

<b>Case Number:</b>	CM13-0028547		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	06/16/2009
<b>Decision Date:</b>	06/04/2014	<b>UR Denial Date:</b>	08/28/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/24/2013

### 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 Osteopathic Manipulative Medicine and is licensed to practice in Arizona. 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 is a 41-year-old male who sustained a slip and fall on June 16, 2009 and injured his back, neck and knee while carrying rebar over his shoulder. Since then he has had chronic lumbar, cervical pain that has greatly affected his ability to perform the most mundane activity of daily living. On a neurosurgical consultation dated August 27, 2012, the patient reported that his lumbar pain will elevate to a 10/10 performing the most menial activities. A repeat evaluation by the same neurosurgeon on September 23, 2013 identified nearly identical complaints with pain in the lumbar region as 7-8/10, cervical pain at 6/10 and his right knee pain at 4-8/10 dependant upon his activities on the 1 to 10 pain scale. He denies radicular pain, but does report foot tingling that occurs approximately 10 times daily that is worsened upon standing, walking and sitting.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**CYMBALTA 30MG DAILY. #30:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines SECTION ON SELECTIVE SEROTONIN AND NOREPINEPHRINE REUPTAKE INHIBIT.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PAIN INTERVENTIONS AND TREATMENTS, (CYMBALTA) Page(s): 43-44.

**Decision rationale:** Duloxetine (Cymbalta®) is recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta®) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The FDA notes that although Duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with comorbid depression. Treatment of fibromyalgia with Duloxetine should be initiated at 30 mg/day for 1 week and then up titrated to the recommended 60-mg dose. With the patient not diagnosed with neuropathic pain associated with diabetes or fibromyalgia, his complaint of lumbar pain does not meet the MTUS guideline for use of this medication and is therefore not medically necessary. However, the patient has documented diagnosis of depression for which Cymbalta was originally designed to treat. For the treatment of his depression, I find that this is medically necessary.

**EPIDURAL INJECTION OF THE LUMBAR SPINE:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OF EPIDURAL STEROID INJECTIONS, Page(s): 46.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OF EPIDURAL STEROID INJECTIONS Page(s): 46.

**Decision rationale:** Epidural steroid injections (ESIs) are recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a "series of three" ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, "series of three." Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If

used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current researches do not support a "series-of-three" injection in either the diagnostic or therapeutic phase.

#### **LEVITRA 20MG DAILY AS NEEDED FOR ERECTILE DYSFUNCTION, #10: 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 'no MTUS guideline for the use of any form of phosphodiesterase inhibitor medication '.

**Decision rationale:** There is no documented evidence of erectile dysfunction within the medical records provided for this independent medical review. There are multiple annotations by the primary treating physician's physician assistant of erectile dysfunction due to pain, but no documentation of appropriate work up for this issue. Although there is no MTUS guideline for the use of any form of phosphodiesterase inhibitor medication for erectile dysfunction, this is not a medical necessity.

#### **OXYCONTIN 80MG EVERY 8 HOURS, #90: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-95.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PAIN INTERVENTIONS AND TREATMENTS Page(s): 92.

**Decision rationale:** Oxycodone immediate release (OxyIR<sup>®</sup> capsule; Roxicodone<sup>®</sup> tablets; generic available), Oxycodone controlled release (OxyContin<sup>®</sup>): [Boxed Warning]: Oxycontin<sup>®</sup> Tablets are a controlled release formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Oxycontin tablets are not intended for use as a prn (as needed) analgesic. Side Effects: See opioid adverse effects. Analgesic dose: (Immediate release tablets) 5mg every 6 hours as needed. Controlled release: In opioid naive patients the starting dose is 10mg every 12 hours. Doses should be tailored for each individual patient, factoring in medical condition, the patient's prior opioid exposure, and other analgesics the patient may be taking. See full prescribing information to calculate conversions from other opioids. Note: See manufacturer's special instructions for prescribing doses of over 80mg and 160mg. Dietary

caution: patients taking 160mg tablets should be advised to avoid high fat meals due to an increase in peak plasma concentration. In this case, the patient has been on this medication since 2012 and has received previous approval for its use. Since he has severe pain as documented on numerous medical visits in the preceding 20 months, I find that continued use is medically necessary.