

Case Number:	CM15-0189109		
Date Assigned:	10/01/2015	Date of Injury:	04/09/2005
Decision Date:	11/18/2015	UR Denial Date:	08/25/2015
Priority:	Standard	Application Received:	09/25/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 56 year old female, who sustained an industrial injury on 4-9-05. The injured worker is being treated for status post anterior cervical discectomy and fusion C4-7 (7-2012), status post right shoulder arthroscopy with decompression without rotator cuff repair, chronic right elbow medial epicondylitis, right sided thumb carpometacarpal arthrosis, left sided thumb carpometacarpal arthrosis with mild sprain, status post anterior posterior spinal fusion L4-5 and L5-S1 with residual lower extremity radiculopathy, medial knee pain right side, bilateral ankle Achilles tenderness and Achilles tendonitis with possible radiculopathic link of left lower extremity and chronic right sided lateral epicondylitis. Treatment to date has included oral medications including Dexilant, Flexeril and Fioricet; transdermal creams, cervical fusion, lumbar fusion and activity modifications. The physician noted she has been on and or is not tolerating oral medication; however she has requested a refill of her oral medications. On 7-27-15, the injured worker reports she has been using the transdermal cream with benefit and is requesting a refill. She is currently not working. Physical exam of right wrist and elbow performed on 7-27-15 revealed exquisite tenderness along the lateral epicondyle; marked dorsiflexion of wrists and fingers and tenderness of wrist at carpometacarpal joint as well as along the scaphoid. Physical exam also noted tenderness along the left superior iliac crest, positive straight leg raise and is able to walk on her heels. On 8-13-15 a request for authorization was submitted for Flurbiprofen 20%-Lidocaine 5% 150gm, Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.05% 150gm and Cyclobenzaprine 10% lidocaine 2% 150gm. On 8-25-15 a request for Flurbiprofen 20%-Lidocaine 5% 150gm, Gabapentin 10%-Amitriptyline

5%-Capsaicin 0.05% 150gm and Cyclobenzaprine 10% lidocaine2% 150gm was non-certified by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20% + Lidocaine 5%, 150 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 09/28/15 progress report provided by treating physician, the patient presents with pain to multiple parts. The patient is status post anterior cervical discectomy and fusion C4-7 on July 2012, right shoulder arthroscopy with decompression without rotator cuff repair, and anterior posterior spinal fusion L4-5 and L5-S1 on unspecified dates. The request is for FLURBIPROFEN 20% + LIDOCAINE 5%, 150 GM. Patient's diagnosis per Request for Authorization form dated 08/13/15 includes lumbosacral joint ligament sprain, pain in joint involving lower leg, sciatica, and sprain of carpometacarpal joint of hand. Physical exam of right wrist and elbow 07/27/15 revealed tenderness along the lateral epicondyle; marked dorsiflexion of wrists and fingers and tenderness of wrist at carpometacarpal joint as well as along the scaphoid. Examination of the lumbar spine revealed tenderness along the left superior iliac crest, and positive straight leg raise. Treatment to date has included surgeries, medications and topical creams. Patient's medications include Dexilant, Flexeril and Fioricet. The patient is off-work, per 07/27/15 report, and retired, per 09/28/15 report. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 07/27/15 report, treater states, "the patient has been on oral analgesics, and/or not tolerating oral medication. Based on this and my hope to avoid or

minimize the amount of oral medication I am prescribing..." Treater has not indicated where this topical is applied and with what efficacy. Furthermore, MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Lidocaine which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.

Gabapentin 10% + Amitriptyline 5% + Capsaicin 0.025%, 150 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 09/28/15 progress report provided by treating physician, the patient presents with pain to multiple parts. The patient is status post anterior cervical discectomy and fusion C4-7 on July 2012, right shoulder arthroscopy with decompression without rotator cuff repair, and anterior posterior spinal fusion L4-5 and L5-S1 on unspecified dates. The request is for GABAPENTIN 10% + AMITRIPTYLINE 5% + CAPSAICIN 0.025%, 150 GM. Patient's diagnosis per Request for Authorization form dated 08/13/15 includes lumbosacral joint ligament sprain, pain in joint involving lower leg, sciatica, and sprain of carpometacarpal joint of hand. Physical exam of right wrist and elbow 07/27/15 revealed tenderness along the lateral epicondyle; marked dorsiflexion of wrists and fingers and tenderness of wrist at carpometacarpal joint as well as along the scaphoid. Examination of the lumbar spine revealed tenderness along the left superior iliac crest, and positive straight leg raise. Treatment to date has included surgeries, medications and topical creams. Patient's medications include Dexilant, Flexeril and Fioricet. The patient is off-work, per 07/27/15 report, and retired, per 09/28/15 report. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 07/27/15

report, treater states, "the patient has been on oral analgesics, and/or not tolerating oral medication. Based on this and my hope to avoid or minimize the amount of oral medication I am prescribing..." Treater has not indicated where this topical is applied and with what efficacy. Furthermore, MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Gabapentin which is not supported for topical use in lotion form, per MTUS. Furthermore, there is no support for anti-depressants such as Amitriptyline in MTUS or ODG for use as a topical cream. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.

Cyclobenzaprine 10% + Lidocaine 2%, 150 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 09/28/15 progress report provided by treating physician, the patient presents with pain to multiple parts. The patient is status post anterior cervical discectomy and fusion C4-7 on July 2012, right shoulder arthroscopy with decompression without rotator cuff repair, and anterior posterior spinal fusion L4-5 and L5-S1 on unspecified dates. The request is for CYCLOBENZAPRINE 10% + LIDOCAINE 2%, 150 GM. Patient's diagnosis per Request for Authorization form dated 08/13/15 includes lumbosacral joint ligament sprain, pain in joint involving lower leg, sciatica, and sprain of carpometacarpal joint of hand. Physical exam of right wrist and elbow 07/27/15 revealed tenderness along the lateral epicondyle; marked dorsiflexion of wrists and fingers and tenderness of wrist at carpometacarpal joint as well as along the scaphoid. Examination of the lumbar spine revealed tenderness along the left superior iliac crest, and positive straight leg raise. Treatment to date has included surgeries, medications and topical creams. Patient's medications include Dexilant, Flexeril and Fioricet. The patient is off-work, per 07/27/15 report, and retired, per 09/28/15 report. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels)

are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 07/27/15 report, treater states, "the patient has been on oral analgesics, and/or not tolerating oral medication. Based on this and my hope to avoid or minimize the amount of oral medication I am prescribing..." Treater has not indicated where this topical is applied and with what efficacy. Furthermore, MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound contains Lidocaine and Cyclobenzaprine, which are not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.