MAXIMUS Federal Services

| Case Number: | CM15-0139896 | | |
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| Date Assigned: | 08/04/2015 | Date of Injury: | 07/14/2011 |
| Decision Date: | 09/15/2015 | UR Denial Date: | 07/08/2015 |
| Priority: | Standard | Application Received: | 07/17/2015 |

## 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: Pediatrics, 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:

The injured worker is a 46 year old male who sustained an industrial injury on 07-14-2011. Current diagnoses include left shoulder partial thickness rotator cuff tear, lumbar spine degenerative disc disease L2-S1 with symptoms of left lower extremity radiculitis, status post lumbar spine epidural injection, left hip acetabular tear, right shoulder status post arthroscopic subacromial decompression with residual rotator cuff tendonitis and arthrosis of the AC joint, right foot plantar fasciitis, and possible thoracic aortic dissection. Previous treatments included medications, surgical intervention, epidural steroid injection, and acupuncture. Previous diagnostic studies included a left knee, right shoulder, and lumbar MRI, and EMG and NCS of the lower extremities. Report dated 07-02-2015 noted that the injured worker presented with complaints that included constant aching pain in the low back. Also noted was a new injury to the left shoulder which the injured worker is being treated for by another clinic. Pain level was not included. Physical examination was positive for diffuse tenderness in the lumbar spine with spasm, diminished sensation in the left leg and left foot, positive impingement in the left shoulder, positive O'Brien's test, and positive crepitus with range of motion in the left shoulder. The treatment plan included following up with pain management specialist for consideration of further treatment or injections to the lumbar spine, sufficient quantities of medications at this time, continue treatment with industrial clinic for left shoulder, will defer treatment for the left shoulder to the industrial clinic as this appears to be a separate industrial injury, continue to work full duty, continue home exercise, and follow up in 4 weeks. Disputed treatments include lidocaine Patch for neuropathic pain, Flector Patch, Naproxen, Zipsor 25mg #60, Ambien 5mg#30, Percocet 10-325 (oxycodone-acetaminophen) #150, Voltaren Gel, Aleever Patch (Menthol 5%, Capsaicin 0.0375% Patch) #60 x 1 refill, docusate sodium 100mg #90, Aleever Patch (Menthol 5%, Capsaicin 0.0375% patch AAA patch) #60, and Soma tablets (Carisoprodol) 350mg #90.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidocaine Patch for neuropathic pain:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Lidoderm Patches.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patches), and Topical Analgesics Page(s): 56-57 and 111-113.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines recommend specific guidelines for the use of Lidoderm patches. Guidelines recommend the use of topical lidocaine 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. Guidelines also state that topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The documentation submitted does not provide a detailed evaluation of the use of any first-line therapy medications referenced above, also the documentation provided did not support a diagnosis of neuropathic pain or post-herpetic neuralgia. Furthermore physical examination did not support any symptoms associated with neuropathic pain. Therefore, the request for lidocaine patch for neuropathic pain is not medically necessary.

**Flector Patch:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory agents (NSAIDs) Page(s): 111-112. Decision based on Non- MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Flector Patches.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics-Non-steroidal anti-inflammatory agents (NSAID's) 111-112 Page(s): 111-113.

**Decision rationale:** According to the MTUS chronic pain medical treatment guidelines topical NSAID's are recommended for short-term use (4-12 weeks). There is little evidence to support the utilization of NSAID's for treatment of osteoarthritis of the spine, hip, or shoulder. Not recommended for neuropathic pain. Flector patches contains diclofenac which is an NSAID. The treating physician's request did not include the quantity, site of application, or directions for use. As such, the prescription is not sufficient and not medically necessary. As the guidelines do not recommend for neuropathic pain and the provider did not provide a rational for the use of a Flector patch the request is not medically necessary. Therefore, the request for Flector patch is not medically necessary.

**Naproxen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs (NSAIDs) Page(s): 67. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, NSAIDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) Page(s): 67-71.

**Decision rationale:** The California MTUS chronic pain medical treatment guidelines recommend specific guidelines for use of non-steroidal anti-inflammatory drugs (NSAIDs). "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." Documentation submitted supports that the injured worker has been prescribed Naproxen since at least 12-24-2014 which supports long term use. Also, there was no documentation submitted to support that the injured worker has tried acetaminophen and the treating physician's request did not include the concentration, quantity, or directions for use. Furthermore the medical records support that the injured worker's complaints are chronic in nature and not an acute exacerbation. As such, the prescription is not sufficient and not medically necessary. Therefore, the request for Naproxen is not medically necessary.

**Zipsor 25mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, NSAIDs, Diclofenac.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) Page(s): 67-71.

