

<b>Case Number:</b>	CM15-0197810		
<b>Date Assigned:</b>	10/13/2015	<b>Date of Injury:</b>	10/30/2013
<b>Decision Date:</b>	11/23/2015	<b>UR Denial Date:</b>	09/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2015

### 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: Montana

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 27 year old male retail pharmacy worker who sustained an industrial injury while lifting product on October 30, 2013. Past history included lumbar epidural injection, December 4, 2014, for diagnosis of herniated disk L3-L4, L4-L5, physical therapy and medication. According to a primary treating physician's progress report dated September 2, 2015, the injured worker presented for a follow-up visit with complaints of continued low back pain with pain radiating down the left side of the leg into the left hip area, as well as the left buttocks. He rated his pain 6-7 out of 10 and feels some improvement with medication. He is using a TENS (transcutaneous electrical nerve stimulation) unit at home with improvement. Objective findings included; lumbar spine- gait normal, heel toe ambulation is painful; tenderness L4-5 and bilateral posterior, superior iliac spine, range of motion can flex to six inches to the ground, straight leg raise is causing hamstring tightness at 45 degrees from a seated position; sensory intact in all dermatomes in the bilateral lower extremities. Assessments are lumbar strain; lumbar radiculitis; lumbar degenerative disease. Treatment plan included awaiting authorization for acupuncture, counseled on weight reduction, healthy diet, and gym membership, and continuing home exercise program. At issue, is the request for authorization dated September 2, 2015, for Baclofen, Naproxen, and Flurbiprofen 20%-Lidocaine 5%. A toxicology report dated March 11, 2015, is present in the medical record. According to utilization review dated September 15, 2015, the requests for Naproxen 550mg, (1) tab PO (by mouth) BID (twice a day) #60 and Flurbiprofen 20%-Lidocaine 5%, (1) local application #60gm were non-certified. The request for Baclofen 10 mg 91) tab PO QHS (at hour of sleep) #30 was modified to Baclofen 10mg, (1) tab PO QHS #7.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Naproxen 550mg 1 tab po bid #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, hypertension and renal function, NSAIDs, specific drug list & adverse effects.

**Decision rationale:** Naproxen is a non-steroidal anti-inflammatory drug (NSAID). The MTUS states that non-steroidal anti-inflammatory medications are recommended at the lowest dose for the shortest period possible in patients with moderate to severe pain. Although NSAIDs are effective they can cause gastrointestinal irritation or ulceration. Studies also show that NSAID use for more than a few weeks can retard or impair bone, muscle, and connective tissue healing and may cause hypertension. For chronic low back pain NSAIDs are recommended as an option for short-term symptomatic relief. Regarding neuropathic pain, the guidelines note inconsistent evidence for the use of these medications to treat long-term neuropathic pain but they may be useful to treat breakthrough pain. Naproxen as sodium salt is available in 550 mg (Anaprox). In this case the medical records note that naproxen/naproxen sodium has been used since 4-8-15. Prior to that he was prescribed fenopufen since at least 12-31-14. This is not consistent with the MTUS recommendation for using the lowest dose for the shortest duration possible. For chronic low back pain the MTUS recommends NSAIDs only for short-term symptomatic relief. Regarding neuropathic pain, the guidelines note inconsistent evidence for the use of these medications to treat long-term neuropathic pain but they may be useful to treat breakthrough pain. The medical records do state that the medications provide some relief but do not demonstrate substantial pain relief and significant functional improvement related to use of naproxen sodium and there is no documentation of side effects. Without documentation of efficacy and functional improvement, the request for ongoing long-term treatment with naproxen sodium 550 mg, 1 tab BID #60, is not consistent with the MTUS recommendations and is not medically necessary.

**Flurbiprofen 20%/Lidocaine 5%, 1 local application #60gm: Upheld**

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

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

**Decision rationale:** The MTUS, in the ACOEM guidelines, states that, for initial treatment, topical medications are not recommended. The Chronic Pain Medical Treatment Guidelines note 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. This topical analgesic contains flurbiprofen, which is a non-steroidal anti-inflammatory medications (NSAIDs). The MTUS states that topical non-steroidal anti-inflammatory agents have not been shown to be effective in long-term studies.

Topical non-steroidal anti-inflammatory agents have shown inconsistent efficacy in clinical trials and most studies are small and of short duration. 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Topical treatment can result in blood concentrations and systemic effects comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) 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 are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. The ODG guidelines also state that Lidoderm patches are not a first-line treatment and are FDA approved only for postherpetic neuralgia. In this case the medical records do not indicate that the injured worker has post herpetic neuralgia. There is no indication of failure of first line treatments such as antidepressants and anticonvulsants. Lidoderm patches are the only commercially approved topical formulations of lidocaine indicated for neuropathic pain. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case the request for Flurbiprofen 20%/Lidocaine 5%, 1 local application #60gm is not medically necessary.

**Baclofen 10mg 1 tab po qhs #30:** Upheld

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

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

**Decision rationale:** The MTUS notes that muscle relaxants are recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases they show no benefit beyond non-steroidal anti-inflammatory drugs in pain and overall improvement. Efficacy does appear to diminish over time. Sedation as the most commonly reported adverse effect of muscle relaxant medications. Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. Baclofen is an antispasticity drug used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). The mechanism of action is blockade of the pre and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007) Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment. Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008) In this case the records show

that baclofen has been used since 4-8-15 and prior to that cyclobenzaprine was used since at least 12-31-14. The current request is for an additional one-month supply of baclofen. This clearly exceeds the MTUS recommendation for short-term use of muscle relaxants. The medical records from the primary treating physician do not document complaint of muscle spasm or objective findings of muscle spasm. The request for baclofen 10mg 1 tab po qhs #30 is not medically necessary.