

<b>Case Number:</b>	CM15-0169277		
<b>Date Assigned:</b>	09/14/2015	<b>Date of Injury:</b>	06/18/2002
<b>Decision Date:</b>	11/03/2015	<b>UR Denial Date:</b>	08/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/27/2015

### 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: New York  
 Certification(s)/Specialty: Internal 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:

This is a 61-year-old male worker who was injured on 6-18-2002. The medical records reviewed indicated the injured worker (IW) was treated for low back pain and radiculopathy. The progress notes (7-30-15) indicated the IW had low back pain radiating to the posterolateral thigh, calf and foot. The pain was unchanged since the previous visit and activity level remained the same. Medications were Aciphex, Zanaflex, Colace, Miralax, Relafen, Oxycodone, Lidoderm 5% patch, Lyrica, Kadian, Clonazepam and Phentermine. His pain rating was 6 out of 10 with medications and 8 out of 10 without them. He denied side effects and stated the medications were working well. The urine toxicology report from 5-19-15 was stated to not include Kadian, Clonazepam, Phentermine or Lyrica in the findings; alcohol was detected. The IW admitted to drinking a glass of wine on occasion. Urine drug screen on 7-20-15 was "consistent, no ethyl present, urine creatinine elevated". The 10-31-13 CURES report was "appropriate". Lab results from 9-9-13 for liver and kidney function were "WNL" (within normal limits). On physical examination (7-30-15), his gait was slowed. Lumbar range of motion was limited with flexion to 50 degrees, with extension to 15 degrees due to pain and left and right lateral bending to 20 degrees. Trigger points, tenderness and spasms were noted in the bilateral paravertebral muscles. Straight leg raise was positive on the left side. Motor exam was normal. Sensation to pinprick was "L5 dermatomal pattern". The provider noted the IW was not working due to intolerance of prolonged sitting. According to the notes (7-16-15 and 7-30-15), treatments have included medications, left L3 to L5 laminectomy and foraminotomy; and lumbar epidural steroid injections. The provider noted (7-30-15) the current medications were not changed essentially for

greater than six months and they were providing optimal improvement of the IW's function and activities of daily living. The records (3-26-15 to 7-30-15) showed the IW was taking the same medications. Per the provider, there was a signed opiate agreement. With medications, he could lift 10 to 15 pounds, walk five blocks, sit 60 minutes and stand 30 minutes and perform household tasks for 30 minutes. Without medications he could lift only five pounds, walk a block or less, sit 30 minutes and stand 15 minutes or less and could perform household tasks for less than 10 minutes at a time. The treatment plan included lab testing, medication refills for 8 weeks and an increase in Kadian from 50mg to 60mg. A Request for Authorization on 8-5-15 asked for Kadian ER 60mg, #30, one daily; Oxycodone HCl 15mg, #180, one every 4 hours as needed (max. 6/day); Aciphex 20mg, #30 with 5 refills, one daily; Miralax powder, #1, mix one packet with 8 ounces of water or juice, 30 day supply with 5 refills; Lidoderm 5% patch, #60, apply 1 to 2 patches for 12 hours per day (dispense as written), 5 refills; Colace 250mg, #60 with 5 refills, one twice daily; Zanaflex 4mg, #60 with 5 refills, one twice daily; Relafen 500mg, #60 with 5 refills, one twice daily; and blood urea nitrogen (BUN) and creatinine. The Utilization Review on 8-11-15 non-certified the request for Kadian ER 60mg, #30, one daily; Oxycodone HCl 15mg, #180, one every 4 hours as needed (max. 6/day); Aciphex 20mg, #30 with 5 refills, one daily; Miralax powder, #1, mix one packet with 8 ounces of water or juice, 30 day supply with 5 refills; Lidoderm 5% patch, #60, apply 1-2 patches for 12 hour per day (dispense as written), 5 refills; Colace 250mg, #60 with 5 refills, one twice daily; Zanaflex 4mg, #60 with 5 refills, one twice daily; Relafen 500mg, #60 with 5 refills, one twice daily; and blood urea nitrogen (BUN) and creatinine.

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

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

**Kadian ER 60mg, 1 daily, #30:** 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, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Opioids.

**Decision rationale:** According to the CA MTUS and ODG, Kadian is an opioid analgesic indicated for moderate to moderately severe 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. There is no compelling evidence presented by the treating provider that indicates this injured worker has had any significant improvements from this medication. Also review of Medical Records do not clarify that previous use of this medication has been effective in this injured worker for maintaining any functional improvement. Based on CA MTUS guidelines and submitted medical records, the request for Kadian is not medically necessary. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms.

**Oxycodone HCl 15mg, 1 tablet by mouth every 4 hours as needed (max 6/day), #180:**  
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, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Opioids.

