

Case Number:	CM14-0030328		
Date Assigned:	06/20/2014	Date of Injury:	05/10/2013
Decision Date:	01/28/2015	UR Denial Date:	02/21/2014
Priority:	Standard	Application Received:	03/10/2014

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 Rehab, has a subspecialty in Pain Medicine and is licensed to practice in California. 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 39 year-old male with a date of injury of May 10, 2013. The patient's industrially related diagnoses include left shoulder pain and s/p left shoulder arthroscopy with mumford, dated 4/17/2014. The disputed issues are Flurbitac 100/100mg capsule #90, Xolido 2% pain relief cream, and Enova RX-Ibuprofen 10% cream. A utilization review determination on 2/21/2014 had non-certified these requests. The stated rationale for the denial of Flurbitac was: "Report and the RFA states that this is a combination of 100mg of flubiprofen and 100mg of ranitidine.... The report states that this compounded is indicated because of the potential for gastrointestinal side effects with flubiprofen and the ranitidine is combined because of that. There is no indication that this patient is at risk for gastrointestinal side effects with oral NSAIDs. Even if he were, there is no rationale provided for this patient cannot take oral generic flubiprofen and oral generic ranitidine." The stated rationale for the denial of Xolido 2% cream was: "This is a topical lidocaine product.... There is no documentation that this patient suffers from annoy of those maladies. MTUS guidelines do not support use of this topical preparation of chronic pain. MTUS guidelines only support use of Topical lidocaine in the formation of the patch. Not approved." Lastly, the stated rationale for the denial Enova RX-Ibuprofen 10% cream was: "The requesting documents indicate that this is a topical ibuprofen cream. The report says that because oral NSAIDs cause significant upper gastrointestinal adverse effects the transdermal is being used because gastrointestinal adverse event are known not to be a feature of the transdermal NSAIDs use. However, MTUS guidelines indicate that topical/transdermal NSAIDs can be systemically absorbed to a high degree and still produce systemic side effects. There is no documentation that this patient has a contraindication to use of oral NSAIDs which is the first-line method of delivery. Not approved."

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbitac 100/100mg capsule #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (non-steroid anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-72.

Decision rationale: Regarding the request for the compounded medication Flurbitac 100/100mg capsule (Flurbiprofen and ranitidine), Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding NSAIDs, the guidelines state that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. California MTUS states that H2 receptor antagonists are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Criteria to determine if a patient is at risk for gastrointestinal events includes age over 65 years, history of GI bleeding or peptic ulcer, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID use. Within the medical records available for review, there was documentation that left shoulder pain and the guidelines recommend NSAIDs such as Flurbiprofen for pain. However, there was no indication that the injured worker had complaints of dyspepsia secondary to NSAID use or was at risk for gastrointestinal events with NSAID as outlined in the guidelines. Without risk for gastrointestinal events, there is no indication for an H2 receptor antagonist for his industrial injury. Since this compounded formulation has a drug that is not recommended, the prescription is not recommended. In light of these issues, the currently requested Flurbitac 100/100mg capsule #90 is not medically necessary.

Xolido 2% pain relief cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (non-steroid anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112.

Decision rationale: Regarding request for Xolido 2% pain relief cream (topical lidocaine), Chronic Pain Medical Treatment Guidelines recommend the use of topical lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Guidelines further stipulate that no commercially approved topical formulations of lidocaine cream, lotion, or gel are indicated for neuropathic pain. Within the medical records available for review, there was no documentation that the injured worker had failed first-line therapy recommendations. Furthermore, guidelines do not support the use of topical lidocaine preparations which are not in patch form. As such, the currently requested Xolido 2% pain relief cream is not medically necessary.

Enova RX-Ibuprofen 10% cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (non-steroid anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: Regarding the request for topical Enova RX-Ibuprofen 10% cream, Chronic Pain Medical Treatment Guidelines state that topical NSAIDs are recommended for short-term use. Oral NSAIDs contain significantly more guideline support, provided there are no contraindications to the use of oral NSAIDs. Within the medical records available for review, there was no indication that the injured worker failed oral NSAIDs or was unable to tolerate oral NSAIDs, which would be preferred. The treating physician prescribed this topical NSAID because oral NSAIDs cause significant upper gastrointestinal adverse events and that "gastrointestinal adverse events are known not to be a feature of transdermal NSAID use." However, there is a risk of gastrointestinal bleeding even with topical NSAIDs. Furthermore, there was no documentation that the injured worker had previous gastrointestinal events or was at risk with oral NSAIDs. In light of these issues, the currently requested topical Enova RX-Ibuprofen 10% cream is not medically necessary.