

<b>Case Number:</b>	CM13-0036690		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	04/01/1994
<b>Decision Date:</b>	02/18/2014	<b>UR Denial Date:</b>	09/23/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology and Pain Management and is licensed to practice in Florida. 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 physician 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 patient is a 73 year old male who reported an injury on 04/01/1994. The patient had subsequently undergone a left shoulder rotator cuff repair on 07/06/2005. On 02/22/1995, the patient also underwent a right shoulder rotator cuff repair, acromioplasty, and AC resection. The patient was seen on 08/27/2013 for a comprehensive follow-up on both shoulders. The patient is still taking Arthrotec and states that his left shoulder is worse than the right. The physician stated that "we felt the Arthrotec is very uncomfortable." Under the examination, range of motion of the arm with abduction/external rotation was 90/75; internal rotation behind his back is to T10. On the left, the patient had 165 degrees of passive flexion, abduction/external is 90/75 with internal rotation behind his back also to T10. The patient was noted to have mild crepitus in the left shoulder, but not on the right. Overall strength is 5-/5 without pain in both flexion and abduction bilaterally. The patient gave no signs of instability on the right with a negative abduction external stress test, and negative inferior sulcus test. At the time of that exam, the patient had had no lab work done for 1 year.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Arthrotec 75mg #60 with 6 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Combination (NSAID/GI protectant), Page(s): 70. Decision based on Non-MTUS

Citation Official Disability Guidelines (ODG) Pain Chapter, Arthrotec® (diclofenac/misoprostol).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Combination (NSAID/GI protectant), Page(s): 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Arthrotec® (diclofenac/ misoprostol).

**Decision rationale:** Regarding the request for Arthrotec 75mg #60 with 6 refills, Arthrotec is listed under the California MTUS as an NSAID/GI protectant. It has the combination of diclofenac and misoprostol, which is an agent that inhibits basal and nocturnal gastric acid secretion and has some mucosal protective properties. The indication of use is for the treatment of the signs and symptoms of osteoarthritis in patients at high risk for developing NSAID induced gastric or duodenal ulcers and their complications. The Official Disability Guidelines has also been referred to in this case and states that Arthrotec is not recommended as a first line due to increased risk profile. The package insert for Arthrotec includes a boxed warning that also relates to potential toxicities of misoprostol. In the treatment of NSAIDs induced ulcers, omeprazole has been proved to be at least as effective as misoprostol, but significantly better tolerated, and therefore misoprostol should not be considered a first choice treatment. In the case of this patient, the documentation even states that the physician felt the Arthrotec is very uncomfortable. Furthermore, there is a lack of sufficient objective information pertaining to the efficacy of this medication towards reducing the patient's discomfort. The only documentation provided for review from 2013 was from approximately 5-1/2 months ago. Therefore, the medical necessity for the continuation of this medication cannot be established. As such, the requested Arthrotec 75mg #60 with 6 refills is non-certified.

**1 blood lab for side effects:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Combination (NSAID/GI protectant), Page(s): 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Arthrotec® (diclofenac/ misoprostol).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Combination (NSAID/GI protectant),.

**Decision rationale:** Regarding the request for 1 blood lab for side effects, under the California MTUS it states that 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. In the case of this patient, because he has been utilizing NSAIDs long term, it would be medically appropriate for the patient to undergo 1 blood lab for side effects. However, the physician did not indicate which lab draw he wishes to have done. A documentation dated 08/27/2013 does show the physician has marked next to the CBC with differential. However, because the request itself does not specify which draw, the requested service cannot be warranted at this time. As such, the request for 1 blood lab for side effects is non-certified.

