

Case Number:	CM15-0010442		
Date Assigned:	01/28/2015	Date of Injury:	12/13/2013
Decision Date:	04/03/2015	UR Denial Date:	01/12/2015
Priority:	Standard	Application Received:	01/19/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: New York
 Certification(s)/Specialty: Emergency Medicine

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 49-year-old female sustained work-related injuries to the right and left ankles on 12/13/2013. The diagnoses listed in the PR2 dated 7/30/2014 include left and right ankle sprain/strain and left and right ankle tenosynovitis. Diagnostic testing has included nerve conduction studies, radiographs, podiatry consultation, and magnetic resonance imaging. Previous treatments include medications, Unna boot application, physical therapy, extracorporeal shockwave therapy and acupuncture. The treating provider requests Naproxen 550 mg #60, Dexamethasone 0.6 gm, Menthol 0.6 Gm, Camphor 0.6 Gm, Capsaicin 0.01 Gm, Mediderm cream base 20.69 Gm, Gabapentin Powder 3 Gm, Amitriptyline Powder 3 Gm, Bupivacaine 1.5 Gm, Mediderm cream base 22.50 Gm, Flurbiprofen Powder 6 Gm and Baclofen 1.5 Gm. The IW has returned to work 19-21 hours per week without limitations. On 1/12/2015, Utilization Review certified a request for omeprazole, but non-certified request for all other requested medications. UR cited ACOEM, ODG, FDA and CA MTUS Chronic Pain Medical Treatment Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen 550 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications: Naproxen Page(s): 65-66.

Decision rationale: According to CA MTUS chronic pain guidelines, Naproxen is a nonsteroidal anti-inflammatory drug that is used for the treatment of osteoarthritis. Further stated, non-steroidal anti-inflammatory agents are "recommended as an option for short term symptomatic relief" for the treatment of chronic low back pain. It is recommended that the lowest dose be utilized for a minimal duration of time. The documentation does not document a diagnosis of osteoarthritis. Improvement of symptoms specifically to the use of NSAIDs currently prescribed is not documented. Additionally, the request does include frequency and dosing of this medication. The request is medically not necessary.

Dexamethasone 0.6 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/dexamethasone.html>.

Decision rationale: CA MTUS and ODG are silent on this topic. According to the above reference, dexamethasone is a steroid medication and is often used for the treatment of inflammatory conditions such as "such as allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis, or breathing disorders." The documentation reviewed does not discuss the rationale for using this medication. The Injured Worker does have listed any of the diagnoses indications. Additionally, the request does include frequency and dosing of this medication. Without this information or an approved indication, the request for dexamethasone is not medically necessary.

Menthol 0.6 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=menthol>.

Decision rationale: CA MTUS and ODG do not discuss methanol specifically. Other references report that methanol is a topical agent that has cooling properties when applied to skin or mucous membranes. It can be applied to skin for the treatment of pain. CA MTUS chronic pain guidelines discuss topical analgesics and state they are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents

are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that is not recommended is not recommended." The request for Menthol does not include dosing frequency, duration, or application site. Without this information and the lack of guideline support for topical agents, the request is not medically necessary.

Camphor 0.6 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia Page(s): 111-112. Decision based on Non-MTUS Citation <http://www.drugs.com/ingredient/camphor.html>.

Decision rationale: CA MTUS and ODG do not discuss camphor specifically. Other references report that camphor is a topical agent that is usually prepared as a compound with other topical agents. It has purposes for treating cough, pain, dermatitis and cold symptoms. It can be applied to skin for the treatment of pain. CA MTUS chronic pain guidelines discuss topical analgesics and state they are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that is not recommended is not recommended." The request for Camphor does not include dosing frequency, duration, or intended application site. Without this information and the lack of guideline support for topical agents, the request is not medically necessary.

Capsaicin 0.01 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), FDA.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, topical Page(s): 28-29.

Decision rationale: CA MTUS guidelines state that topical Capsaicin is "recommended only as an option in patients who have not responded or are intolerant to other treatment." Additionally, indications are listed in the treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain. Documentation does not support any of these diagnoses, nor does it support a lack of response to other treatment. The Injured Worker has been cleared to return to work.

Mediderm cream base 20.69 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia Page(s): 111-112. Decision based on Non-MTUS Citation <http://medi-derm.net/>.

