

<b>Case Number:</b>	CM14-0210327		
<b>Date Assigned:</b>	12/23/2014	<b>Date of Injury:</b>	02/28/1999
<b>Decision Date:</b>	02/20/2015	<b>UR Denial Date:</b>	12/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/15/2014

### 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. 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: New Jersey, Michigan, California  
 Certification(s)/Specialty: Neurology, Neuromuscular 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 patient is a 65-year-old woman who sustained a work-related injury on February 28, 1999. Subsequently, she developed chronic right foot and hip pain. According to a progress note dated December 4, 2014, patient complained of chronic daily right foot pain with numbness. She stated that her right hip catches often with pain radiating down the right leg causing limbing gait. Physical examination revealed a slow gait. Straight leg raise to 33 degrees exacerbated left back and leg pain proximal to the knees. Tightness and guarding of hamstrings. Active range of motion of neck, thoracic spine, and low back decreased due to pain. Tenderness to palpation to paraspinal muscles mostly at the neck and base of skull areas. The patient was diagnosed with ACO spondylolisthesis, symptoms involving head/neck, myofascial pain disorder, pain in limb, pain in joint, right sciatica, gait derangement, comorbid insomnia, and possible bone density issue related to chronic pain. The provider requested authorization for lumbar brace, Topical Cream- Flurbiprofen/Lidocaine, 4gm, Cyclobenzaprine/Lidocaine, 4gm, Kadian, Norco, Flexeril, and Savella.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lumbar Brace purchase:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301.

**Decision rationale:** According to MTUS guidelines, lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief. A lumbar corset is recommended for prevention and not for treatment. Therefore, the request for Lumbar Brace purchase is not medically necessary.

**Topical Cream- Flurbiprofen/Lidocaine, 4gm; Cyclobenzaprine/Lidocaine, 4gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**Decision rationale:** According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111); topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no clear evidence that the patient failed or was intolerant to first line of oral pain medications. There is no documentation that all component of the prescribed topical analgesic is effective for the treatment of chronic pain. Flurbiprofen is not recommended by MTUS guidelines. Therefore, Topical Cream- Flurbiprofen/Lidocaine, 4gm; Cyclobenzaprine/Lidocaine, 4gm is not medically necessary.

**Kadian 10mg #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 76-79.

**Decision rationale:** Kadian is a brand of morphine sulfate. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the

occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. Despite the continuous use of Kadian, there is no documentation of functional improvement and reduction in pain. There is no recent and continuous documentation of compliance of the patient with her medications. There is no recent documentation of failure of first line pain medications to manage the patient pain. Therefore, the prescription of Kadian 10mg #30 is not medically necessary.

**Norco 10/325mg #40:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 76-79.

**Decision rationale:** According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. According to the patient file, there is no objective documentation of pain and functional improvement to justify continuous use of Norco. Norco was used for longtime without documentation of functional improvement or evidence of return to work or improvement of activity of daily living. Therefore, the prescription of Norco 10/325mg #40 is not medically necessary.

**Flexeril 10mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** According to MTUS guidelines, Flexeril, non-sedating muscle relaxants, is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic spasm and pain. Efficacy appears to diminish over time and prolonged use may cause dependence. There is no recent evidence of pain flare or spasm

and the prolonged use of Flexeril is not justified. Therefore the request for authorization Flexeril 10mg #30 is not medically necessary.

**Savella:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines SNRIs (serotonin noradrenaline reuptake inhibitors) Page(s): 105.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) (ODG) Pain (Chronic), Milnacipran (Savella)(<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm> Alignment).

**Decision rationale:** Milnacipran (Savella) is a serotonin-norepinephrine reuptake inhibitor (SNRI) used in the clinical treatment of fibromyalgia. According to ODG guidelines, Savella is under study as a treatment for fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of Milnacipran for treatment of fibromyalgia syndrome. Milnacipran has been approved for the treatment of depression outside of the U.S. and is a dual serotonin- and norepinephrine-reuptake inhibitor (SNRI). Milnacipran, one of the pioneer serotonin and norepinephrine reuptake inhibitors (SNRIs), was designed from theoretic considerations to be more effective than selective serotonin reuptake inhibitors (SSRIs) and better tolerated than tricyclic antidepressants (TCAs). See also the Mental Chapter. FDA has now approved Milnacipran (Savella) for the management of fibromyalgia. Milnacipran should be prescribed with caution in patients with a history of seizure disorder, mania, or controlled narrow-angle glaucoma and should ordinarily not be prescribed in patients with substantial alcohol use or evidence of chronic liver disease. As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan. There is no clinical evidence that the patient suffered from fibromyalgia. Furthermore there is no objective documentation of the efficacy of previous use of the medication. Therefore, the prescription for Savella is not medically necessary.