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| Case Number: | CM14-0037679 | | |
| Date Assigned: | 06/25/2014 | Date of Injury: | 12/10/2010 |
| Decision Date: | 08/19/2014 | UR Denial Date: | 02/27/2014 |
| Priority: | Standard | Application Received: | 03/28/2014 |

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, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. 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 male in his mid forties who reported a slip and fall on 12/22/2010. The main injury which resulted from his slip and fall was a fractured right wrist. There was also mild head trauma. The wrist was not healing properly and eventually he was diagnosed with reflex sympathetic dystrophy (RSD). He had 3 stellate ganglion blocks which provided 10% temporary relief. He then underwent 8 sessions of physical therapy and 2 more stellate ganglion blocks which were associated with brachioplexus blocks. As with the previous blocks, the results did not last long. On 09/23/2013, his medications included Nucynta 50 mg, Cymbalta 30 mg, and trazodone 150 mg. He reported disturbances with his sleep. He stated that he does not get a restful night's sleep. It takes him approximately 2 hours to fall asleep and he awakens 4 or 5 times during the night. He reported having anxiety and feeling depressed and has attended an unknown number of counseling sessions. He was diagnosed with adjustment disorder with mixed anxiety and depressed mood. On 02/24/2014, his medications included Pennsaid, Lidoderm, Nucynta, trazodone, and Cymbalta. There were no dosages indicated. There was no rationale or request for authorization included with the submitted paperwork.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucyntin 50mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 74-95.

Decision rationale: The request for Nucyntin 50 mg #120 is not medically necessary. The submitted documentation notes that this injured worker was taking Nucynta. The request is asking for Nucyntin, and this report will continue with the belief that there was a typographical error and the requested medication was Nucynta 50 mg. The California MTUS Guidelines attest that opioid drugs are considered the most powerful class of analgesics that may be used to manage chronic pain. Ongoing review consists of documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessments should include current pain, the least reported pain over the period since last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief, and how long the pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Opioids should be continued if the patient has returned to work, or if the patient has improved functioning and decreased pain. There are no trials of long-term use. Failure to respond to a time-limited course of opioids leads to reassessment and consideration of alternative therapy. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to, but not substituted for, the less efficacious drugs. A major concern for the use of opioids for chronic pain is that most randomized control trials have been limited to a short term period of less than 70 days. Long-term use may result in immunological and endocrine problems. There is no documentation in the submitted chart to attest to appropriate long-term monitoring, evaluations, including side effects, failed trials of NSAIDs, aspirin, and/or anticonvulsants, quantified efficacy, drug screens or collateral contacts. Additionally, there is no frequency specified in the request. Therefore, this request for Nucyntin 50 mg #120 is not medically necessary.

Trazadon 20mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines ANTIDEPRESSANTS FOR CHRONIC PAIN Page(s): 13-16.

Decision rationale: The request for trazodone 20 mg #90 is not medically necessary. The California MTUS Guidelines recommend antidepressants as a first-line option for neuropathic pain, and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medications, sleep quality and duration, and psychological assessment. It is recommended that these outcome measurements should be initiated at 1 week of treatment with a

recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). Long-term effectiveness of antidepressants has not been established. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. Antidepressants are recommended as an option in depressed patients, but their effectiveness is limited. This injured worker has been diagnosed with depression and sleep disturbances have been described. However, there is no documentation of quantifiable functional improvement with either his depression or the quality of his sleep based on the use of trazadone. Additionally, the request did not include frequency of administration. Therefore, this request for trazadone 20 mg #90 is not medically necessary.

Cymbalta 60mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines ANTIDEPRESSANTS FOR CHRONIC PAIN Page(s): 13-16.

Decision rationale: The request for Cymbalta 60 mg #60 is not medically necessary. The California MTUS Guidelines recommend antidepressants as a first-line option for neuropathic pain, and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medications, sleep quality and duration, and psychological assessment. It is recommended that these outcome measurements should be initiated at 1 week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). Long-term effectiveness of antidepressants has not been established. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. Antidepressants are recommended as an option in depressed patients, but their effectiveness is limited. Cymbalta has been FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. This injured worker has been diagnosed with depression and sleep disturbances have been described. However, there is no documentation of quantifiable functional improvement with either his depression or the quality of his sleep based on the use of Cymbalta. Additionally, the request did not include frequency of administration. Therefore, this request for Cymbalta 60 mg #60 is not medically necessary.

Pennsaid 25mg (quantity unknown): Upheld

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

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

Decision rationale: The request for Pennsaid 25 mg, quantity unknown, is not medically necessary. The California MTUS Guidelines refer to topical analgesics as largely experimental with few randomized control trials to determine efficacy or safety, and primarily recommended

for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. The efficacy in clinical trials for NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown 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. They are recommended for short-term use of 4 to 12 weeks. The only FDA-approved NSAID for topical application is diclofenac, which is the primary ingredient in Pennsaid. However, the only medication which has been approved is Voltaren gel 1%, which is indicated for the relief of osteoarthritis pain in joints that lend themselves to topical treatment which does include the wrist. There was no submitted documentation of previously failed trials of oral NSAIDs, antidepressants, or anticonvulsants for pain relief. The request did not specify which body part the Pennsaid was to be applied to. Additionally, there was no frequency of application included with the request. Therefore, this request for Pennsaid 25 mg, quantity unknown, is not medically necessary.

Lidoderm patch #92: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 13-16.

Decision rationale: The request for Lidoderm patch #92 is not medically necessary. The California MTUS Guidelines refer to topical analgesics as largely experimental with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Lidocaine is recommended for localized peripheral pain after there has been evidence of trials of first-line therapy including tricyclic or SNRI antidepressants or anti-epileptic drugs such as gabapentin or Lyrica. Topical lidocaine in the form of a dermal patch has been designated by the FDA for neuropathic pain. There was no documentation of previously failed trials of antidepressants or anti-epileptic drugs. There is no quantifiable evidence of diminished pain or improved functional status with the use of Lidoderm. Additionally, there was no body part specified in the request to which the patch was to be applied. Also, the frequency of application was omitted from the request. Therefore, the request for Lidoderm patch #92 is not medically necessary.