**Decision rationale:** Zipsor is diclofenac a liquid-filled capsules used to treat mild to moderate acute pain. The California MTUS chronic pain medical treatment guidelines recommend specific guidelines for use of non-steroidal anti-inflammatory drugs (NSAIDs). "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." There was no documentation submitted to support that the injured worker has tried acetaminophen. Furthermore the medical records support that the injured worker's complaints are chronic in nature and not an acute exacerbation. As such, the prescription is not sufficient and not medically necessary. Therefore the request for Zipsor 25mg #60 is not medically necessary.

**Ambien 5mg #30:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Zolpidem (Ambien).

**Decision rationale:** The California MTUS does not address Ambien. The Official Disability Guidelines (ODG) state that Ambien (zolpidem) is approved for short term use, usually 2-6 weeks, treatment of insomnia, and should be used for only a short period of time. The submitted medical records do not support that the injured worker has complaints of insomnia. Also, medical records do not indicate how long this medication has been used, nor did they provide a thorough evaluation of the medications effectiveness. Therefore, the request for Ambien is not medically necessary.

**Percocet 10-325 (Oxycodone-Acetaminophen) #150:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78-81.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional improvement, Opioids sections Page(s): 1, 74-96.

**Decision rationale:** According to 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 also recommends 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 medications. 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. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of activities of daily living with use of the Percocet, and dependency on continued medical care remains unchanged. Therefore, the request for Percocet 10-325 (Oxycodone-Acetaminophen) #150 is not medically necessary.

**Voltaren Gel:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Voltaren Gel 1% (diclofenac) Page(s): 112.

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

**Decision rationale:** According to the California MTUS Guidelines, Voltaren Gel 1% (Diclofenac) is indicated for the relief of osteoarthritis in joints that lend themselves to topical treatment, such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip, or shoulder. The maximum dose should not exceed 32 g per day. The submitted documentation does not indicate that the injured worker had a diagnosis of osteoarthritis. Additionally, the efficacy of the medication was not submitted for review, nor was it indicated that it helped with any functional deficits. In addition, the treating physician's request did not include the concentration, quantity, site of application, or directions for use. Medical necessity for the requested topical gel has been not established. The requested 1% Voltaren Gel is not medically necessary.

**Aleever Patch (Menthol 5%, Capsaicin 0.0375% Patch) #60 x 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical analgesics Page(s): 27-28, 111-113. Decision based on Non-MTUS Citation UpTodate: menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** According to the MTUS chronic pain medical treatment guidelines, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. The medical records submitted do not support that the injured worker has an intolerance to other treatments. Therefore the request for Aleever Patch (Menthol 5%, Capsaicin 0.0375% Patch) #60 x 1 refill is not medically necessary.

**Docusate sodium 100mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Opioid-induced constipation treatment.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids initiating therapy Page(s): 77. Decision based on Non-MTUS Citation Pain (chronic), Opioid induced constipation.

**Decision rationale:** According to the California MTUS and Official Disability Guidelines (ODG), if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. In this case, with non-approval of opioid use, the medical necessity of ducosate sodium is not established. The request for docusate sodium 100mg #90 is not medically necessary.

**Aleever Patch (Menthol 5%, Capsaicin 0.0375% patch AAA patch) #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical analgesics Page(s): 27-28, 111-113. Decision based on Non-MTUS Citation UpTodate: menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** According to the MTUS chronic pain medical treatment guidelines, topical analgesics are recommended for neuropathic pain when trials of anti-depressants and anti- convulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. The medical records submitted do not support that the injured worker has an intolerance to other treatments. Therefore the request for Aleever Patch (Menthol 5%, Capsaicin 0.0375% Patch) #60 x 1 refill is not medically necessary.

**Soma tablets (Carisoprodol) 350mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) Page(s): 29, 65. Decision based on Non-MTUS Citation Tapering schedule developed by the Department of Veterans Affairs Medical Center, www.medicaid.state.ar.us/Download/provider/pharm/CarisoTaper.pdf.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain, and Carisoprodol (Soma) Page(s): 63-65.

**Decision rationale:** The California MTUS chronic pain medical treatment guidelines provide specific guidelines for the use of muscle relaxants. "Recommendation is for non-sedating muscle relaxants with caution as a second-line option for short term treatment of acute exacerbations in patients with chronic low back pain." Carisoprodol (Soma) is not recommended for longer than a 2-3 week period. Documentation provided supports that the injured worker has been prescribed carisoprodol (Soma) since at least 12-24-2014, there is no documentation submitted to support improvement in reducing pain or increasing function with the use of this medication. Therefore, the request for Soma tablets (Carisoprodol) 350mg #90 is not medically necessary.