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| Case Number: | CM14-0042991 | | |
| Date Assigned: | 06/30/2014 | Date of Injury: | 03/14/2007 |
| Decision Date: | 08/21/2014 | UR Denial Date: | 03/12/2014 |
| Priority: | Standard | Application Received: | 04/10/2014 |

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 Occupational 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:

The patient is a 61-year-old female who has submitted a claim for cervical disc displacement without myelopathy, and psychogenic pain associated with an industrial injury date of March 14, 2007. Medical records from 2013 through 2014 were reviewed, which showed that the patient complained of neck pain radiating to the left upper extremity. Physical examination revealed tenderness over the posterior cervical paraspinal muscles. There was limitation in cervical spine range of motion with flexion to 40 degrees, extension to 40 degrees, lateral tilt to 20 degrees and rotation to 50 degrees. Spurling's test was positive. There was tenderness over the left trapezius and left medial border of the scapula primarily at the superior aspect. There was decreased sensation to light touch and pinprick from the approximate levels of C6 and C7 distribution. Deep tendon reflexes were 1+ in the left biceps with 2+ in the left triceps and brachioradialis. Treatment to date has included aquatic therapy, physical therapy, and medications, which include Gabapentin, Oxycodone, Tylenol, Diazepam, Fentanyl patch, Ketamine 5% cream, and Doxepin 3.3% cream. Utilization review from March 12, 2014 denied the request for Ketamine 5% cream 60gr #2 and Doxepin 3.3% cream 60gr #2. Ketamine 5% cream was denied because the documentation does not describe well-demarcated neuropathic pain that has failed a gamut of readily available oral agents in the antidepressant, antiepileptic, or Non-Steroid Anti-Inflammatory Drugs (NSAIDs) class to support the medical necessity of topical agents. The documentation does not identify failure of all first-line treatments and does not suggest that the patient has CRPS (complex regional pain syndrome) or postherpetic neuralgia. Doxepin 3.3% cream was denied because the requested formulation contains agents that have no proven efficacy in topical application (Doxepin, which is a tricyclic antidepressant).

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketamine 5% cream 60gr #2: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 56, 111-113.

Decision rationale: According to pages 111-113 of CA MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. 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. Ketamine is only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatments have been exhausted. In this case, the patient has been on Ketamine cream since July 2013. An appeal dated 3/20/14 mentioned that the patient's objective and subjective findings are indicative of cervical radiculopathy and neuropathic pain for which Ketamine is recommended. There was also mention that the use of Ketamine and Doxepin cream helps with her neuropathic symptoms (tingling and numbness). Patient has a history of failed treatment with first-line and second-line medications. She has previously tried Gabapentin (antiepileptic) and Lyrica (antidepressant) but discontinued them secondary to side effects. She has also tried Oxycodone HCl, Diazepam, and Tylenol without much benefit. Morphine and Fentanyl patches were discontinued due to nausea. Patient has a history of GERD therefore the use of oral NSAIDs was not advisable according to the AP. The attending physician also mentioned that given the patient's hepatitis C and stage IV liver cirrhosis, there is a need to optimize non-medication adjunctive treatment strategies as long-term medication may exacerbate her liver function. Patient has had extensive conservative management however she continues to have pain. The AP also added that since conservative therapy is not helping and the patient is intolerant of oral medications, the use of these topical creams is appropriate as these creams will help in minimizing the use of her oral medications. Therefore, the request for Ketamine 5% cream 60gr # 2 is medically necessary and appropriate.

Doxepin 3.3% cream 60gr #2: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 56, 111-113.

Decision rationale: According to pages 111-113 of CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor antagonists). There is little to no research to support the use of many of these agents.

Compounded products have limited published studies concerning its efficacy and safety. Topical agents are primarily recommended for the treatment of neuropathic pain when trials of antidepressants or anticonvulsants have failed. In this case, the patient has been on Doxepin cream since July 2013. An appeal dated 3/20/14 mentioned that the patient's objective and subjective findings are indicative of cervical radiculopathy and neuropathic pain for which topical agents may be utilized. There was also mention that the use of Ketamine and Doxepin cream helps with her neuropathic symptoms (tingling and numbness). Patient has a history of failed treatment with first-line and second-line medications. She has previously tried Gabapentin (antiepileptic) and Lyrica (antidepressant) but discontinued them secondary to side effects. She has also tried Oxycodone HCl, Diazepam, and Tylenol without much benefit. Morphine and Fentanyl patches were discontinued due to nausea. Patient has a history of GERD (Gastroesophageal Reflux Disease) therefore the use of oral NSAIDs was not advisable according to the AP. The attending physician also mentioned that given the patient's hepatitis C and stage IV liver cirrhosis, there is a need to optimize non-medication adjunctive treatment strategies as long-term medication may exacerbate her liver function. Patient has had extensive conservative management however she continues to have pain. The AP also added that since conservative therapy is not helping and the patient is intolerant of oral medications, the use of these topical creams is appropriate as these creams will help in minimizing the use of her oral medications. Therefore, the request for Doxepin 3.3% cream 60gr #2 is medically necessary and appropriate.