

Case Number:	CM14-0120201		
Date Assigned:	08/06/2014	Date of Injury:	02/03/2007
Decision Date:	10/03/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	07/29/2014

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:

Patient is a 46-year-old male who has submitted a claim for sprain lumbar region associated with an industrial injury date of 02/03/2007. Medical records from 2014 were reviewed. The patient complained of low back pain radiating to the left lower extremity with numbness and tingling. Pain is rated at 8 out of 10. Physical examination of the lumbar spine revealed tenderness and spasms noted. Range of motion was also decreased. Treatment to date has oral medications, surgery, physical therapy, and epidural steroid injections. Utilization review from 07/22/2014 denied the requests for Xolindo and Terocin patches because it has an active ingredient of Lidocaine, is not approved for use by the guidelines other than for neuropathic pain. The same review denied the request for Menthoderm because there are no long-term studies on efficacy or safety. The request for Theramine was also denied because it is not approved by the guidelines as a medical food.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective review of 1 Container of Xolindo 2% cream DOS 4/30/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): Pages 111-112.

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

Decision rationale: As stated on pages 111-113 of CA MTUS Chronic Pain Medical Treatment Guidelines, Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in anything greater than a 0.025% formulation, Baclofen, Boswellia Serrata Resin, other muscle relaxants, Gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the patient has been prescribed with Xolindo 2% (Lidocaine) since 04/09/2014 (5 months to date). However, records reviewed did not show that the patient had failure of antidepressants or anticonvulsants. Likewise, the duration and frequency of the drug was non-specific. Therefore, the request for 1 container of Xolindo 2% cream (retrospective DOS 4/30/14) is not medically necessary.

Retrospective review of 20 Terocin Pain Patches DOS 4/30/14: 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, 112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter, Topical salicylates

Decision rationale: Terocin Patch contains 4% lidocaine and 4% menthol. 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. In addition, topical lidocaine may be 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). Regarding the Menthol component, CA MTUS does not cite specific provisions, but the 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. In this case, patient has been prescribed usage of Terocin patch since at least 04/09/2014 (5 months to date). However, there was no documented evidence of functional improvement from the medication. Furthermore, there was no indication of a trial of antidepressants or AED and intolerance to oral analgesics. Therefore, the request for 20 Terocin pain patches (retrospective DOS 4/30/14) is not medically necessary.

Retrospective review of Methoderm 240 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals, Topical Analgesics Page(s): 105, 111.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug (drug class) that is not

recommended is not recommended. The guidelines state that while the guidelines referenced support the topical use of methyl salicylates, the requested Methoderm has the same formulation of over-the-counter products such as BenGay. It has not been established that there is any necessity for this specific brand name. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, or methyl salicylate, may in rare instances cause serious burns. In this case, the patient was prescribed Methoderm since 04/09/2014 (5 months to date). There was no documentation of intolerance to oral pain medications; it is unclear as to why oral pain medications will not suffice. Furthermore, the guidelines state that there is lack of published evidence proving that Methoderm is superior compared with over-the-counter methyl salicylate and menthol products. There is no discussion as to why the specific brand is needed. Therefore, the request for retrospective review of Methoderm 240 grams is not medically necessary.

Theramine 90 capsules: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Theramine

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Theramine is not recommended. It is a medical food that is a proprietary blend of GABA and choline bitartrate, L-arginine, and L-serine intended for management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated. Regarding choline, there is no known medical need for supplementation. Regarding L-Arginine, this medication is not indicated in current references for pain or inflammation. Regarding L-Serine, there is no indication for the use of this product. In this case, patient was prescribed Theramine since 04/09/2014 (5 months to date). However, guidelines do not support the use of Theramine. There is no discussion concerning need for variance from the guidelines. Therefore, the request for Theramine 90 capsules is not medically necessary.