of daily living with the use of medications. There is a lack of documentation regarding side effects with the use of these medications. There is a lack of documentation regarding consistent urine drug screens and when the last test was performed. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

Magnesium oxide 400mg, #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Magnesium Oxide:MedlinePlus.

Decision rationale: The injured worker has been utilizing this medication since at least 12/2013. Magnesium is an element your body needs to function normally. Magnesium oxide may be used for different reasons. Some people use it as an antacid to relieve heartburn, sour stomach, or acid indigestion. Magnesium oxide also may be used as a laxative for short term, rapid emptying of the bowel (before surgery, for example). It should not be used repeatedly. Magnesium oxide also is used as a dietary supplement when the amount of magnesium in the diet is not enough. Magnesium oxide is available without a prescription. There is a lack of documentation regarding the medical necessity of this medication as the injured worker was not identified as having a magnesium deficiency. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Metaxalone 800mg, #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: The injured worker has been utilizing this medication since at least 12/2013. The California Chronic Pain Medical Treatment Guidelines recommend non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. There is a lack of documentation regarding efficacy of this medication and the request failed to provide the frequency at which this medication is to be utilized. Additionally, the Guidelines recommend short term utilization for this medication and the injured worker has been utilizing this medication for over 6 months. Therefore, the request is not medically necessary.

Flector patches daily, #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The injured worker has been utilizing this medication since at least 03/2014. The California Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The Guidelines state the efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward or with a diminishing effect over another 2 week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for up to 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if effective results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long term studies of their effectiveness or safety. The Guidelines indications for topical NSAIDs is for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis at the spine, hip, or shoulder. The FDA approved agent that is a topical NSAID modality is Voltaren gel 1% which is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for the treatment of the spine, hip, or shoulder. The Guidelines do not recommend diclofenac for the spine, hip, or shoulder due to the lack of evidence. Additionally, the FDA approved agent diclofenac 1% is recommended and the Flector patch which is 1.3% exceeds Guideline recommendations. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.