

Case Number:	CM15-0192931		
Date Assigned:	10/07/2015	Date of Injury:	10/02/2014
Decision Date:	11/19/2015	UR Denial Date:	09/10/2015
Priority:	Standard	Application Received:	10/01/2015

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 59 year old female, who sustained an industrial injury on 10-2-2014. She reported bilateral knee pain and right ankle pain following a fall. Diagnoses include chondromalacia patellae and joint pain, left leg. Treatments to date include activity modification, Advil, Motrin, and Diclofenac (prescribed on 6-30-15) and physical therapy. The records indicated topical compound creams had been prescribed in January 2015; however, the subsequent medical visit records did not list topicals in current medications or document efficacy. On 8-25-15, she reported increasing left knee pain associated with swelling, weakness, instability and locking-catching. The provider documented she was "using Advil with mild relief but otherwise denied taking pain medication." The physical examination documented bilateral knee tenderness, mild swelling, and a bilaterally positive valgus collapse with single leg squat. The appeal requested authorization for topical compounds including Flurbiprofen-Lidocaine; Gabapentin-Amitriptyline-Capsaicin; and Cyclobenzaprine-Lidocaine, for date of service 8-4-15. The Utilization Review dated 9-10-15, denied this request.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Flurbiprofen/Lidocaine (DOS: 08/04/2015): 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: Based on the 07/13/15 progress report provided by treating physician, the patient presents with bilateral knee pain due to patellofemoral syndrome and right ankle pain due to sprain. The request is for Retrospective Flurbiprofen/Lidocaine (DOS: 08/04/2015). RFA with the request not provided. Patient's diagnosis on 07/13/15 includes chondromalacia patella, sprain of ankle NOS, and left leg joint pain. Physical examination to the bilateral knees on 07/13/15 revealed mild swelling and tenderness to iliotibial band, patella and patellar tendon. Decreased patellar tilt and moderate crepitation noted. Treatment to date has included imaging and electrodiagnostic studies, physical therapy and medications. Patient's medications include Advil, Motrin, Famotidine, Metoprolol tartrate, Triamterene, Klonopin and Trazodone. The patient is off-work, per 07/13/15 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." Progress report with the request not provided. Treater has not provided medical rationale for the request. In this case, given patient's pain symptoms to the knees and ankle, flurbiprofen portion of this topical would be indicated. However, 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 which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, this retrospective request IS/WAS NOT medically necessary.

Retrospective Gabapentin/Amitriptyline/Capsaicin (DOS: 08/04/2015): 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: Based on the 07/13/15 progress report provided by treating physician, the patient presents with bilateral knee pain due to patellofemoral syndrome and right ankle pain due to sprain. The request is for Retrospective Gabapentin/Amitriptyline/Capsaicin (DOS: 08/04/2015). RFA with the request not provided. Patient's diagnosis on 07/13/15 includes chondromalacia patella, sprain of ankle NOS, and left leg joint pain. Physical examination to the bilateral knees on 07/13/15 revealed mild swelling and tenderness to iliotibial band, patella and patellar tendon. Decreased patellar tilt and moderate crepitation noted. Treatment to date has included imaging and electrodiagnostic studies, physical therapy and medications. Patient's medications include Advil, Motrin, Famotidine, Metoprolol tartrate, Triamterene, Klonopin and Trazodone. The patient is off-work, per 07/13/15 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." Progress report with the request not provided. Treater has not provided medical rationale for the request. Nonetheless, 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 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 nor ODG for topical use. This request is not in accordance with guidelines. Therefore, this retrospective request IS/WAS NOT medically necessary.

Retrospective Cyclobenzaprine/Lidocaine (DOS: 08/04/2015): 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: Based on the 07/13/15 progress report provided by treating physician, the patient presents with bilateral knee pain due to patellofemoral syndrome and right ankle pain due to sprain. The request is for Retrospective Cyclobenzaprine/Lidocaine (DOS: 08/04/2015). RFA with the request not provided. Patient's diagnosis on 07/13/15 includes chondromalacia patella, sprain of ankle NOS, and left leg joint pain. Physical examination to the bilateral knees on 07/13/15 revealed mild swelling and tenderness to iliotibial band, patella and patellar tendon. Decreased patellar tilt and moderate crepitation noted. Treatment to date has included imaging and electrodiagnostic studies, physical therapy and medications. Patient's medications include Advil, Motrin, Famotidine, Metoprolol tartrate, Triamterene, Klonopin and Trazodone. The patient is off-work, per 07/13/15 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." Progress report with the request not provided. Treater has not provided medical rationale for the request. Nonetheless, 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, this retrospective request IS/WAS NOT medically necessary.