

<b>Case Number:</b>	CM15-0018239		
<b>Date Assigned:</b>	02/06/2015	<b>Date of Injury:</b>	07/13/2007
<b>Decision Date:</b>	03/30/2015	<b>UR Denial Date:</b>	01/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/30/2015

### 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: Internal 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 58-year-old female, with a reported date of injury of 07/13/2007. The diagnoses include chronic intractable low back pain secondary to lumbosacral degenerative disc disease, lumbar radiculopathy, and myofascial pain. Treatments have included ice packs, oral medications and topical pain medications. The progress report dated 01/06/2015 indicates that the injured worker was doing very well and was currently maintaining her dose of her pain medications. She had not had any severe major flare-ups. The injured worker had difficulty standing and walking for prolonged periods of time. The objective findings included no antalgic gait, limited lumbar range of motion, normal motor strength in the lower extremity, tenderness to palpation to the lumbar paraspinals, intact sensation, and negative straight leg raise test. The treating physician requested a refill for Flector patch 1.3% for severe flare-ups, Flexeril 10mg #60 for muscle spasms, and Ibuprofen 800mg #60 for pain. On 01/27/2015, Utilization Review (UR) denied the request for Flector patch 1.3% #60, with three refills, Flexeril 10mg #60, with three refills, and Ibuprofen 800mg #60, with three refills. The UR physician noted that there was no diagnosis of osteoarthritis, the injured worker had not failed a trial of oral non-steroidal anti-inflammatory drugs (NSAIDs), and there was no specific effectiveness noted or evidence of measurable objective functional benefit with either oral or topical NSAID use. The MTUS Chronic Pain Guidelines and the Non-MTUS Official Disability Guidelines were cited.

### 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 refills: 3:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS. Decision based on Non-MTUS Citation Official Disability Guidelines- TWC, Pain

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All non-steroidal anti-inflammatory drugs (NSAIDs) have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). Use of NSAIDs may compromise renal function. FDA medication guide recommends lab monitoring of a CBC complete blood count and chemistry profile (including liver and renal function tests). Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records document the long-term use of NSAIDS. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The use of the topical NSAID Flector is not supported by MTUS guidelines. Therefore, the request for Flector patch #60 with 3 refills is not medically necessary.

**Flexeril 10mg #60 refill: 3:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant. Decision based on Non-MTUS Citation Official Disability Guidelines- TWC, Pain

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 49, Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Pages 41-42. Muscle relaxants Pages 63-66. Decision based on Non-MTUS Citation FDA Prescribing Information Flexeril Cyclobenzaprine <http://www.drugs.com/pro/flexeril.html>

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine (Flexeril) is an option for a short course of therapy. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. FDA guidelines state that Cyclobenzaprine is indicated for acute musculoskeletal conditions. Cyclobenzaprine should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available. Medical records document that the patient's occupational injuries are chronic. MTUS, ACOEM, and FDA guidelines do not support the use of Cyclobenzaprine (Flexeril) for chronic conditions. Medical records indicate the long-term use of the muscle relaxant Cyclobenzaprine, which is not supported by MTUS and FDA guidelines. The request for Flexeril 10 mg #60 with 3 refills is not supported by MTUS or ACOEM guidelines. Therefore, the request for Flexeril is not medically necessary.

**Ibuprofen 800mg #60 refills: 3:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines- TWC, Pain

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The request for the NSAID Ibuprofen 800 mg #60 with 3 refills is not supported by MTUS guidelines. Therefore, the request for Ibuprofen is not medically necessary.