

<b>Case Number:</b>	CM15-0107282		
<b>Date Assigned:</b>	06/11/2015	<b>Date of Injury:</b>	04/26/2002
<b>Decision Date:</b>	09/23/2015	<b>UR Denial Date:</b>	05/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/03/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 64 year old male who sustained an industrial injury on 04/26/2002. The injured worker was diagnosed with cervical discopathy with disc displacement, cervical radiculopathy, and lumbar discopathy with disc displacement, lumbar radiculopathy and sacroiliac (SI) sprain. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. According to the primary treating physician's progress report on April 23, 2015, the injured worker continues to experience neck pain, which radiates down both arms associated with numbness and tingling and lumbar pain, which radiates into both legs associated with numbness and tingling. The injured worker also reports bilateral hip pain and difficulty sleeping. Examination of the cervical spine demonstrated tenderness to palpation over the cervical paraspinal muscles with decreased range of motion secondary to pain and stiffness. Spurling's sign was negative bilaterally. Examination of the lumbar spine revealed tenderness to palpation over the lumbar paraspinal muscles with decreased range of motion secondary to pain and stiffness with positive supine straight leg raise at 20 degrees in the bilateral lower extremities. The bilateral hips were noted to be tender over the sacroiliac (SI) joints with positive Fabere and Patrick's test. Motor and sensory examinations were within normal limits. A urine drug screening in February 2015 was noted to be inconsistent for prescribed medications. Current medications are listed as Nalfon, Ultram ER, Fexmid, Ambien, Prilosec, and Cyclobenzaprine 10%/Tramadol 10% topical cream. Treatment plan consists of continuing with medication regimen, home exercise program and the current request for Nalfon, Ultram ER,

Ambien, Cyclobenzaprine 10%/Tramadol 10% topical cream and urine drug screening using high complexity testing.

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

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

**Nalfon 400mg #90:** Upheld

**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: Fenoprofen (Nalfon) (2015).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

**Decision rationale:** The current request is for Nalfon 400mg #90. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. MTUS Chronic Pain Medical Treatment Guidelines, pg. 22 for Anti-inflammatory medications states: 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. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. According to progress report on April 23, 2015, the patient continues to experience neck pain, which radiates down both arms associated with numbness and tingling and lumbar pain which radiates into both legs associated with numbness and tingling. The patient also reports bilateral hip pain and difficulty sleeping. Current medications are listed as Nalfon, Ultram ER, Fexmid, Ambien, Prilosec, and Cyclobenzaprine 10%/Tramadol 10% topical cream. The treater is requesting a refill of Nalfon. The patient has been prescribed this medication since 02/15/15. Per report 04/23/15, "medications and compound cream are helpful in alleviating his pain." MTUS Chronic Pain Guidelines under MEDICATIONS FOR CHRONIC PAIN, page 60, states "A record of pain and function with the medication should be recorded." The treater does not discuss the efficacy of Nalfon, in terms of functional changes as required by MTUS for chronic medication use and further use cannot be supported. This request IS NOT medically necessary. supported. This request IS NOT medically necessary.

**Ultram ER 150mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** The current request is for Ultram ER 150mg #90. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS page 77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." According to progress report on April 23, 2015, the patient continues to experience neck pain which radiates down both arms associated with numbness and tingling and lumbar pain which radiates into both legs associated with numbness and tingling. The patient also reports bilateral hip pain and difficulty sleeping. Current medications are listed as Nalfon, Ultram ER, Fexmid, Ambien, Prilosec, and Cyclobenzaprine 10%/Tramadol 10% topical cream. The treater is requesting a refill of Ultram. The patient has been prescribed this medication since 02/15/15. Per reports 02/15/15 through 04/23/15, "medications and compound cream are helpful in alleviating his pain." MTUS requires appropriate discussion of all the 4A's; however, in addressing the 4A's, the treater does not discuss how this medication significantly improves patient's activities of daily living. No validated instrument is used to show analgesia. There are multiple UDS, but no CURES or opioid contract are provided. Given the lack of documentation as required by MTUS, the request does not meet guidelines indication. Therefore, the request IS NOT medically necessary.

**Cyclobenzaprine 10%/Tramadol 10% 15gm: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The current request is for Cyclobenzaprine 10%/Tramadol 10% 15gm. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. MTUS Chronic Pain Guidelines under Topical analgesics has the following on page 111 "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." 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. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The treater states that the compound cream is to "directly target pain associated with inflammation and spasm." In this case, Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. MTUS Chronic Pain Medical Treatment Guidelines page 111 through 113 under topical analgesic state, "Any

compounded product that contains at least 1 drug or drug class that is not recommended is not recommended." This request IS NOT medically necessary.

**Cyclobenzaprine 10%/Tramadol 10% 60gm: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The current request is for Cyclobenzaprine 10%/Tramadol 10% 60gm. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. MTUS Chronic Pain Guidelines under Topical analgesics has the following on page 111 "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." 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. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The treater states that the compound cream is to "directly target pain associated with inflammation and spasm." In this case, Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. MTUS Chronic Pain Medical Treatment Guidelines page 111 through 113 under topical analgesic state, "Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended." This request IS NOT medically necessary.

**Ambien 10mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain : Zolpidem (Ambien) (2015).

**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) Chapter, Zolpidem (Ambien).

**Decision rationale:** The current request is for Ambien 10mg #30. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. ODG-TWC, Pain (Chronic) Chapter, Zolpidem (Ambien) Section states: "Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more

than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008)" According to progress report on April 23, 2015, the patient continues to experience neck pain, which radiates down both arms associated with numbness and tingling and lumbar pain which radiates into both legs associated with numbness and tingling. The patient also reports bilateral hip pain and difficulty sleeping. ODG recommends Ambien for short-term (7-10 days) for the treatment of insomnia. The patient has been prescribed Ambien since 03/23/15 and continued use of this medication is not in accordance with guidelines. Therefore, the request IS NOT medically necessary.

**One urine toxicology testing using high complexity-laboratory test protocols including GC/MS, LC/MS and Elisa technology:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opiates, steps to avoid misuse/addiction.

**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) Chapter under the Urine Drug Testing.

**Decision rationale:** The current request is for one urine toxicology testing using high complexity-laboratory test protocols including GC/MS, LC/MS and Elisa technology. The RFA is dated 04/23/15. Treatment to date includes diagnostic testing, physical therapy, home exercise program and medications. The patient is not working. ODG guidelines, Pain (Chronic) Chapter under the Urine Drug Testing section states that "chromatography/mass spectrometry (GM/MS) or liquid chromatography mass spectrometry (LC/MS/MS) are "considered confirmatory tests," and particularly important when results of a test are contested. Confirmation should be sought for: (1) all samples testing negative for prescribed drugs, (2) all samples positive for non-prescribed opioids, and (3) all samples positive for illicit drugs." Current medications are listed as Nalfon, Ultram ER, Fexmid, Ambien, Prilosec, and Cyclobenzaprine10%/Tramadol 10% topical cream. The patient was administered a UDS on 02/12/15 which was inconsistent and negative for medications prescribed. It appears the treater is requesting a confirmatory test. Given that the patient was not compliant with his prior urine drug screen and is currently prescribed opioids, a confirmatory test appears reasonable. Therefore, the requested test IS medically necessary.