

Case Number:	CM15-0008415		
Date Assigned:	01/23/2015	Date of Injury:	09/26/2007
Decision Date:	04/10/2015	UR Denial Date:	12/24/2014
Priority:	Standard	Application Received:	01/14/2015

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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 33-year-old female, who sustained an industrial injury on 9/26/2007 secondary to repetitive work activities. The treating physician has reported ongoing pain to shoulders and wrists with sharp stabbing, burning, aching, throbbing and radiating pain associated with numbness, tingling, nausea, swelling, locking weakness relieved by medicines. Additional complaints include low back pain, left leg pain and myofascial pain. The diagnoses have included cervicobrachial syndrome (diffuse), brachial plexus lesions, lateral epicondylitis, myalgia and myositis, low back pain, and thoracic outlet syndrome. Treatment to date has included pain medication, braces/casts, physical therapy, traction, massage, an exercise program, trigger point injections, biofeedback, psychotherapy, acupuncture and chiropractic treatment. On 12/24/14 Utilization Review non-certified Lyrica 50mg #60, and Flector patch 1.3% #6 noting the MTUS Guidelines Shoulder Complaints, forearm, wrist, and hand complaints, Chronic Pain Medical Treatment Guidelines and ODG were cited. On 1/14/15, the injured worker submitted an application for IMR for review of Lyrica 50mg #60, and Flector patch 1.3% #6.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lyrica 50mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 11 Forearm, Wrist, and Hand Complaints, Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs Page(s): 16-20. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Pregabalin, (Lyrica).

Decision rationale: Lyrica (pregabalin) is an anti-epilepsy drug. The MTUS recommends use of antiepileptic drugs as a first-line treatment for neuropathic pain. Most randomized controlled trials for the use of this class of medications for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy. There are few randomized control trials directed at central pain and none for painful radiculopathy. The choice of specific agents depends on the balance between effectiveness and adverse reactions. A good response to the use of antiepileptic drugs is defined as a 50% reduction in pain and a moderate response as a 30% reduction. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects that occurred with use. The continued use of antiepileptic drugs depends on improved outcomes versus tolerability of adverse effects. The ODG guidelines recommend pregabalin (Lyrica) in neuropathic pain conditions and fibromyalgia, but not for acute pain. Pregabalin (Lyrica), an anticonvulsant, has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. This Cochrane review concluded that pregabalin has proven efficacy in neuropathic pain conditions and fibromyalgia. A minority of patients will have substantial benefit with pregabalin, and more will have moderate benefit. Many will have no or trivial benefit, or will discontinue because of adverse events. Individualization of treatment is needed to maximise pain relief and minimise adverse events. There is no evidence to support the use of pregabalin in acute pain scenarios. (Moore-Cochrane, 2009) In treating diabetic neuropathy and postherpetic neuralgia compared with placebo, pregabalin is associated with a modest increase in the number of patients experiencing meaningful pain reduction. In treating fibromyalgia, compared with placebo, pregabalin alone is associated with a small increase in the number of patients experiencing meaningful pain reduction. The medical records provided do not indicate a diagnosis of diabetic neuropathy, postherpetic neuralgia, or fibromyalgia. There is evidence however, of neuropathic pain secondary to thoracic outlet syndrome/brachial plexus injury and neuropathic symptoms in the extremities with consideration of a diagnosis of CRPS. In this case, it would be reasonable to attempt a trial of anti-epilepsy medication for neuropathic pain. As such, I am recommending reversal of the prior Utilization Review decision. The request for Lyrica 50mg #60 is medically necessary.

Flector patch 1.3% #6: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) (Online Edition); Pain Chronic, Flector Patch (Diclofenac Epolamine).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Drug formulary, Flector Patches.

Decision rationale: The MTUS recommends topical analgesics as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Topical 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. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. The ODG guidelines note that Flector Patches (diclofenac epolamine) are not recommended as a first-line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. (FDA, 2007) The efficacy in clinical trials for topical NSAIDs 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. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate Flector efficacy beyond two weeks. In this case there is no documentation of failure of oral NSAID medications or contraindications. The records show that Flector Patches were prescribed on 9/22/14 with no indication of efficacy or functional improvement. Without evidence to substantiate efficacy beyond 2 weeks of use, the request for Flector patch 1.3%, applied every 3 days, #6 is not supported by the MTUS and ODG guidelines and is not medically necessary.