

Case Number:	CM13-0062830		
Date Assigned:	12/30/2013	Date of Injury:	10/29/2012
Decision Date:	12/09/2015	UR Denial Date:	11/21/2013
Priority:	Standard	Application Received:	12/09/2013

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. 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: California, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 42 year old female, who sustained cumulative industrial trauma injuries from 10-29-2011-10-29-2012. A review of the medical records indicates that the worker is undergoing treatment for C4-C5, C5-C6 disc herniation, bilateral upper extremity overuse tendinopathy and lumbar sprain-strain syndrome. Subjective complaints (06-03-2013, 09-13-2013 and 10-14-2013) included neck, low back and bilateral upper extremity pain that was documented as 7-10 out of 10 during the 10-14-2013 visit and was not quantified during the other office visits. Objective findings (06-03-2013 and 09-13-2013) revealed tenderness, spasm and tightness in the paracervical musculature, decreased range of motion, decreased grip strength, swelling to dorsum of the right hand, tenderness, spasm and tightness in the paralumbar musculature, decreased range of motion and slow gait. The physician's treatment plan included an MRI of the lumbar spine, electromyography-nerve conduction studies of the lower extremity and pain medication. Objective findings (10-14-2013) included tenderness of the paracervical musculature positive head compression sign, pain on scapular retraction and discomfort with compression and palpation. Treatment has included Toradol injections, acupuncture, oral pain medication and transdermal creams (Exoten-C lotion and Gabaketolido rub). The injured worker was noted to be using Fluriflex and TGIce which was applied to the neck, shoulders, elbows and upper extremities but there was no documentation as to the effectiveness of the medication at relieving pain. Start date of these medications is unclear. Toradol injections were administered and the treatment plan included an MRI of the cervical spine, physical therapy of the cervical spine and transdermal creams including Fluriflex and TGIce. A utilization review dated 11-21-2013 non-certified requests for Fluriflex Cream (Flurbuprofen 15%-Cyclobenzaprine 10%) 180 grams and TGIce Cream (Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%) 180 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fluriflex Cream (Flurbiprofen 15%/Cyclobenzaprine 10%) 180 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product. [besides Baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. The MTUS C Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product. [besides Baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications 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." (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic

effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The requested treatment is not medically necessary. Chronic Pain Medical Treatment Guidelines state that topical medications 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Because topical cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.

TGIce Cream (Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%) 180 grams:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: TGHot contains tramadol, gabapentin, menthol, camphor and capsaicin. Capsaicin may have an indication for chronic knee pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses." Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. As the injured worker has osteoarthritis of the knees, capsaicin may be indicated. Per MTUS p113 with regard to topical

gabapentin: "Not recommended. There is no peer-reviewed literature to support use." The MTUS is silent on the use of tramadol and camphor topically. However, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states a "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.