

Case Number:	CM15-0135925		
Date Assigned:	07/23/2015	Date of Injury:	01/05/2011
Decision Date:	08/25/2015	UR Denial Date:	06/12/2015
Priority:	Standard	Application Received:	07/14/2015

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: Texas, California

Certification(s)/Specialty: Family Practice

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 54 year old female who sustained an industrial injury on 1-5-11. Diagnoses are status post anterior cervical discectomy and fusion 1-26-15, status post arthroscopic repair of the right shoulder with good resolution of symptoms 7-24-14, and right upper extremity radiculopathy. In a progress report dated 5-7-15, the treating physician notes the injured worker states neck pain and right upper extremity radicular symptoms have improved since surgery. The cervicogenic headaches have significantly improved but she does complain of needle type pain in the right hand, which she rates at 5 out of 10. Physical therapy improves her shoulder range of motion and the pain is rated at 6 out of 10. Medication is Tylenol as needed. Cervical range of motion is painful on extension and there is some loss of sensation in the C5-C6 nerve distribution in the right upper extremity, although grip strength is improving. Work status is to remain off of work until 6-18-15. In a progress report dated 5-21-15, the treating physician notes subjective complaints of continued soreness and aching pain. Objective exam reveals mild pain to palpation over the anterior aspect of the shoulder. There is weakness with overhead activities. Xrays of the right shoulder show no increase in osteoarthritis. The treatment plan is for a urine toxicology screening, continue physical therapy, KeraTek Gel 4 ounce bottle for pain and inflammation and Flurbiprofen-Cyclobenzaprine-Menthol 20%-10%-4% 180mg for pain, and to use heat and ice contrast therapy to help with symptoms. The requested treatment is KeraTek Gel #113 (apply 2-3 times per day) and Flurbiprofen-Cyclobenzaprine-Menthol Cream 20%, 10%, 4% (apply 2-3 times per day). The patient has had EMG of upper extremity on 6/26/13 that revealed cervical radiculopathy and MRI of the right

shoulder on 11/23/13 that revealed osteoarthritis and supraspinatus tendinitis and MRI of the cervical spine on 6/14 13 that revealed disc protrusions. The patient's surgical history include right shoulder surgery in 3/11/014 and Gastric sleeve surgery on 4/15/14 and cervical fusion on 1/26/15. Patient cannot handle strong medication and therefore she takes only Tylenol. The medication list includes Tylenol and Ultram. A recent detailed clinical examination of the gastrointestinal tract was not specified in the records provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Kera Tek gel #113 4oz (apply 2-3x per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain - Topical Analgesics.

Decision rationale: Kera Tek gel #113 4oz (apply 2-3x per day). Kera-Tek analgesic gel contains methyl salicylate and menthol. According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed." There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Non-neuropathic pain: Not recommended. MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anti-convulsants have failed to relieve symptoms. There is no evidence in the records provided that the pain is neuropathic in nature. The records provided do not specify that trials of antidepressants and anti-convulsants have failed. It is noted that the pt has had gastric sleeve surgery. This may cause intolerance to NSAIDs, however any intolerance to other (non NSAID) medications for chronic pain like antidepressants and anti-convulsants or low potency opioids like tramadol was not specified in the records provided. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is also no evidence that menthol is recommended by the CA, MTUS, Chronic pain treatment guidelines. Topical menthol is not recommended in this patient for this diagnosis. The medical necessity of the request for Kera Tek gel #113 4oz (apply 2-3x per day) is not fully established in this patient. The request is not medically necessary.

Flurbiprofen/Cyclobenzaprine/Menthol cream 20%.10%/4% (apply 2-3x per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain - Topical Analgesics, pages 111-112.

Decision rationale: Flurbiprofen/Cyclobenzaprine/Menthol cream 20%.10%/4% (apply 2-3x per day). According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed." There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Non-neuropathic pain: Gabapentin: Not recommended. There is no peer-reviewed literature to support use. MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anti-convulsants have failed to relieve symptoms. There is no evidence in the records provided that the pain is neuropathic in nature. The records provided do not specify that trials of antidepressants and anti-convulsants have failed. It is noted that the pt has had gastric sleeve surgery. This may cause intolerance to NSAIDs, however any intolerance to other (non NSAID) medications for chronic pain like antidepressants and anti-convulsants or low potency opioids like tramadol was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Cyclobenzaprine is a muscle relaxant. Per the cited guidelines, other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The medication Flurbiprofen is a NSAID. As per cited guideline "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." There is also no evidence that menthol is recommended by the CA, MTUS, Chronic pain treatment guidelines. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Flurbiprofen, Cyclobenzaprine and menthol are not recommended by MTUS in this patient. The medication Topical compounded Flurbiprofen/Cyclobenzaprine/Menthol cream 20%.10%/4% (apply 2-3x per day) is not fully established in this patient. The request is not medically necessary.