

<b>Case Number:</b>	CM14-0217930		
<b>Date Assigned:</b>	01/07/2015	<b>Date of Injury:</b>	03/01/2004
<b>Decision Date:</b>	03/09/2015	<b>UR Denial Date:</b>	12/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/29/2014

### 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: California  
 Certification(s)/Specialty: Family Practice

### 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 a work related injury March 1, 2004. According to a treating orthopedic surgeon's progress report dated October 1, 2014, the injured worker is collecting Social Security Disability benefits and has not worked since 2005. X-rays obtained in 2011 showed a 2mm articular surface standing on both knees; an MRI of the lumbar spine revealed stenosis and repeat showed disc disease from L2-S1 and facet wear from L3 to S1 in 2012(present in the medical record). Nerve studies in 2011 were unremarkable. The right knee received two cortisone injections and surgery in another practice. He walks with a cane and uses a Donjoy brace on the right, back brace, hot/cold wrap as well as H-wave. According to a treating orthopedic surgeon's progress report dated November 5, 2014, the injured worker presented for follow-up evaluation regarding low back, both knees, right ankle and both feet. Physical examination reveals tenderness across the lumbar paraspinal muscles and pain along both knees medial greater than lateral joint line. He cannot stand on toes or heels or squat and has limited flexion and extension secondary to pain. Diagnoses are listed as; discogenic lumbar condition; internal derangement of the right knee, s/p meniscectomy medially and laterally; internal derangement of the left knee which is not approved as a compensable issue compounding the previous fracture of the tibia with rodding in 1985(injured worker states 1988); ankle joint inflammation on the right and chronic pain syndrome. Treatment plan included a request for a Donjoy brace for the right knee, ankle brace, prescription medications, and 10 panel urine screen. According to utilization review performed December 1, 2014, the request for OxyContin 30mg #180 has been modified to OxyContin 30mg #60. The requests for (1) Donjoy

brace for the right knee is non-certified; the request for Lidopro lotion (4) ounces is non-certified; the request for Flexeril 7.5mg #60 is non-certified and the request for (second prescription) OxyContin 30mg #180 is non-certified. Regarding the prescription of OxyContin (oxycodone) and citing MTUS Chronic Pain Medical Treatment Guidelines, recommending this medication is indicated for moderate to severe pain when continuous, around the clock analgesic is needed for an extended period of time. Guidelines further state that opioid medications are an option for the management of chronic low back and severe knee pain for a short course of therapy. The submitted records indicate a lack of improvement in pain and functioning despite using OxyContin since at least September 2012. Furthermore, the weaning of OxyContin has been recommended in two prior reviews and therefore continuing the weaning process appears to be medically warranted at this time. The request for OxyContin 30mg #180 is certified with modification to a prescription for OxyContin 30mg #60 with the remaining #120 being non-certified. Regarding the Donjoy brace and citing ACOEM guidelines, Knee Brace; while the submitted documentation does show evidence of meniscal tearing, the injured worker has not worked since 2005 and there is no indication that the knee will be under increased stress or load. Further, there is no indication that she is involved in a rehabilitation program. Therefore, the use of a Donjoy brace does not appear to be medically necessary. Regarding Lidopro lotion and citing MTUS Chronic Pain Medical Treatment Guidelines, recommendations do not support the use of any compounded product that contains at least one drug (or drug class). This medication is a topical analgesic that contains capsaicin, Lidocaine, menthol, and methyl salicylate. Methyl salicylate is not recommended for usage greater than 4-12 weeks. Review of submitted documentation indicates usage since 11/8/2013. Therefore, continued use of this compounded cream is not medically necessary. Regarding Flexeril and citing MTUS Chronic Pain Medical Treatment Guidelines recommends using a short course of therapy and not to be used for longer than 2-3 weeks. The submitted records reveal the injured worker has been using Flexeril since at least 1/25/2013 which is significantly longer than the guideline recommendation and therefore does not appear medically warranted at this time. Regarding OxyContin, the injured worker was certified earlier in this review for a modified prescription of OxyContin for weaning purposes. Therefore, proceeding with the use of a second prescription for OxyContin is not medically warranted and non-certified.

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

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

#### **1 DONJOY BRACE FOR RIGHT KNEE: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 340.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 329-358.

**Decision rationale:** The MTUS/ACOEM Guidelines comment on treatment modalities for different types of knee complaints. On page 338 (Table 13-3) they list the methods of symptom control for knee complaints. For injuries to the meniscus, they state that treatment includes: partial weight bearing, a knee immobilizer and quadricep strengthening exercises. On page 346

(Table 13-6) they provide a summary of recommendations for the management of knee complaints. As part of these recommendations that state that functional knee bracing should be part of a rehabilitation program. A prophylactic brace was given the lowest evidence-based rating (Level D) for its efficacy. In this case there is no evidence that the knee brace is part of a rehabilitation program. The type of brace requested appears to be consistent with a prophylactic brace, which is not supported as an effective treatment intervention. The Donjoy brace is not a type of knee immobilizer, as listed in Table 13-3. For these reasons, a Donjoy brace for the right knee is not medically necessary.

## **1 PRESCRIPTION FOR OXYCONTIN 30MG, #180: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the "4 A's for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring." The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with OxyContin is not considered as medically necessary.

**Lidopro lotion, 4 ounces: Upheld**

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

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

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics as a treatment modality. Lidopro is a compounded medication including lidocaine, capsaicin, menthol and methyl salicylate. The guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally 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 NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adenosine, cannabinoids, cholinergic receptor agonists, prostanooids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain

has not been controlled successfully with conventional therapy. In this case there is insufficient documentation that the intent of this topical analgesic is to treat neuropathic pain. Given that this is the primary indication for the use of two components of Lidopro (capsaicin and lidocaine), the use of this compounded medication is not medically necessary.

**Flexeril 7.5, #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines provide comment on the use of Flexeril as a treatment modality. These guidelines state the following: Muscle relaxants (for pain) Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Regarding the use of Flexeril; the MTUS guidelines state the following: Cyclobenzaprine (Flexeril, Amrix, Fexmid™, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. This medication is not recommended to be used for longer than 2-3 weeks. In this case the records indicate that the use of Flexeril is intended for the long-term treatment of this patient's medical problems. There is insufficient documentation provided to justify the long-term use of this drug. Therefore, Flexeril is not considered as a medically necessary treatment.