

Case Number:	CM14-0127755		
Date Assigned:	09/23/2014	Date of Injury:	09/26/2008
Decision Date:	10/22/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	08/11/2014

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 62-year-old male who has submitted a claim for status post C4-C7 hybrid cervical reconstruction and thoracic spine pain referred from the cervical associated with an industrial injury date of September 26, 2008. Medical records from 2010 to 2014 were reviewed. The patient complained of cervical spine and low back pain with stiffness and difficulty sleeping. Physical examination showed tenderness over the cervical and lumbar spine with spasm, limitation of motion, and positive straight leg raise. The diagnoses were C4-C7 multilevel cervical spondylosis with instability/junctional kyphotic deformity status post cervical spine surgery (November 1, 2013), and lumbar spine herniated nucleus pulposus with radiculitis. Treatment to date has included Naproxen, tramadol, omeprazole, odansetron, tizanidine, cyclobenzaprine, gabapentin, Medrox ointment, Lenza Gel, Terocin patch, quazepam, alprazolam and physical therapy. Utilization review from July 22, 2014 denied the request for Lidocaine/hyaluronic patch 6% 0.2% CRM QTY: 120 and Cooleeze menth/camp cap/hyalor acid 3.5% 0.5%/0.006%/0.2% G QTY: 120. The documentation submitted did not provide evidence of failed outcomes from first line therapies, including antidepressants and anticonvulsants. Additionally, the documentation did not provide objective measurements for pain, strength, and range of motion (on a numeric scale) or subjective complaints of functional deficits to support the need for pain medication.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidocaine/hyaluronic patch 6% 0.2% CRM QTY: 120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch); Topical Analgesics, Lidocaine Page(s): 56-57; 111-112.

Decision rationale: According to CA MTUS Chronic Pain Medical Treatment Guidelines, topical lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). With regards to hyaluronic acid, there were no guidelines found that supports its use as topical preparation. In addition, the guideline states that any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. In this case, the patient has prior use of Terocin patch noted on October 2013. However, there were no documented trials of first-line antidepressants or anticonvulsants. Moreover, there was no objective evidence of significant analgesia and functional improvement with its use. Likewise, most recent physical examination do not show specific neurologic deficits that warrant use of topical lidocaine. The guideline recommends use of topical lidocaine in the form a dermal patch for neuropathic pain, and only after trial of first-line therapy. In addition, the requested compounded medication contains hyaluronic acid. No literature was found to support this component in the form of topical preparation. Any compounded medication that contains at least one drug that is not recommended is not recommended. The medical necessity has not been established because guideline criteria were not met. Therefore, the request for Lidocaine/hyaluronic patch 6% 0.2% CRM QTY: 120 is not medically necessary.

Cooleeze menth/camp cap/hyalor acid 3.5% 0.5%/ .006%/0.2% G QTY: 120:

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; Capsaicin, topical, Page(s): 111-113; 28. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Topical Salicylates

Decision rationale: Pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many these agents. CA MTUS Chronic Pain Medical Treatment Guidelines on page 28 states that topical Capsaicin is only recommended as an option when there was failure to respond or intolerance to other treatments. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter issued an FDA safety warning which identifies rare cases of serious burns that have been reported to occur on the skin where menthol, methyl salicylate, or capsaicin were applied. The guidelines do not address

Camphor and Hyaluronic Acid Gel. In addition, the guideline states that any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. In this case, there was no discussion concerning intolerance or failure of oral medications that warrant topical drug formulation. There was also no evidence of trial and failure of first line therapies such as antidepressants and anti-convulsants in managing pain. The medical necessity was not established. There was no compelling rationale concerning the need for variance from the guideline. Therefore, the request for Cooleeze menth/camp cap/hyalor acid 3.5% 0.5%/.006%./0.2% G QTY: 120 is not medically necessary.