

<b>Case Number:</b>	CM14-0153082		
<b>Date Assigned:</b>	10/23/2014	<b>Date of Injury:</b>	03/01/2004
<b>Decision Date:</b>	11/24/2014	<b>UR Denial Date:</b>	09/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/19/2014

### 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 Preventive 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 a 67 year old employee with date of injury of 3/1/04. Medical records indicate the patient is undergoing treatment for chronic low back pain and leg pain; post lami syndrome, L3/4 and L4/5 fusion in 4/04; s/p revision fusion at multi-level with post-op infection/complications/sequelae; s/p intrathecal pump placement; poor sleep hygiene due to pain; history of lumbar fusion and depression; spasm of back; increased ideal body weight since injury/surgery; cervical myelopathy since last injury due to due to multiple falls; s/p IT pump and s/p left ankle fracture and s/p removal of hardware. She has depression. Subjective complaints include her pump is empty and she wants to restart her previous medications. She complains of chronic severe low back pain and bilateral leg pain. She does not take care of her own activities of daily living. Her average pain is 8/10 at its worst and its best 6/10. She complains of poor sleep quality due to pain. Objective findings include: non-ambulatory, she presents in a wheelchair; left ankle weakness; non-weight bearing and ongoing baseline and back pain. Treatment has consisted of Ambien, Celebrex, Dilaudid, Fentora, Lisinopril and Lyrica. The utilization review determination was rendered on 9/4/14 recommending non-certification of IT pump exchange to 20 (twenty) cc pump/medications; Ambien CR 12.5 mg QHS, #30; Celebrex 200mg BID, #60; Lyrica 100mg BID, #120; Cymbalta 60mg BID, # 60; Prozac 40mg QD; Dilaudid 4mg QID PRN, #120 and Fentora 600ugm PO QD PRN, #28.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**IT pump exchange to 20 (twenty) cc pump/medications: 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)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug-delivery systems (IDDSs) Page(s): 51-54.

**Decision rationale:** MTUS states, "Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial". MTUS further states "Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met: 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated; and 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record; and 3. Further surgical intervention or other treatment is not indicated or likely to be effective; and 4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin and that benefit would occur with implantation despite any psychiatric comorbidity; and 5. No contraindications to implantation exist such as sepsis or coagulopathy; and 6. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of functional improvement and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met". While the treating physician has met some of the above criteria, the treating physician has not met all six criteria for an Implantable drug-delivery system (IDDSs). As such, the request for IT pump exchange to 20 (twenty) cc pump/medications is not medically necessary at this time.

**Ambien CR 12.5 mg QHS, #30: 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 Chapter

**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, Zolpidem, insomnia treatment

**Decision rationale:** The CA MTUS is silent regarding this topic. ODG states that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. 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 everyday; (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. ODG additionally states "The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical documents provided do not detail these components. As such, the request for Ambien CR 12.5 mg QHS, #30 is not medically necessary at this time.

**Celebrex 200mg BID, #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, Celebrex, NSAIDs Page(s): 22,30,70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** Anti-inflammatory medications are the traditional first line treatment for pain, but COX-2 inhibitors (Celebrex) should be considered if the patient has risk of GI complications, according to MTUS. The medical documentation provided does not indicate a reason for the patient to be considered high risk for GI complications. Risk factors for GI bleeding according to ODG include: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose or multiple NSAID (e.g., NSAID + low-dose ASA). The medical records do not indicate that the patient is undergoing treatment for any of the FDA approved uses such as osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. In addition, the treating physician did not document objective improvement or benefit from Celebrex. As such, the request for Celebrex 200mg BID, #60 is not medically necessary.

**Lyrica 100mg BID, #120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pregabalin (Lyrica) Page(s): 99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain

**Decision rationale:** MTUS and ODG state that "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references."Based on the clinical documentation provided, there is no evidence that Lyrica has decreased pain and improved functionality. The patient continues to complain of 8-10/10 pain while on Lyrica and opioid medications. As such, the request for Lyrica 100mg BID, #120 is not medically necessary.

**Cymbalta 60mg BID, # 60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain interventions and Treatments Page(s): 15-16.

**Decision rationale:** MTUS state regarding antidepressants for pain, "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur." The treating physician does not indicate failure of first-line agents and does not indicate how a first line agent is ineffective, poorly tolerated, or contraindicated. MTUS states regarding Cymbalta: "Selective serotonin and norepinephrine reuptake inhibitors (SNRIs): Duloxetine (Cymbalta): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%).....Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation."Cymbalta is FDA approved for the treatment of depression and requires continued monitoring for effectiveness per MTUS guidelines. The treating physician does not detail any improvement in pain and/or depressive symptoms while on the medication. In addition, the patient is also on another Serotonin containing medication, Prozac, putting the patient at increased risk for serotonin syndrome. As such, the request for Cymbalta 60mg BID, # 60 is not medically necessary.

**Prozac 40mg QD:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain interventions and Treatments Page(s): 15-16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Prozac

**Decision rationale:** MTUS state regarding antidepressants for pain, "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week,

whereas antidepressant effect takes longer to occur." The treating physician does not indicate failure of first-line agents and does not indicate how a first line agent is ineffective, poorly tolerated, or contraindicated. ODG states "Fluoxetine (Prozac, generic available): Also approved for major depressive disorder, OCD and premenstrual dysphoric disorder. Dosing information: 20-60 mg daily". The treating physician does not detail any improvement in pain and/or depressive symptoms while on the medication. In addition, the patient is also on Serotonin containing medication, Cymbalta, putting the patient at increased risk for serotonin syndrome. As such, the request for Prozac 40mg QD is not medically necessary.

**Dilaudid 4mg QID PRN, #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): 51,74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids

**Decision rationale:** Per MTUS, Dilaudid is the brand name version of Hydromorphone, which is a pure agonist/short acting opioid and "they are often used for intermittent or breakthrough pain." ODG 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." MTUS further recommends opioid dosing not to exceed 120mg oral morphine equivalent per day cumulatively for all different opioids used. 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. In addition, the patient is also on Dilaudid another opioid medication. As such, the question for Dilaudid 4mg QID PRN, #120 is not medically necessary

**Fentora 600ugm PO QD PRN, #28:** 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:** 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. ODG states "Not recommended for musculoskeletal pain. Fentora is an opioid painkiller currently approved for the treatment of breakthrough pain in certain cancer patients. Cephalon had applied to the FDA for approval to market the drug for patients with other pain conditions such as chronic low back pain and chronic neuropathic pain, but approval was not obtained". The treating physician has not provided documentation of a cancer diagnosis. As such the request for Fentora 600ugm PO QD PRN, #28 is not medically necessary.