

Case Number:	CM15-0188093		
Date Assigned:	09/30/2015	Date of Injury:	02/20/2013
Decision Date:	11/13/2015	UR Denial Date:	08/18/2015
Priority:	Standard	Application Received:	09/24/2015

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 31 year old female, who sustained an industrial injury on 2-20-13. Medical records indicate that the injured worker is undergoing treatment for lumbar disc herniations and left lower extremity radiculopathy. The injured worker was noted to be working with restrictions. On (7-21-15) the injured worker complained of low back pain with radiation down the left lower extremity. Examination of the lumbar spine revealed tenderness to palpation along the incision bilaterally. Range of motion was decreased. The injured worker had more pain on flexion than extension. A straight leg raise test was positive on the left side. The injured worker was noted to have good overall pain relief with the transdermal creams: Flurbiprofen, Cyclobenzaprine and Gabapentin. However, once the creams wear off the pain was noted to return. Treatment and evaluation to date has included medications, topical analgesics, MRI of the lumbar spine and a lumbar laminectomy (2-11-14). Treatments tried and failed include epidural steroid injections and physical therapy. Current medications include the compound creams: Flurbiprofen 20%-Lidocaine 5%, Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.025% and Cyclobenzaprine 10%-Lidocaine 2%. The injured worker has been prescribed the compound creams since at least May of 2015. Current requested treatments include the compound creams: Flurbiprofen 20%-Lidocaine 5% 150 grams, Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.025% 150 grams and Cyclobenzaprine 10%-Lidocaine 2% 150 grams. The Utilization Review documentation dated 8-18-15 non-certified the request for the compound creams: Flurbiprofen 20%-Lidocaine 5% 150 grams, Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.025% 150 grams and Cyclobenzaprine 10%-Lidocaine 2% 150 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound medication: Flurbiprofen 20%, Lidocaine 5%, 150gm: 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 07/21/15 progress report provided by treating physician, the patient presents with low back pain with radiation down the left lower extremity. The patient is status post lumbar laminectomy on 02/11/14. The request is for Compound medication: Flurbiprofen 20%, Lidocaine 5%, 150gm. RFA with the request not provided. Patient's diagnosis on 07/21/15 includes disc herniation L3-L4, left lower extremity radiculopathy. Physical examination of the lumbar spine on 07/21/15 revealed tenderness to palpation along the incision bilaterally. Range of motion was decreased. Positive straight leg raise test on the left.

Treatment to date has included surgery, imaging studies, injections, physical therapy and medications. The patient may return to modified work with restrictions, per 06/10/15 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 antiinflammatory 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 07/21/15 report, treater states "at this point, 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 the following transdermal creams..." However, 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.

Compound medication: Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 150gm: 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 07/21/15 progress report provided by treating physician, the patient presents with low back pain with radiation down the left lower extremity. The patient is status post lumbar laminectomy on 02/11/14. The request is for Compound medication: Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 150gm. RFA with the request not provided. Patient's diagnosis on 07/21/15 includes disc herniation L3-L4, left lower extremity radiculopathy. Physical examination of the lumbar spine on 07/21/15 revealed tenderness to palpation along the incision bilaterally. Range of motion was decreased. Positive straight leg raise test on the left. Treatment to date has included surgery, imaging studies, injections, physical therapy and medications. The patient may return to modified work with restrictions, per 06/10/15 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 antiinflammatory 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 07/21/15 report, treater states "at this point, 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 the following transdermal creams..." However, 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 and Amitriptyline 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.

Compound medication: Cyclobenzaprine 10%, Lidocaine 2%, 150gm: 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 07/21/15 progress report provided by treating physician, the patient presents with low back pain with radiation down the left lower extremity. The patient is status post lumbar laminectomy on 02/11/14. The request is for Compound medication: Cyclobenzaprine 10%, Lidocaine 2%, 150gm. RFA with the request not provided. Patient's diagnosis on 07/21/15 includes disc herniation L3-L4, left lower extremity radiculopathy. Physical examination of the lumbar spine on 07/21/15 revealed tenderness to palpation along the incision bilaterally. Range of motion was decreased. Positive straight leg raise test on the left.

Treatment to date has included surgery, imaging studies, injections, physical therapy and medications. The patient may return to modified work with restrictions, per 06/10/15 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 antiinflammatory 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 07/21/15 report, treater states "at this point, 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 the following transdermal creams..." However, 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 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.