

Case Number:	CM14-0028629		
Date Assigned:	06/25/2014	Date of Injury:	03/22/2011
Decision Date:	08/18/2014	UR Denial Date:	02/14/2014
Priority:	Standard	Application Received:	03/06/2014

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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Oklahoma and Texas. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 53-year-old female with a reported date of injury on 03/22/2011. The mechanism of injury was noted to be from a slip and fall. Her diagnoses were noted to include lumbar sprain/strain, lumbar paraspinal muscle spasms, lumbar disc herniations, lumbar radiculitis/radiculopathy of the lower extremities and sacroiliitis of the bilateral sacroiliac joint. Her previous treatments were noted to include physical therapy, acupuncture, epidural steroid injections, and medications. The progress note dated 03/06/2014 revealed the injured worker received significant improvement from previous bilateral transforaminal lumbar epidural steroid injection. The injured worker revealed she was experiencing increasing movement when she had to stand up from a sitting position as well as her daily functionalities. The physical examination of the lumbar spine revealed improvement of decreased pain with palpation over L4-5 and L5-S1. There was improvement on palpation over the bilateral sacroiliac joint, previous suggestive of severe sacroiliitis with physical improvement with improvement of the patient's pain. There was decreased range of motion to the lumbar spine and the straight leg raise tests were improved bilaterally in both the seated and supine position. The progress note dated 05/10/2014 revealed the injured worker complained of stomach complaints, depression, and back end leg pain. The physical examination revealed a decreased range of motion and a positive straight leg to the right leg with muscle spasms. The Request for Authorization Form was not submitted within the medical records. The request was for flurbiprofen 20%, capsaicin 0.025%, methyl salicylate 4%, DMSO in Lidoderm base 120 grams and gabapentin 5%, tramadol 10%, baclofen 2.5% in Lidoderm base 120 grams for pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

NON-CERTIFICATION FOR REQUESTED FLURBIPROFEN 20%, CAPSAICIN 0.025%, METHYL SALICYLATE 4%, DMSO IN LIDODERM BASE 120 GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 105, 111, 112, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Salicylate Topicals Page(s): 111-113, 105.

Decision rationale: The request for non-certification for requested flurbiprofen 20%, capsaicin 0.025%, methyl salicylate 4%, DMSO in Lidoderm base 120 grams and gabapentin 5%, tramadol 10%, baclofen 2.5% in Lidoderm base 120 grams is non-certified. The injured worker has been utilizing this medication since 01/2014. The California Chronic Pain Medical Treatment Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of any of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The efficacy of clinical trials for topical NSAIDs has been inconsistent and most studies are of small and 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. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long term studies of their effectiveness for safety. The guidelines indications for topical NSAIDs is osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The guidelines do not recommend topical NSAIDs for neuropathic pain as there is no evidence to support use and the topical NSAID recommended is Voltaren gel 1% for relief of osteoarthritis and pains in joints that lend themselves to topical treatment. The guidelines recommend topical lidocaine for neuropathic pain after there has been evidence of a first line trial of therapy (tricyclic or SNRI) antidepressants or an AED such as gabapentin or Lyrica. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Topical lidocaine is not recommended for nonneuropathic pain. The guidelines state capsaicin is recommended only as an option for inpatients who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and this is no current indication that this increase over a 0.025% formulation would provide any further efficacy. There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic nonspecific back pain but it should be considered

experimental and very high doses. Baclofen is not recommended by the guidelines. There is currently 1 day 3 study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy/induced for referral neuropathy. There is no peer reviewed literature to support the use of topical baclofen. The guidelines recommend topical salicylate and report it is significantly better than placebo in chronic pain. The guidelines do not recommend gabapentin as there is no peer reviewed literature to support topical use. Flurbiprofen, gabapentin, baclofen, and Lidoderm based is not recommended by the guidelines. The guidelines state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Therefore, the request is non-certified.

GABAPENTIN 5%, TRAMADOL 10%, BACLOFEN 2.5% IN LIDODERM BASE 120 GM.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 105, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical Salicylates Page(s): 105, 111-113.

Decision rationale: The request for non-certification for requested flurbiprofen 20%, capsaicin 0.025%, methyl salicylate 4%, DMSO in Lidoderm base 120 grams and gabapentin 5%, tramadol 10%, baclofen 2.5% in Lidoderm base 120 grams is not medically necessary . The injured worker has been utilizing this medication since 01/2014. The California Chronic Pain Medical Treatment Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of any of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The efficacy of clinical trials for topical NSAIDs has been inconsistent and most studies are of small and 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. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long term studies of their effectiveness for safety. The guidelines indications for topical NSAIDs is osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short term use (4 to 12 weeks. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The guidelines do not recommend topical NSAIDs for neuropathic pain as there is no evidence to support use and the topical NSAID recommended is Voltaren gel 1% for relief of osteoarthritis and pains in joints that lend themselves to topical treatment. The guidelines recommend topical lidocaine for neuropathic pain after there has been evidence of a first line trial of therapy (tricyclic or SNRI) antidepressants or an AED such as gabapentin or Lyrica. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain.

Topical lidocaine is not recommended for nonneuropathic pain. The guidelines state capsaicin is recommended only as an option for inpatients who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and this is no current indication that this increase over a 0.025% formulation would provide any further efficacy. There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic nonspecific back pain but it should be considered experimental and very high doses. Baclofen is not recommended by the guidelines. There is currently 1 day 3 study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy/induced for referral neuropathy. There is no peer reviewed literature to support the use of topical baclofen. The guidelines recommend topical salicylate and report it is significantly better than placebo in chronic pain. The guidelines do not recommend gabapentin as there is no peer reviewed literature to support topical use. Flurbiprofen, gabapentin, baclofen, and Lidoderm based is not recommended by the guidelines. The guidelines state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Therefore, the request is not medically necessary .