

Case Number:	CM15-0148008		
Date Assigned:	08/11/2015	Date of Injury:	07/11/2012
Decision Date:	09/14/2015	UR Denial Date:	06/22/2015
Priority:	Standard	Application Received:	07/30/2015

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: Anesthesiology

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 51 year old male, who sustained an industrial injury on 7-11-2012. He reported being electrocuted, and the shock threw him off the platform he was standing on, causing him to land on his back. The injured worker was diagnosed as having thoracic spine sprain and strain, lumbar spine sprain and strain, probable herniated nucleus pulposus of the lumbar spine, and rule out radiculopathy of the lower extremity, and right hip strain and tronchanteric bursitis. Treatment to date has included medications, physical therapy, x-rays, magnetic resonance imaging of the lumbar spine (10-19-2014). The current request is for Terocin patches with Lidocaine 4% and Menthol 14%; Ketoprofen 10%, Cyclobenzaprine 2% 180 grams; Gabapentin 10%, Flurbiprofen 15%, Cyclobenzaprine 2% 180 grams; and Diclofenac 10%, Flurbiprofen 10%, Tetracin 5% 180 grams. On 11-11-2013, he reported mid back and low back pain. He rated his pain 4-5 out of 10. His work status is restricted. The treatment plan included: electrodiagnostic studies, magnetic resonance imaging of the lumbar spine, x-rays of the lumbar spine, Ultram, Motrin, Prilosec, FluriFlex compound, transdermal analgesics and anti-inflammatory compounds, physical therapy, and TENS unit. On 12-22-2014, he reported neck pain, mid back and low back pain, bilateral leg and bilateral hip pain. He indicated the low back and bilateral leg pain to have increased and having radiation and weakness of the right leg. The treatment plan included: Prilosec, Ultram, Motrin, Gaba-flur compound, x-rays of the lumbar spine, x-rays of the right hip, lumbar spine epidural injection, functional capacity evaluation, urine testing, and follow up in 6 weeks. On 4-27-2015, he reported sharp, aching neck pain; mid and low back pain, bilateral leg and hip pain. He indicated his low back and

bilateral leg pain to be increased and with radiation into the right leg. The treatment plan included: Ultram, Motrin, Prilosec, Gaba-flur compound, lumbar spine x-rays, lumbar epidural injection, left hand cane, and follow up in 4 months. On 6-30-2015, he reported right hip pain. Physical findings revealed tenderness to the anterior and lateral right hip, and right inguinal region. The treatment plan included: physical therapy, Ketoprofen 75mg, Orphenadrine 100mg, hot pack, mineral ice, and light duty work status.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Terocin patches with Lidocaine 4%, Menthol 14% quantity 30 DOS 4-17-15:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: There is no documentation provided necessitating the use of the requested topical medication, Terocin. According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. In addition, the prescription for the Terocin patches does not indicate for which body part it is to be applied, duration or frequency of use. Therefore, the request for retrospective Terocin patches for DOS 4-17-15 was not medically necessary.

Retrospective Ketoprofen 10% Cyclobenzaprine 2% 180gms DOS 4-17-15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. MTUS guidelines state that Ketoprofen, lidocaine, capsaicin and/or muscle relaxants (Cyclobenzaprine in this case) are not recommended for topical applications. Ketoprofen is not currently FDA approved for a topical application, and has an extremely high incidence of photo-contact dermatitis. In this case, there is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. In addition, the prescription for the Terocin patches does not indicate for which body part it is to be applied, duration or frequency of use. In addition, the requested prescription does not indicate for which body part it is to be applied, duration or frequency of use. Therefore, the request for retrospective compounded topical analgesic, Ketoprofen 10% Cyclobenzaprine 2% 180gms (DOS 4-17-15), is not medically necessary.

**Retrospective Gabapentin 10% Flurbiprofen 15% Cyclobenzaprine 2% quantity 180gms
DOS 4-17-15: Upheld**

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the topical analgesic compound contains: Gabapentin 10% Flurbiprofen 15% Cyclobenzaprine 2%. Gabapentin is an anti-epilepsy drug (AED), which has been shown to be effective for the treatment of diabetic painful neuropathy and post-herpetic neuralgia. The CA MTUS does not recommend Gabapentin as a topical analgesic as there is no peer-reviewed literature to support its use. Flurbiprofen is an NSAID. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Cyclobenzaprine is a muscle relaxant. Per the CA MTUS, there is no evidence for use of any muscle relaxant as a topical product. According to the CA MTUS, all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of

treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. There was a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. In addition, the prescription did not indicate for which body part it was to be applied, duration or frequency of use. Therefore, the request for retrospective Gabapentin 10% Flurbiprofen 15% Cyclobenzaprine 2% quantity 180gms (DOS 4-17-15), was not medically necessary.

Retrospective Diclofenac 10% Flurbiprofen 10% Tetracain 5% quantity 180gm DOS 4-17-15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: There is no documentation provided necessitating use of the requested topical medication. Per California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the topical analgesic contains Diclofenac, Flurbiprofen, and Tetracain. Topical Diclofenac comes in a 1% gel and is indicated for the relief of osteoarthritis in joints that lend themselves to topical treatment, such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip, or shoulder. Flurbiprofen and Tetracain are not FDA approved for topical application. Medical necessity for the requested topical analgesic compound was not established. The requested topical compound was not medically necessary.