

<b>Case Number:</b>	CM15-0202487		
<b>Date Assigned:</b>	10/19/2015	<b>Date of Injury:</b>	03/28/1998
<b>Decision Date:</b>	12/01/2015	<b>UR Denial Date:</b>	09/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/14/2015

### 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: California

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 75 year old male, who sustained an industrial injury on March 28, 1998. The injured worker was diagnosed as having cervical disc displacement, degenerative disc disease cervical disc degeneration, and long term use of medications not elsewhere classified. Treatment and diagnostic studies to date has included medication regimen and a functional restoration program. In a progress note dated July 30, 2015 the treating physician reports complaints of "severe" pain to the neck with muscle spasms, stiffness, and flexion deformity. The treating physician also noted "difficulty with range of motion". The review of the systems performed on July 30, 2015 noted no complaints of constipation or abdominal pain. Examination performed on July 30, 2015 was revealing for the ability to bring the neck to neutral position with the flexion deformity, decreased lateral tilt and rotation to the neck bilaterally by greater than 75%, and tenderness to the upper thoracic spine and the lumbosacral junction. The injured worker's current medication regimen on July 30, 2015 included Tramadol ER, Orphenadrine ER, Diclofenac Sodium EC, Flector Patch (since at least prior March 16, 2015), Colace (since at least prior to June 11, 2015), Aspirin, Atenolol, Pepcid, and Zocor. The progress note from July 30, 2015 noted that the injured worker's use of the Flector Patch "is quite effective in combination with oral anti-inflammatory and when he is having severe flare-up of pain in the patch really makes a difference", but the progress note did not indicate the injured worker's pain level prior to use of his medication regimen and after use of his medication regimen to indicate the effects with the use of the injured worker's medication regimen. Also, the documentation provided did not indicate if the injured worker experienced any functional improvement with activities of daily

living with the use of his medication regimen. The progress note on July 30, 2015 also noted the discontinuation of the medication Tramadol ER indicating that this medication is "very constipating". On July 30, 2015 the treating physician requested Flector patch 1.3% with a quantity of 60 with 2 refills and Colace 100mg with a quantity of 60 with 2 refills noting current use of these medications. On September 16, 2015 the Utilization Review determined the requests for Flector patch 1.3% with a quantity of 60 with 2 refills and Colace 100mg with a quantity of 60 with 2 refills for the date of service of July 30, 2015 to be non-certified.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Flector patch 1.3% #60 with 2 refills (DOS 7/30/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Flector patch.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), Topical Analgesics.

**Decision rationale:** The Flector Patch is a topical analgesic containing diclofenac epolamine. The MTUS Guidelines recommend the use of NSAIDs for osteoarthritis at the lowest dose for the shortest period in patients with moderate to severe pain. 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. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, and after considering the increased risk profile with diclofenac, including topical formulations. In this case, the injured worker has been using the flector patch and oral NSAIDs. Flector patches are only recommended with there is a contraindication or adverse reaction to NSAIDs, therefore, the request for Flector patch 1.3% #60 with 2 refills (DOS 7/30/15) is determined to not be medically necessary.

#### **Colace 100mg #60 with 2 refills (DOS 7/30/15): Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Opioid Induced Constipation Treatment Section.

**Decision rationale:** The MTUS guidelines and ODG do not address the use of Colace for the treatment of opioid-induced constipation. The MTUS guidelines and the ODG do address the use of laxatives in general. Per manufacture information, Colace is a stool softener. The MTUS Guidelines recommends the prophylactic treatment of constipation when initiating opioid therapy. The ODG states that first line treatment for opioid induced constipation includes

laxatives to help stimulate gastric motility, as well as other medications to help loosen hard stools, add bulk, and increase water content of the stool. The injured worker is noted be treated with opioid medications, and reports problems with constipation, therefore, the request for Colace 100mg #60 with 2 refills (DOS 7/30/15) is determined to be medically necessary.