

Case Number:	CM14-0038957		
Date Assigned:	06/27/2014	Date of Injury:	02/25/2013
Decision Date:	08/14/2014	UR Denial Date:	03/24/2014
Priority:	Standard	Application Received:	04/02/2014

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 Internal Medicine & Emergency Medicine, and is licensed to practice in Florida. 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:

This patient is a 25 year-old with a date of injury of 02/25/13. A progress report associated with the request for services, dated 02/12/14, identified subjective complaints of neck and low back pain. Objective findings included tenderness to palpation of the cervical and lumbar spines. There was decreased sensation in the lower extremities in a dermatomal distribution. Diagnoses included cervical, lumbar, and thoracic disc herniation. Previous treatment was not outlined. A Utilization Review determination was rendered on 03/24/14 recommending non-certification of Topical-compound: Lidocaine 6%, Gabapentin 10%, Tramadol 10% - QTY: 180GM, 2 refills; Muscular pain topical compound- flurbiprofen 14%, cyclobenzaprine 2%, baclofen 2%, lidocaine 5%, QTY: 180GM, 2 refills; and Tramadol 50MG #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topical-compound: Lidocaine 6%, Gabapentin 10%, Tramadol 10% - QTY: 180GM, 2 refills: Upheld

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

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

Disability Guidelines (ODG) Pain, Topical Analgesics Other Medical Treatment Guideline or Medical Evidence: www.updates.pain-topics.org; J Anesth. 2010 Oct; 24(5):705-8.

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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. The MTUS Guidelines state that gabapentin is: Not recommended. There is no peer-reviewed literature to support use. Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this patient. Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (ODG). There is some data that topical Tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation. Therefore, the request is not medically necessary.

Muscular pain topical compound- flurbiprofen 14%, cyclobenzaprine 2%, baclofen 2%, lidocaine 5%, QTY: 180GM, 2 refills: Upheld

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

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

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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. Flurbiprofen 14% is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and or short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to

utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is diclofenac. Baclofen 2% is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that Lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. Cyclobenzaprine 2% is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation. Therefore, the request is not medically necessary.

Tramadol 50MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93-94. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Tramadol; Opioids, page(s) 74-96; 113 Page(s): 74-96; 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids, specific drug list: Tramadol.

Decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The Guidelines also state that with chronic low back pain, opioid therapy Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited. Additionally, There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007). Opioids are not recommended for more than 2 weeks and the Guidelines further state that tramadol is not recommended as a first-line oral analgesic. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy in view of

the recommendations to avoid long-term therapy; likewise, that other first-line oral analgesics have been tried and failed. Therefore, the request is not medically necessary.