**Decision rationale:** The California MTUS chronic pain medical treatment guidelines recommend specific guidelines for the ongoing use of narcotic pain medication to treat chronic pain. "Recommendations include the lowest possible dose be used as well as ongoing review and documentation of pain relief, functional status, appropriate medication use and its side effects. It is also recommended that providers of opiate medication document the injured worker's response to pain medication including the duration of symptomatic relief, functional improvements, and the level of pain relief with the use of the medication." The CA MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. The medical records submitted for review does not include the above recommended documentation. There were no functional improvements noted with the use of the medication. The injured worker's work status remains unchanged and there is no change on medical dependence. Therefore, the request treatment Oxycodone HCl 15mg, is not medically necessary and appropriate. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms.

**Aciphex 20mg, 1 daily, # 30 with 5 refills:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Proton pump inhibitors (PPIs).

**Decision rationale:** As per CA MTUS guidelines, in patients who are taking NSAID medications, the risk of gastrointestinal (GI) risk factors should be determined. MTUS makes the following recommendations regarding increased gastrointestinal event risk: "Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a proton- pump inhibitor (PPI) if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI." As per ODG, PPI's are recommended for

patients at risk for GI events and should be used at the lowest dose for the shortest possible amount of time. The risks of long-term PPI use must be weighed against the risks including the potential for cardiovascular events. Aciphex should be used as a second-line therapy. There is no explanation as to whether the injured worker had attempted and failed a first line proton-pump inhibitor and no documentation as to whether Aciphex was effective at treating the injured worker's symptoms. There is no mention of ongoing GI complaints and as Relafen is determined medically not necessary, therefore, the request for Aciphex 20mg, 1 daily, # 30 with 5 refills is not medically necessary and appropriate.

**Colace 250mg, 1 twice daily, #60 with 5 refills:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Opioid-induced constipation treatment.

**Decision rationale:** According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. In this case of injured worker, discussion about first line treatment cannot be located within the submitted medical records. Also, with non-approval of opioid use, the medical necessity of Colace is not established. The requested treatment Colace 250mg, 1 twice daily, #60 with 5 refills is not medically necessary.

**Zanaflex 4mg, 1 twice daily, #60 with 5 refills:** 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): Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Muscle relaxants.

**Decision rationale:** According to the reviewed literature, Zanaflex is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. In addition, 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 nonsteroidal anti-inflammatory medications alone. In this case, the available records are not clear if the injured worker has shown a documented benefit or any functional improvement from prior Zanaflex use. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. The requested treatment Zanaflex 4mg, 1 twice daily, #60 with 5 refills is not medically necessary.

**Relafen 500mg, 1 twice daily with 5 refills, #60:** 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:** According to the California MTUS chronic pain medical treatment guidelines, there are specific guidelines for use of non-steroidal anti-inflammatory drugs (NSAID). They 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. Also per the MTUS NSAIDs are recommended for acute exacerbations of chronic low back pain, as a second-line treatment after acetaminophen. According to the documentation submitted the injured worker has been prescribed Relafen on a long-term basis, and the complaints are not an acute exacerbation. There has been no compelling evidence presented by the provider to document that the injured worker has had any significant functional improvements from this medication. Also, there is no documentation of failure with acetaminophen. Therefore, the request for Relafen 500mg, 1 twice daily with 5 refills, #60 is not medically necessary and appropriate.

**Miralax Powder, SI; mix 1 packet with 8oz of water or juice, 30 days supply with 5 refills, #1:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Opioid-induced constipation treatment.

**Decision rationale:** According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient

to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. In this case of injured worker, discussion about first line treatment cannot be located within the submitted medical records. Also, with non-approval of opioid use, the medical necessity of Miralax Powder is not established. The requested treatment Miralax Powder, SI; mix 1 packet with 8oz of water or juice, 30 days supply with 5 refills, is not medically necessary.

**Lidoderm 5% patch, apply 1-2 patches for every 12 hours per day (DAW), 5 refills, #60:**  
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, such as the Lidoderm 5% Patch, 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, NSAIDs, opioids or antidepressants. Lidoderm is the brand name for a lidocaine patch. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. There is no documentation that the injured worker has failed a trial of antidepressants and anticonvulsants and is intolerant to other medicines. In this case, the treating provider indicates this injured worker has had some subjective improvements from this medication, but review of Medical Records do not indicate that previous use of this medication in this injured worker has been effective in maintaining any measurable functional improvement. Medical necessity of the requested item has not been established. Therefore, the request for Lidoderm 5% patch, apply 1-2 patches for every 12 hours per day (DAW), 5 refills, #60 is not medically necessary.

**Blood urea nitrogen (BUN)/creatinine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<http://labtestsonline.org/understanding/analytes/creatinine/tab/test>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, hypertension and renal function.

**Decision rationale:** Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Within the submitted medical records, the treating provider's note mentions "9/9/2013 Labwork: Liver and Kidney WNL". With a history of long-term use of NSAIDs, and no recent renal function tests, the requested treatment Blood urea nitrogen (BUN)/creatinine is not medically necessary and appropriate.