

Case Number:	CM14-0001238		
Date Assigned:	01/22/2014	Date of Injury:	08/18/2010
Decision Date:	07/08/2014	UR Denial Date:	12/17/2013
Priority:	Standard	Application Received:	01/03/2014

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 Anesthesiology, has a subspecialty in Pain Management 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:

Medical records from 2013 were reviewed, the latest of which dated October 31, 2013 revealed that the patient has recently underwent shoulder arthroscopy with repair of rotator cuff and partial acromionectomy; however, the surgery did not help. She states that her condition did not improve and that she has remained symptomatic. She says she has pain everyday and in the evening. She has pain with activities of daily living. On physical examination, there was tenderness in the shoulder. She is hesitant to abduct and externally rotate her upper arm, complaining of pain. She winces in pain and withdraws her shoulder. There is limitation in range of motion in abduction to approximately 80 degrees, pain limited. There is tenderness over the subacromial area and over the acromioclavicular joint. On the clinical evaluation done last October 3, 2013, the patient complains of ankle, foot, and left shoulder pain. She has paresthesia into her right foot. On physical examination, there is pain in the lateral aspect of the left ankle. There is decreased muscular strength in plantarflexion 4/5, inversion 4/5 and eversion 4/5. There is pain in the medial aspect of the right ankle. There is decreased muscular strength in dorsiflexion 3/5, plantarflexion 4/5, inversion 4/5 and eversion 4/5. There is decreased sensation to light touch in a non-anatomical distribution. There is hypersensitivity noted over the dorsum of the right foot. There is pain over the left superior trapezius. There is limitation in active range of motion of the left shoulder in flexion to approximately 120 degrees, abduction to approximately 120 degrees, internal rotation to approximately 60 degrees, external rotation to approximately 70 degrees. There is decreased in muscular strength in abduction 4/5. The left shoulder is positive for Yergason test and impingement test. Treatment to date has included shoulder arthroscopy with repair of rotator cuff and partial acromionectomy, cortisone injection (4/19/13), right ankle injection (1/21/13), physical therapy, home exercise program, and medications which include Relafen, Lyrica, citalopram hydrobromide, hydrocodone/APAP,

hydroxyzine hydrochloride, zolpidem, topical gabapentin and tramadol cream. Utilization review from December 13, 2013 denied the requests for Gabapentin/Ketoprofen/Lidocaine 7/10/5% in UL 120gm,2; Gabapentin powder 8.4 units, Ketoprofen Powder 12 units, Lidocaine HCL powder 6 units, PCCA Lidoderm base 93.6 units 120gm; Ketoprofen 10%, Cyclobenzaprine 3%, Capsaicin 0.0375%, Menthol 2%, Camphor 1% 120gm; and Ketoprofen powder 12 units, Cyclobenzaprine HCL powder 3.6 units, Capsaicin powder 0.045 units, menthol crystals 2.4 units, camphor crystals 1.2 crystals, PCCA Lipoderm base 100.76 units because guidelines do not recommend compounded topical analgesics if one or more ingredients are not recommended and there is no documentation that the patient has not responded to or is intolerant to other treatments.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE GABAPENTIN/KETOPROFEN/LIDOCAINE 7/10/5/5 IN UL 120GM DOS: 10/30/2013: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUNDED TOPICAL PRODUCTS Page(s): 112.

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

Decision rationale: According to page 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, the use of topical creams are only optional and is still largely experimental in use with few randomized controlled trials to determine efficacy or safety. Most of these agents are compounded. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In this case, the patient was prescribed gabapentin/ketoprofen/lidocaine cream on October 29, 2012; however, the rationale is unknown due to lack of documentation. The guidelines state that there is little evidence to support the use of topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder, and there is no evidence to support the use for neuropathic pain. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Additionally, the guidelines state that there is no evidence to support the use of topical gabapentin and Lidocaine (in creams, lotion or gels). The use of ketoprofen, gabapentin or lidocaine in a topical formulation is not recommended. Also, the patient is on oral pain medications and there is no discussion in the medical records that the patient has not responded or intolerant to other treatments. Therefore, the request for Gabapentin/Ketoprofen/Lidocaine 7/10/5% in UL 120gm is not medically necessary.