Decision rationale: CA MTUS and ODG do not discuss Mediderm cream specifically. Other references report that Mediderm is a topical pain treatment agent which contains a "unique blend of naturally occurring ingredients." pain relief. It has purposes for treating pain caused by arthritis. CA MTUS chronic pain guidelines discuss topical analgesics and state they are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that in not recommended is not recommended." The specific ingredients in this requested product are not readily available. Additionally, the request for Mediderm does not include dosing frequency, duration, or intended application site. Without this information and the lack of guideline support for topical agents, the request is not medically necessary.

Gabapentin powder 3 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia Page(s): 111-112.

Decision rationale: CA MTUS chronic pain guidelines, topical analgesics are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that in not recommended is not recommended." One of the included compounds in the requested medication is Gabapentin. MTUS guidelines states that gabapentin is not recommended as there is no peer-reviewed literature to support its use. Additionally, the request does not include dosing frequency or duration. The request is not medically necessary.

Amitriptyline powder 3 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia Page(s): 111-112.

Decision rationale: Amitriptyline is a tricyclic antidepressant. CA MTUS and ODG do not discuss amitriptyline specifically. Other references report that amitriptyline is a tricyclic antidepressant. There are a few commercially available compounds that use amitriptyline as a component with other topical pain treatment agents. It is unclear from the request, how a powder

form would be application. It can be applied to skin for the treatment of pain. CA MTUS chronic pain guidelines discuss topical analgesics and state they are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that in not recommended is not recommended." The request for amitriptyline does not include dosing frequency, duration, or intended application site. The intended use of this medication is not clear. Without this information and the lack of guideline support for topical agents, the request is not medically necessary.

Bupivacaine 1.5 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia: Lidocaine Indication Page(s): 112.

Decision rationale: CA MTUS guidelines recommend the use of lidocaine topical application for localized peripheral pain. Topical lidocaine is utilized for neuropathic pain and off label diabetic neuropathy. Bupivacaine is a variant of lidocaine. Guideline state "no other commercially approved topical formulations of lidocaine are not indicated for neuropathic pain. This medication is not recommended for non-neuropathic pain. The request does not include dosing, frequency, or intended site of application for this product. Without this information and the lack of supporting guideline, the request is not medically necessary.

Mediderm cream base 22.50 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia Page(s): 111-112. Decision based on Non-MTUS Citation <http://medi-derm.net/>.

Decision rationale: CA MTUS and ODG do not discuss Mediderm cream specifically. Other references report that Mediderm is a topical pain treatment agent which contains a "unique blend of naturally occurring ingredients." pain relief. It has purposes for treating pain caused by arthritis. CA MTUS chronic pain guidelines discuss topical analgesics and state they are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control... There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that in not recommended is not recommended." The specific ingredients in this requested product are not readily available. Additionally, the request for Mediderm does not include dosing frequency, duration, or intended application site. Without this information and the lack of guideline support for topical agents, the request is not medically necessary.

Flurbiprofen powder 6 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesia, non-steroidal anti-inflammatory agents Page(s): 111-112. Decision based on Non-MTUS Citation http://www.caremark.com/portal/asset/FEP_Rationale_Flurbiprofen.pdf.

Decision rationale: Ca MTUS guidelines state the efficacy of topical NSAIDs is greatest in the first 2 weeks of use. They are "recommended for short-term use (4-12 weeks)." In addition guidelines state, "there is little evidence to utilize topical NSIDs for treatment of osteoarthritis of the spine, hip, or shoulder." Chronic pain guidelines do not discuss the specific product flurbiprofen. Other cited resources state "There are no clinical studies to support the safety and effectiveness of flurbiprofen in a topical delivery system (excluding ophthalmic)." The documentation and request do not indicate the dosing, frequency or application site of this medication. Without this information or supporting guidelines, the request for flurbiprofen is not medically necessary.

Baclofen 1.5 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesia: Baclofen Page(s): 113.

Decision rationale: CA MTUS guidelines state that topical Baclofen is not recommended, citing the lack of peer reviewed literature to support its use. It is assumed this is a request for a topical agent as the request is for dispensed "Grams" and not an appropriate oral dose. The request does not include dosing, frequency or site of product application. Without this information and the lack for guideline support make this request not medically necessary.