

<b>Case Number:</b>	CM14-0129918		
<b>Date Assigned:</b>	08/20/2014	<b>Date of Injury:</b>	02/14/2000
<b>Decision Date:</b>	10/03/2014	<b>UR Denial Date:</b>	07/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/14/2014

### 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 and is licensed to practice in 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 63 year old male who was injured on 02/14/2000, sustaining chronic low back, hip and knee pain. The mechanism of injury was undisclosed. Clinical diagnoses include joint pain of the lower leg, lumbago and cervicgia. A clinical note dated 02/26/14 indicated injured worker continues to have back and knee pain which feel burning at times. The injured worker indicated the pain is so severe that he feels as if he will fall. Pain level was rated as 6/10. Clinical note dated 04/24/14 indicated the injured worker complains of increase in pain after walking. The injured worker indicated the pain is in the low back through buttock down to right leg and getting worse. He also indicated the pain is controlled for 4 hrs. Pain level was rated as 10/10 without medications and unable to function. With medication, pain was rated as 4/10 and is able to complete activities of daily living, like, walking less block, standing 10 minutes, and sitting for 15 min. The injured worker indicated Arthrotec increases his function. Physical examination revealed the injured worker is able to transfer from sit to stand without assistance, ambulates with stiff antalgic gait. There was limited range of motion of the lower extremities and muscle strength was 4/5. There was decreased sensation to light touch on right to left. The range of motion on his back is limited in all directions and there was tenderness to palpation in the lumbar spinous processes. Treatment plan included Norco 10-325mg Q 6hrs for pain, Flexeril 10mg Q 12hrs for muscle spasms, Voltaren gel 1% apply QID for local pain, and Arthrotec 75mg PO BID for inflammation. The requests for the following medications, Flexeril 10mg #60 has been certified with modification to 1 prescription, Voltaren gel 1%#40 with 3 refills has been non-certified, and Arthrotec 75mg # 180 with 3 refills has been determined not medically necessary on 07/22/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 Prescription of Flexeril 10mg #60 between 7/17/14-09/16/14: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril)> Page(s): 41 of 127.

**Decision rationale:** As noted on page 41 of the Chronic Pain Medical Treatment Guidelines, cyclobenzaprine is recommended as a second-line option for short-term (less than two weeks) treatment of acute low back pain and for short-term treatment of acute exacerbations in injured workers with chronic low back pain. Studies have shown that the efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Based on the clinical documentation, the injured worker has exceeded the 2-4 week window for acute management also indicating a lack of efficacy if being utilized for chronic flare-ups. As such, the request for 1 prescription of Flexeril 10 mg #60 cannot be recommended as medically necessary.

**1 Prescription of Voltaren gel 1% #40 with 3 refills between 7/14/14-11/15/14: Upheld**

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

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

**Decision rationale:** As noted on page 112 of the Chronic Pain Medical Treatment Guidelines, Voltaren Gel (diclofenac) is not recommended as a first-line treatment. Diclofenac is recommended for osteoarthritis after failure of an oral NSAID, contraindications to oral NSAIDs, or for injured workers who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to FDA MedWatch, post-marketing surveillance of Diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. As such the request for this medication, Voltaren gel 1% #40 with 3 refills, cannot be recommended as medically necessary at this time.

**1 Prescription of Arthrotec 75mg# 180 with 3 refills between 7/17/14-11/15/14: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITIES 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), online version < Pain (Chronic)>, <NSAIDs, specific drug list and adverse effects>

**Decision rationale:** Arthrotec is a combination product containing Diclofenac sodium, a nonsteroidal anti-inflammatory drug (NSAID) with analgesic properties, and misoprostol, an agent with that inhibits basal and nocturnal gastric acid secretion that has some mucosal protective properties. Arthrotec is indicated for treatment of signs and symptoms of osteoarthritis in injured workers at high risk for developing NSAID-induced gastric or duodenal ulcers and their complications. As per Official Disability Guidelines, Diclofenac is not recommended as first line treatment due to increased risk profile. In the treatment of NSAIDs induced ulcer, omeprazole has proved to be at least as effective as misoprostol, but significantly better tolerated, therefore, misoprostol should not be considered a first choice treatment. There is no indication in the clinical documentation that the injured worker has osteoarthritis, nor is at high-risk for developing NSAID-induced gastric or duodenal ulcers. Moreover, there was no recent documentation submitted for review limiting the ability to assess the injured worker's current clinical status to substantiate the medical necessity of the medication requested. As such, the request for 1 prescription of Arthrotec 75mg #180 with 3 refills cannot be recommended as medically necessary.