

Case Number:	CM13-0002038		
Date Assigned:	01/15/2014	Date of Injury:	10/22/2001
Decision Date:	04/09/2014	UR Denial Date:	07/02/2013
Priority:	Standard	Application Received:	07/18/2013

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 64 year-old with a date of injury of 10/22/01. A progress report associated with the request for services, dated 05/02/13, states that the patient's condition was stable with the use of medications. No other symptoms were listed. Objective findings included tenderness in the shoulders and fingers that were stiff and achy. Diagnoses included cervical sprain/strain; bilateral impingement of the shoulders; and bilateral carpal tunnel syndrome. Treatment has included home exercise, oral NSAIDs and analgesics. A Utilization Review determination was rendered on 07/01/13 recommending non-certification of "FluriFlex (flurbiprofen 15%/cyclobenzaprine 10%) 180gm; TGHOT (Tramadol 8%/Gabapentin 10%/Menthol 2%/Camphor 2%/Capsaicin 0.5% 180gm; Flurbiprofen, Cyclobenzaprine, UltraDerm; Tramadol, Gabapentin, menthol, camphor, Capsaicin, UltraDerm".

IMR ISSUES, DECISIONS AND RATIONALES

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

FluriFlex (flurbiprofen 15%/cyclobenzaprine 10%) 180gm: 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): s 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics.

Decision rationale: FluriFlex is a topical compound containing flurbiprofen and cyclobenzaprine. 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; primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen 15% 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). The only FDA approved topical NSAID is diclofenac. Ketoprofen is not approved and "... has an extremely high incidence of photocontact dermatitis and photosensitization reactions." Cyclobenzaprine 10% 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. Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient. 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 are ingredients that are not recommended and therefore no medical necessity for the compound.

**TGHot (Tramadol 8%/Gabapentin 10%/Menthol 2%/Camphor 2%/Capsaicin 0.5%
180gm:** 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): s 111-113. Decision based on Non-MTUS Citation www.updates.pain-topics.org; J Anesth. 2010 Oct; 24(5):705-8.

Decision rationale: TGHot is a combination of Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%, and Capsaicin 0.5%. 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; primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The efficacy of topical Tramadol is not specifically addressed in the MTUS or the 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. Gabapentin is an anti-epilepsy drug. The California Medical Treatment Utilization Schedule (MTUS) states that topical analgesics are primarily recommended when

other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The MTUS Guidelines further state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." 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) states that neither salicylates nor capsaicin show efficacy in the treatment of osteoarthritis. The Guidelines note that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, there are ingredients that are not recommended and therefore no medical necessity for the compound.

Flurbiprofen, Cyclobenzaprine, UltraDerm: 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): s 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: 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; primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen 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. Ketoprofen is not approved and "... has an extremely high incidence of photocontact dermatitis and photosensitization reactions." Cyclobenzaprine 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. Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient. The Guidelines note that "Any compounded product that contains at least one drug (or

drug class) that is not recommended is not recommended." In this case, there are ingredients that are not recommended and therefore no medical necessity for the compound.

Tramadol, Gabapentin, menthol, camphor, Capsaicin, UltraDerm: 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): s 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics; and www.updates.pain-topics.org; J Anesth. 2010 Oct; 24(5):705-8.

Decision rationale: The requested compound consists of gabapentin, an anti-seizure agent, capsaicin, a topical analgesic, and tramadol, a centrally acting opioid analgesic. 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; 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." The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this patient. Capsaicin has shown success in musculoskeletal conditions. The Guidelines 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. They are recommended only as an option in patients who have not responded or are intolerant to other treatments. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the 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. Therefore, medical necessity for topical Tramadol has not been established. 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 are ingredients that are not recommended and therefore no medical necessity for the compound.