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| Case Number: | CM15-0121467 | | |
| Date Assigned: | 07/08/2015 | Date of Injury: | 09/26/2011 |
| Decision Date: | 09/10/2015 | UR Denial Date: | 06/04/2015 |
| Priority: | Standard | Application Received: | 06/22/2015 |

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: New York
 Certification(s)/Specialty: Emergency Medicine

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 46 year old female, who sustained an industrial injury on September 26, 2011. She reported low back, legs, and right ankle injuries. The injured worker was diagnosed as having reflex sympathetic dystrophy, complex regional pain syndrome, and right ankle pain. Diagnostic studies to date have included: On August 26, 2013, x-rays of the right ankle were unremarkable. On February 24, 2015, x-rays of the lumbar spine revealed degenerative anterior superior, anterior inferior, and right lateral endplate osteophytes at lumbar 3-lumbar 5. On March 13, 2015, a Sudoscan-Sudomotor testing was performed, which revealed abnormal hands and feet symmetry, but normal conductance levels. Surgeries: spinal cord stimulator in 2013, spinal cord stimulator revision in February 2014, and a new spinal cord stimulator implantation on December 1, 2014. Treatment to date has included physical therapy, a transcutaneous electrical nerve stimulation (TENS) unit, a fracture brace walker, an ankle brace, psychotherapy, and medications including opioid analgesic, anti-epilepsy, topical analgesic, muscle relaxant, and non-steroidal anti-inflammatory. There were no noted previous injuries or dates of injury. Comorbid diagnoses included history of anxiety and depression. On May 21, 2015, the injured worker complains of right lower back pain radiating down the right leg, right hip, and right ankle pain, 8/10. She complains of constant burning and throbbing right ankle pain extending up her right leg, which is worsened since the prior visit. She complains of a new onset of right leg tingling, and the pain is now in the left leg. Her pain is constant and unrelieved by medications. She reports minimal improvement with the use of a TENS unit throughout most of the day and physical therapy can exacerbate her pain. Her current medications include Ketamine cream,

which provides only 30 minutes relief. She stopped using Lidoderm because it wasn't helping. She does not report any relief of symptoms by her spinal cord stimulator since 1.5 months after her spinal cord stimulator revision. Her pain was rated: 6/10 = rest, 8-9/10 = activity and 4/10 =best. Her pain is aggravated by pain and relieved by elevating leg, rest, and TENS. The physical exam revealed clean, dry, and intact surgical sites over the right chest/flank, lumbar spine, and left upper buttock. There was burning along the lumbar spine incision with touch. There was no sign of infection of the lumbar spine surgical site. There were no focal neurological deficits. The treatment plan includes Lidoderm 5% topical patch 1 daily, Ibuprofen 600mg 1 tablet every 6 hours as needed, and Ketamine/Ketoprofen/Lidocaine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidoderm 5 Percent Topical Patch #30: Upheld

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

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

Decision rationale: According to the California Medical Treatment Utilization Schedule guidelines recommends Lidoderm only for localized peripheral neuropathic pain after trials of "tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica". Lidoderm is the only form of topical lidocaine that is indicated for neuropathic pain. The California Medical Treatment Utilization Schedule guidelines recommends against Lidoderm for low back pain or osteoarthritis. Any topical agent with lidocaine is not recommended if it is not Lidoderm. Lidoderm is the only topical lidocaine indicated for neuropathic pain. There was lack of evidence of any trials of first-line therapy with tri-cyclic or SNRI anti-depressants or an anti-epilepsy drugs such as gabapentin or Lyrica. The medical records show that the injured worker had stopped using the Lidoderm patch as it was not helping. Therefore, the request for Lidoderm patches 5% is not medically necessary.

Ibuprofen 600 MG #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, specific drug list & adverse effects: Ibuprofen (Motrin, Advil [otc], generic available) Page(s): 67-68; 70-71.

Decision rationale: The requested medication is Ibuprofen. Per the California Medical Treatment Utilization Schedule (CMTUS) guidelines, non-steroidal anti-inflammatory drugs are recommended as a second-line treatment after acetaminophen for short-term treatment of osteoarthritis, including the knee and hip, acute exacerbations of low back pain symptoms, and

chronic low back pain. The injured worker has been taking Ibuprofen since at least January 6, 2015, which exceeds the guideline recommendation. There was documentation that her medications were not relieving her pain. Therefore, the Ibuprofen is not medically necessary.

Ketamine/Ketoprofen/Lidocaine: Upheld

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

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

Decision rationale: The requested medication is Ketamine/Ketoprofen/Lidocaine topical cream, is noted in the medical records as Ketamine/Ketoprofen/Lidocaine 5.525 gm-5.525gm-2.48 gm. This compounded topical medication contains Ketamine 10%, Ketoprofen 20%, and Lidocaine 3%. The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In addition, CMTUS does not recommend any compound product that contains at least one drug (or drug class) that is not recommended. Per the CMTUS guidelines, Ketamine is under study and is only recommended after all primary and secondary treatment has been exhausted for the treatment of neuropathic pain in refractory cases. "Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results." Per the CMTUS guidelines, topical Lidocaine is recommended for neuropathic pain after trials of "tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica". Lidoderm is the only form of topical lidocaine that is indicated for neuropathic pain. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are recommended for the short-term (4-12 weeks) treatment of osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. Ketoprofen is a non-Food and Drug Administration (FDA) approved agent that is not currently approved for topical application. There was lack of evidence of any trials of first-line therapy with tri-cyclic or SNRI anti-depressants or an anti-epilepsy drugs such as gabapentin or Lyrica. There was documentation of topical Ketamine only provided 30 minutes of pain relief. This compounded topical medication contains topical lidocaine and any topical agent with lidocaine is not recommended if it is not Lidoderm. Therefore, the request for Lidoderm 5% topical patch is not medically necessary.