

<b>Case Number:</b>	CM15-0160871		
<b>Date Assigned:</b>	09/03/2015	<b>Date of Injury:</b>	11/15/2006
<b>Decision Date:</b>	10/19/2015	<b>UR Denial Date:</b>	07/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/18/2015

### 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: Arizona, Michigan  
 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 48 year old male, who sustained an industrial injury on 11-15-06. The injured worker was diagnosed as having lumbar discopathy with disc displacement, lumbar stenosis and lumbar radiculopathy. Treatment to date has included oral medications including Fexmid 7.5mg, Nalfon 400mg, Prilosec 20mg, Ultram ER 150 mg; topical Flurbiprofen-Menthol-Camphor-Capsaicin cream and Cyclobenzaprine-Tramadol cream. Currently on 6-29-15, the injured worker complains of low back pain radiating down both legs associated with numbness and tingling which is greater on right leg than on left leg. He states the low back pain is aggravated by any sort of bending, twisting or lifting activity. He is currently not working. Physical exam performed on 6-29-15 revealed tenderness to palpation in lumbar paraspinal musculature with decreased range of motion secondary to pain and stiffness. A request for authorization was submitted on 6-29-15 for L3-4, L4-5 and L5-S1 minimally invasive posterior lumbar interbody fusion with pedicle screw fixation, Fexmid 7.5mg #120, Nalfon 400mg #90, Prilosec 20mg #90, Ultram ER 150mg #120, 30gm and 120gm, Flurbiprofen 25%-Menthol 10%-Camphor 3% and Capsaicin 0.0375% topical cream; 15gm and 60gm Cyclobenzaprine 10%-Tramadol 10%, and urine toxicology screening.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Minimally invasive posterior lumbar interbody fusion with pedicle screw at L3-S1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004.

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Surgical Considerations.

**Decision rationale:** Per the MTUS /ACOEM "Within the first three months after onset of acute low back symptoms, surgery is considered only when serious spinal pathology or nerve root dysfunction not responsive to conservative therapy (and obviously due to a herniated disk), is detected evidence of direct contact between neural elements and disk material. Therefore, referral for surgical consultation is indicated for patients who have: "Severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise; Activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms; Clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair, and Failure of conservative treatment to resolve disabling radicular symptoms." "Many patients with strong clinical findings of nerve root dysfunction due to disk herniation recover activity tolerance within one month; there is no evidence that delaying surgery for this period worsens outcomes in the absence of progressive nerve root compromise. With or without surgery, more than 80% of patients with apparent surgical indications eventually recover. Although surgery appears to speed short- to mid-term recovery, surgical morbidity (recovery and rehabilitation time and effects) and complications must be considered. Surgery benefits fewer than 40% of patients with questionable physiologic findings. Moreover, surgery increases the need for future surgical procedures with higher complication rates." A review of the injured workers medical records do not reveal that he has failed all options for conservative treatment that are available to him, therefore the request for minimally invasive posterior lumbar interbody fusion with pedicle screw at L3-S1 is not medically necessary.

**Fexmid/Cyclobenzaprine 7.5mg #120, DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**Decision rationale:** According to the reviewed literature, Cyclobenzaprine (Fexmid) is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. Guidelines state that this medication is not recommended to be used for longer than 2-3 weeks. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than non-steroidal anti-inflammatory medications alone. The injured worker has utilized Fexmid since at least 5-30-15. In this case, there are no muscle spasms documented on physical exam. There is no documentation of functional improvement from any previous use of this medication. Based on the currently available information, the

medical necessity for this muscle relaxant medication has not been established. The requested medication is not medically necessary.

**Nalfon/Fenoprofen Calcium 400mg #90, DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Fenoprofen calcium (Nalfon) is a non-steroidal anti-inflammatory drug (NSAID). Oral NSAIDs are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. According to the California MTUS Guidelines, NSAIDs reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. NSAIDs are recommended for acute pain, acute low back pain (LBP), short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function. There is inconsistent evidence for the use of NSAIDs to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain. Current evidence based guidelines indicate that Fenoprofen is an NSAID medication which is less effective, and has greater side effects than Naproxen or Ibuprofen. Guidelines indicate that Fenoprofen should not be used unless there is a sound medical basis for not using a safer or more effective alternative NSAID. In this case, there was no rationale provided which explained the request for Fenoprofen and no indication of a recent exacerbation of chronic pain. Medical necessity of the requested medication has not been established. The requested item is not medically necessary.

**Prilosec/Omeprazole DR 20mg #90, DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** According to the California MTUS (2009), Omeprazole (Prilosec), is proton pump inhibitor (PPI) that is recommended for patients taking NSAIDs, with documented gastrointestinal (GI) distress symptoms, or at risk for gastrointestinal events. GI risk factors include: age greater than 65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose-multiple NSAIDs. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. There is no documentation indicating that this patient had any GI symptoms or risk factors. Based on the available information provided for review, the patient has not been maintained on NSAIDs. The medical necessity for Omeprazole has not been established. The requested medication is not medically necessary.

**Ultram ER Tramadol HCL ER 150mg #90 DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The medication requested for this patient is Tramadol. According to the California MTUS, Tramadol is a synthetic opioid which affects the central nervous system and is indicated for the treatment of moderate to severe pain. The treatment of chronic pain, with any opioid, requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. According to the medical documentation there has been no indication of the medication's pain relief effectiveness and no clear documentation that the patient has responded to ongoing opioid therapy. Per California MTUS Guidelines, there have to be certain criteria followed, including an ongoing review and documentation of pain relief and functional status. This does not appear to have occurred with this patient. A urine drug screen performed on 3-19-15 was inconsistent for medications prescribed. Medical necessity for the requested medication has not been established. The requested treatment with Tramadol is not medically necessary.

**Norco/Hydrocodone Bitartrate Acetaminophen 10/325mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** According to the CA MTUS, Norco 10-325mg (Hydrocodone-Acetaminophen) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's functional benefit, relief from pain or duration of pain relief. A urine drug screen performed on 3-19-15 was inconsistent with medications prescribed. He is currently not working. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Topical Flurbiprofen 25%/ Menthol 10%/ Camphor 3%/ Capsaicin 0.0375% 30gm & 120gm, DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), Topical Analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (for example including, NSAIDs, opioids, Capsaicin, muscle relaxants, local anesthetics and/or antidepressants). Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound contains: Flurbiprofen 25%-Menthol 10%-Camphor 3%-Capsaicin 0.0375%. In this case, there is no documentation provided necessitating this compounded topical analgesic. There is no documentation of intolerance to other previous oral medications. Flurbiprofen is not FDA approved for topical application and not addressed in CA MTUS; Menthol and Camphor are not addressed in CA MTUS and Capsaicin is only recommended when other, conventional treatments have failed. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Cyclobenzaprine 10%/ Tramadol 10% 15gm & 60gm DOS: 6/29/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, Capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. Tramadol and Cyclobenzaprine are not approved for topical applications and not outlined in MTUS guidelines. The requested topical analgesic compound for this patient contains Cyclobenzaprine and Tramadol. Therefore the request for Cyclobenzaprine 10%/ Tramadol 10% 15gm & 60gm DOS: 6/29/15 is not medically necessary.