RETROSPECTIVE GABAPENTIN POWDER 8.4 UNITS, KETOPROFEN POWDER 12 UNITS, LIDOCAINE POWDER 6 UNITS, PCCA LIPODERM BASE 93.6 UNITS 120GM DOS: 10/1/2012: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUNDED TOPICAL PRODUCTS Page(s): 112.

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

Decision rationale: According to page 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, the use of topical creams are only optional and is still largely experimental in use with few randomized controlled trials to determine efficacy or safety. Most of these agents are compounded. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In this case, the patient was prescribed Gabapentin/Ketoprofen/Lidocaine cream on October 29, 2012; however, the rationale is unknown due to lack of documentation. The guidelines state that there is little evidence to support the use of topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder, and there is no evidence to support the use for neuropathic pain. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Additionally, the guidelines state that there is no evidence to support the use of topical Gabapentin and Lidocaine (in creams, lotion or gels). The use of Ketoprofen, Gabapentin or Lidocaine in a topical formulation is not recommended. Also, the patient is on oral pain medications and there is no discussion in the medical records that the patient has not responded or intolerant to other treatments. Therefore, the request for Gabapentin/Ketoprofen/Lidocaine 7/10/5% in UL 120gm is not medically necessary.

RETROSPECTIVE KETOPROFEN 10%, CYCLOBENZAPRINE 3%, CAPSAICIN 0.037%, MENTHOL 2%, CAMPHOR 1% 120GM DOS: 1/14/2013: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUNDED TOPICAL PRODUCTS Page(s): 112.

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

Decision rationale: According to page 111 -113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, the use of topical creams are only optional and is still largely experimental in use with few randomized controlled trials to determine efficacy or safety. Most of these agents are compounded. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In this case, the patient was prescribed ketoprofen/cyclobenzaprine/capsaicin/menthol/camphor cream on October 29, 2012; however, the rationale is unknown due to lack of documentation. The guidelines state that there is little evidence to support the use of topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder, and there is no evidence to support the use for neuropathic pain. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Additionally, the guidelines state that there is no evidence to support the use of topical cyclobenzaprine and camphor. Also, the patient is on oral pain medications and there is no discussion in the medical records that the patient has not responded or intolerant to other treatments. Therefore, the request for Ketoprofen 10%,

Cyclobenzaprine 3%, Capsaicin 0.0375%, Menthol 2%, Camphor 1% 120gm is not medically necessary.

RETROSPECTIVE KETOPROFEN POWDER 12 UNITS, CYCLOBENZAPRINE HCL POWDER 3.6 UNITS, PCCA LIPODERM BASE 100.76 UNITS DOS: 1/1/2013: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUNDED TOPICAL PRODUCTS Page(s): 112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Salicylate Topicals.

Decision rationale: According to page 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, the use of tropical creams are only optional and is still largely experimental in use with few randomized controlled trials to determine efficacy or safety. Most of these agents are compounded. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In this case, the patient was prescribed Ketoprofen/Cyclobenzaprine/Capsaicin/menthol/camphor cream on October 29, 2012; however, the rationale is unknown due to lack of documentation. The guidelines state that there is little evidence to support the use of topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder, and there is no evidence to support the use for neuropathic pain. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, Methyl Salicylate, or Capsaicin, may in rare instances cause serious burns. Additionally, the guidelines state that there is no evidence to support the use of topical Cyclobenzaprine and camphor. Also, the patient is on oral pain medications and there is no discussion in the medical records that the patient has not responded or intolerant to other treatments. Therefore, the request for Ketoprofen 10%, Cyclobenzaprine 3%, Capsaicin 0.0375%, Menthol 2%, Camphor 1% 120gm is not medically necessary.