

Case Number:	CM13-0062876		
Date Assigned:	01/17/2014	Date of Injury:	03/19/2010
Decision Date:	04/22/2014	UR Denial Date:	11/27/2013
Priority:	Standard	Application Received:	12/09/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a Physician Reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The Physician Reviewer is Board Certified in Internal Medicine and 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 Physician 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 45 year-old with a date of injury on 03/19/10. A progress report associated with the request for services, dated 11/06/13, identified subjective complaints of lower back and extremity pain. Pain level was listed as a 4. Physical therapy was noted to be helpful. Objective findings included tenderness to palpation of the lumbar spine and an antalgic gait. An ankle scar was noted. Diagnoses included lumbar degenerative disc disease; status-post closed ankle fracture, postoperative with acute pain. Treatment has included home exercise, physical therapy, transcutaneous electric nerve stimulation (TENS), and Tramadol for several months. A request was made also for a Lidopro trial. A utilization review determination was rendered on 11/27/13 recommending non-certification of "Lidopro ointment 121gm; Tramadol ER 150mg, #30".

IMR ISSUES, DECISIONS AND RATIONALES

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

LIDOPRO OINTMENT 121 GM: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics; Salicylate Topicals, Page(s): 105, 111-113,. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section Pain: Topical Analgesics; Salicylate Topicals.

Decision rationale: Lidopro is a compounded agent consisting of menthol and the active ingredients capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The MTUS chronic pain guidelines indicate that topical analgesics are recommended as an option in specific circumstances. However, they do indicate that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The guidelines for chronic pain indicate that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) indicate that neither salicylates nor capsaicin have shown efficacy in the treatment of osteoarthritis. 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. Therefore, in this case, there is no demonstrated medical necessity for lidocaine as a cream in the compound. The chronic pain guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note, however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. The Guidelines 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, there is no medical necessity of the compounded formulation, Lidopro.

TRAMADOL ER 150 MG, #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids..

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308; Chronic Pain Treatment Guidelines Section Opioids, Tramadol, Page(s): 74-83, 113;. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section Pain, Opioids, specific drug list: Tramadol.

Decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. The Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids indicate 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. The Guidelines also indicate 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." Opioids are not recommended for more than 2 weeks and the Guidelines further indicate that tramadol is not recommended as a first-line oral analgesic. This employee has been on Tramadol in excess of 16 weeks. 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 record does not document the medical necessity for tramadol.

MENTHODERM: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Salicylate Topicals, Topical Analgesics, Page(s): 105, 111-113;. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section Pain, Low Back, Topical Analgesics, Salicylate Topicals, Biofreeze Cryotherapy Gel.

Decision rationale: Menthoderm is a combination topical consisting of methylsalicylate and menthol. The MTUS Chronic Pain Guidelines indicate that topical analgesics are recommended as an option in specific circumstances. However, they do indicate that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Methylsalicylate is a non-steroidal anti-inflammatory being used as a topical analgesic. The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Menthol is a topical form of cooling. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) indicate that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. In this case, there is documentation of chronic pain not completely responsive to other therapies. The non-certification was based upon lack of recommendation in the Guidelines for menthol topical.

However, it is recommended at least for acute pain and a study found significant pain reduction after each week of treatment. Therefore, there is documented medical necessity for Methoderm cream.