

<b>Case Number:</b>	CM14-0207516		
<b>Date Assigned:</b>	12/19/2014	<b>Date of Injury:</b>	10/09/2006
<b>Decision Date:</b>	02/13/2015	<b>UR Denial Date:</b>	12/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/11/2014

### 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. The expert reviewer is Board Certified in Physical Medicine Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 45 year old male with an injury date of 10/09/06. Per the 11/18/14 report the patient presents with continuing lower back and lower extremity pain. There is increased frequency of pain in the left buttock radiating to the posterior thigh as well as a new onset of medial thigh pain which radiates to the pelvic floor. The patient also presents with numbness in the genitalia and ongoing numbness in the right anterior thigh with cramping in the distal lower extremities. Pain is rated 4-5/10. The 10/08/14 report states the patient presents with neck pain. He has antalgic gait, and ambulation is assisted by a single point cane. Examination shows bilateral lumbar paraspinous tenderness with diffuse myofascial tenderness from L1 to S1 with positive muscle spasm in the lumbosacral junction. Straight leg raise is positive. There is hypesthesia over the right lateral thigh and in the left L5 dermatome. The patient's diagnoses include: 1. Chronic severe lower back pain s/p L3-S1 posterior lumbar fusion 2. Bilateral lower extremity radiculopathy 3. Depression secondary to pain syndrome 4. Cervical sprain/strain (10/08/14 report) 5. Acid reflux (10/08/14 report) 6. Insomnia (10/08/14 report) The patient has a history of acupuncture treatment. An orthopedic spine evaluation (date unknown) recommended lumbar surgery. Updated imaging and electrodiagnostic studies are requested. Current medications are listed as Butrans, Hydrocodone, Diclofenac SR, KGL cream and Ranitidine. The utilization review is dated 12/01/14. Reports were provided for review from 05/16/14 to 12/05/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen, Gabapentin & lidocaine (KGL cream) 240g: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The patient presents with continuing lower back and lower extremity pain along with neck pain as well as left buttock pain radiating to the posterior thigh and medial thigh pain radiating to the pelvic floor. Pain is rated 4-5/10. The current request is for Ketoprofen, Gabapentin & lidocaine (KGL cream) 240g, per 11/18/14 report. MTUS Topical Analgesics guidelines pages 111 and 112 has the following regarding topical creams, "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." MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis." MTUS guidelines page 112 state regarding Lidocaine, "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." The reports show that the patient is starting this medication 11/18/14. The treating physician states the use is for neuropathic pain which reports document in this patient. However, this compounded topical medication contains Ketoprofen that is not approved for topical applications as well as Gabapentin that MTUS specifically states is not recommended in the topical cream section. Furthermore, the medication contains lidocaine that is approved only in patch form for neuropathic pain. Therefore, this request is not medically necessary.

**Diclofenac SR 100mg #30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Diclofenac

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Anti-Inflammatory Medications Page(s): 60-61; 22.

**Decision rationale:** The patient presents with continuing lower back and lower extremity pain along with neck pain as well as left buttock pain radiating to the posterior thigh and medial thigh pain radiating to the pelvic floor. Pain is rated 4-5/10. The current request is for Diclofenac SR 100mg #30 (non-steroidal anti-inflammatory drug (NSAID)), per 11/18/14 report. MTUS Anti-inflammatory medications page 22 stated, "Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted." The reports provided show this medication was started 11/18/14. The 10/08/14 report shows the patient was prescribed naproxen. On 12/05/14 the treating physician

states the patient was utilizing naproxen twice a day which was discontinued as the patient did not feel the medication helped inflammation and swelling. The treating physician also notes that Ibuprofen, Meloxicam and Relafen were trialed and discontinued as they were deemed to be ineffective. Due to this, the patient was placed on a trial of Diclofenac which was found to be effective despite dyspepsia and aggravation of GERD. In regards to that, the patient uses ranitidine which has been "beneficial." This report states, "Overall Diclofenac has been effective in reducing pain, inflammation and swelling and providing him functional improvement." In this case, the request is indicated for first line treatment of the pain present in this patient, and the treating physician documents Diclofenac has been effective. Therefore, this request is medically necessary.