

<b>Case Number:</b>	CM14-0160908		
<b>Date Assigned:</b>	10/06/2014	<b>Date of Injury:</b>	02/15/2006
<b>Decision Date:</b>	11/26/2014	<b>UR Denial Date:</b>	09/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2014

### 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 Preventative Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This patient is an employee with date of injury of 2/15/2006. Medical records indicate the patient is undergoing treatment for cervical disc displacement; lumbar disc displacement and joint pain in the left leg. Also, depressive psychosis-unspecified; depressive disorder- not elsewhere classified (nec); fx scapula nec-closed; psychogenic pain-not elsewhere classified (nec); therapeutic drug monitor; long-term use meds not elsewhere classified (nec); recurrent depression psychos-unspecified; lumbar/lumbosacral disc degenerative; lumbar spinal stenosis and postsurgical states not elsewhere classified (nec). Subjective complaints include chronic low back pain and persistent back pain. He continues to have depressive symptoms but no suicidal ideation. Objective findings include the lumbar spine is tender to palpation at the lumbosacral junction with muscle tension extending from the low back to mid back. His range of motion (ROM) is decreased by 20% with flexion and extension and decreased by 25% with rotation bilaterally. He was uncomfortable and has decreased sensation in the right leg, L5-S1 distribution. His gait is antalgic. Clonus is negative bilaterally. He has tenderness to palpation of the left knee joint line and the superior medial aspect of the left knee. He has no swelling or erythema. Range of motion is limited to 100 degrees. MRI (6/18/2012) of the lumbar spine revealed: mild development tapering of the spinal canal; L4-L5: 4-5mm central and left paracentral sub ligamentous command to this disc protrusion. Pronounced thecal sac effacement with moderately severe spinal stenosis. Bilateral L5 nerve impingement and suggested in part secondary to accompanying ligamentum flavum and moderate hypertrophic facet change. Mild bilateral neural foraminal stenosis. L5-S1: Bilateral spondylosis at L5 with associated grade 1 spondylolisthesis of L5 with respect to S1. 3-4mm broad-based and lateral sub ligamentous disc protrusion. Mild to moderate proximal bilateral neural foraminal stenosis. Treatment has consisted of home exercise, knee brace, TENS, 12 sessions of physical therapy, Ketamine,

Zaleplon, Omeprazole, Hydrocodone bit/APAP, Senokot-s, Doxepin 3.3%, Cyclobenzaprine, Gabapentin, Nabumetone-Relafen and Lidoderm patch. The utilization review determination was rendered on 9/29/2014 recommending non-certification of Ketamine 5% 60gm #2 Dos: 09/04/14; Zaleplon 10mg #30 With 1 Refill; Hydrocodone/APAP 10/325mg #30; (MS) Quantity 120; Doxepin 3.3 60gm #1; Cyclobenzaprine 5mg #90 with 1 Refill; Gabapentin 600mg #60 and (MS) Quantity 120.

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

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

#### **Ketamine 5% 60gm #2: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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 states regarding topical Ketamine, "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted." Medical records do not indicate that all primary and secondary treatment options have been exhausted. As such, the request for Ketamine 5% 60GM #2 is not medically necessary.

#### **Zaleplon 10mg #30 with 1 Refill: Upheld**

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

**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, Zaleplon (Sonata, insomnia treatment)

**Decision rationale:** The California MTUS is silent regarding this topic. Official Disability Guidelines states that Zaleplon (Sonata) is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication as early as July 2013. There has been no discussion of the patient's sleep hygiene or the need for variance from the guidelines, such as "(a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool;

(f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping." Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. Official Disability Guidelines additionally states "The specific component of insomnia should be addressed: sleep onset; sleep maintenance; sleep quality; and next-day functioning." Medical documents provided do not detail these components. As such, the request for Zaleplon 10mg #30 with 1 Refill is not medically necessary at this time.

**Hydrocodone/APAP 10/325mg #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone; Opioids Page(s): 51; 74-95. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck, Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids, Pain

**Decision rationale:** Official Disability Guidelines does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the question for Hydrocodone/APAP 10/325mg #30 is not medically necessary.

**(MS) Quantity 120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids

**Decision rationale:** Morphine Sulfate is a pure opioid agonist. Official Disability Guidelines does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the

period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such the request for (MS) Quantity 120 is not medically necessary.

**Doxepin 3.3 60gm #1: 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 Page(s): 13. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, TCA's

**Decision rationale:** MTUS states that "Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated." Official Disability Guidelines states "Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken." Official Disability Guidelines states "Dosing Information: Amitriptyline: Neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007)." The treating physician has not provided evidence of improved pain control, improved function and sleep quality from Medical records are not clear if Doxepin is being used as a sleep aid, antidepressant, or for pain control. As such, the request for Doxepin 3.3 60gm #1 is not medically necessary.

**Cyclobenzaprine 5mg #90 with 1 Refill: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril); Other Medical Treatment Guideline or Medical Evidence: UpToDate, Flexeril

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" UpToDate "Flexeril" also states "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of Cyclobenzaprine. Official Disability Guidelines states regarding Cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of Cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with Cyclobenzaprine, which Official Disability Guidelines recommends against. As such, the request for is Cyclobenzaprine 5mg #90 with 1 Refill not medically necessary.

**Gabapentin 600mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin)

**Decision rationale:** The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. Official Disability Guidelines states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, Official Disability Guidelines states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain". The treating physician does not document a history of diabetic neuropathic pain or postherpetic neuralgia. Based on the clinical documentation provided, there is no evidence that after starting a trial of Gabapentin that the patient was asked at each subsequent visit if the patient had

decreased pain and improved functionality. As such, without any evidence of neuropathic type pain, the request for Gabapentin 600mg #60 is not medically necessary.

**(MS) Quantity 120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids

**Decision rationale:** Morphine Sulfate is a pure opioid agonist. Official Disability Guidelines does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such the request for (MS) Quantity 120 is not medically necessary.