

Case Number:	CM13-0040635		
Date Assigned:	06/02/2014	Date of Injury:	06/09/2013
Decision Date:	07/24/2014	UR Denial Date:	10/08/2013
Priority:	Standard	Application Received:	10/09/2013

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 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 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 67 year-old with a date of injury of 07/09/13. A handwritten progress report associated with the request for services, dated 09/25/13, was not entirely legible. It identified subjective complaints of what appeared to be neck and low back pain. Objective findings were eligible. Diagnoses included backache; pain in the thoracic spine; cervical disc disease. Previous treatment and any response to therapy were not outlined. A Utilization Review determination was rendered on 10/08/13 recommending non-certification of "acupuncture for cervical spine once weekly x 6 weeks; 240 gram topical compound capsaicin 0.025%, flurbiprofen 30%, methyl salicylate 4%; 240 gram topical compound flurbiprofen 20%, tramadol 20%; and Medrox patches 30".

IMR ISSUES, DECISIONS AND RATIONALES

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

ACUPUNCTURE FOR CERVICAL SPINE ONCE WEEKLY X 6 WEEKS: Overturned

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: This patient is a 67 year-old with a date of injury of 07/09/13. A handwritten progress report associated with the request for services, dated 09/25/13, was not entirely legible.

It identified subjective complaints of what appeared to be neck and low back pain. Objective findings were eligible. Diagnoses included backache; pain in the thoracic spine; cervical disc disease. Previous treatment and any response to therapy were not outlined. A Utilization Review determination was rendered on 10/08/13 recommending non-certification of "acupuncture for cervical spine once weekly x 6 weeks; 240 gram topical compound capsaicin 0.025%, flurbiprofen 30%, methyl salicylate 4%; 240 gram topical compound flurbiprofen 20%, tramadol 20%; and Medrox patches 30". Acupuncture For Cervical Spine Once Weekly X 6 Weeks is medically necessary and appropriate.

240 GRAM TOPICAL COMPOUND CAPSAICIN 0.025%, FLURBIPROFEN 30%, METHYL SALICYLATE 4%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Topical Analgesics, page(s) 111-113 Page(s): 111-113.

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 30% 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 of 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. Menthol is a topical form of cryotherapy. 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) state 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. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state 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) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. Capsaicin is available as a 0.025% formulation (for the treatment of osteoarthritis) and a 0.075% formulation primarily from studies for neuropathic pain. 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. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the record does not document the medical necessity of the compounded formulation.

240 GRAM TOPICAL COMPOUND FLURBIPROFEN 20%, TRAMADOL 20%,: Upheld

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

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." Tramadol 20% is an opioid analgesic being used as a topical agent. 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. Flurbiprofen 20% 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 of 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. In this case, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of flurbiprofen as an NSAID topical agent. Likewise, lacking definitive data on the efficacy of topical tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy or other compelling reason for its use. Therefore, there is no documentation for the medical necessity for topical tramadol.

MEDROX PATCHES 30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylate Topicals; Topical Analgesics, page(s) 28-29; 105; 111-113 Page(s): 28-29, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain: Topical Analgesics; Salicylate Topicals.

Decision rationale: Medrox has multiple ingredients that include methyl salicylate 20%, capsaicin 0.0375%, and menthol USP 5%. The 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 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. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state 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. It is further noted that a 0.025% formulation is available for treatment of osteoarthritis and a 0.075% formulation for neuropathic pain. They state that there have been no studies of the 0.0375% formulation and no current indication that the increase over the 0.025% formulation would provide any further efficacy. The Official Disability Guidelines (ODG) states that neither salicylates nor capsaicin has shown any efficacy in the treatment of osteoarthritis. 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) state 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. 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, Medrox.