

Case Number:	CM14-0140801		
Date Assigned:	09/10/2014	Date of Injury:	08/27/2002
Decision Date:	10/06/2014	UR Denial Date:	08/05/2014
Priority:	Standard	Application Received:	09/01/2014

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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 73 year old male. The date of injury is August 27, 2002. The patient sustained an injury to his lumbar spine and right leg. The specific mechanism of injury was not elaborated on in the notes available for review. The patient currently reports ongoing low back pain and lower extremity pain. The patient carries the current diagnosis of disc degeneration not otherwise specified. The patient is maintained any multimodal pain medication regimen including Flector patch and Naproxen. Your request for Flector patch and Naproxen was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector Patches #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, CHRONIC, FLECTOR PATCH

Decision rationale: According to the official disability guidelines, Flector patch is not recommended as a first-line treatment. See the Diclofenac listing, where 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) On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing Diclofenac. Post marketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac. (FDA, 2009) 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. See also topical analgesics, Non-steroidal antiinflammatory agents (NSAIDs), and the Diclofenac topical listing. [Flector ranked #17 in amount billed for WC in 2011. (Coventry, 2012)] According to the documents available for review, the patient has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Naproxen 375mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67, 70-73.

Decision rationale: According to the MTUS Anti-inflammatories are the traditional first lines of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) Recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDS have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing

Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. According to the documents available for review, it appears that the patient is taking this medication for long-term therapy of a chronic condition. Given the increased risks associated with long-term use of this medication and no documented evidence that the lowest possible dose is being used for the shortest period of time, the requirements for treatment have not been met and medical necessity has not been established.