

Case Number:	CM15-0031107		
Date Assigned:	02/24/2015	Date of Injury:	03/19/2014
Decision Date:	04/02/2015	UR Denial Date:	02/05/2015
Priority:	Standard	Application Received:	02/19/2015

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: Family Practice

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 37 year old male sustained an industrial injury on 3/19/14, with subsequent ongoing low back and right hip pain. Magnetic resonance imaging lumbar spine (5/9/14), showed mild central stenosis on bilateral L4-5 and L5-S1 with lumbar facet arthropathy. Treatment included medications, physical therapy and acupuncture. In the most recent office visit submitted for review dated 9/25/15, the injured worker complained of pain to the low back with radiation to the right hip, 8/10 on the visual analog scale. The injured worker reported that previous physical therapy and medications had been helpful. However, the injured worker complained that medications caused complications. Previous acupuncture had not helped. Current medications included Tramadol and Naproxen. Physical exam was remarkable for tenderness to palpation to the right lumbar paraspinals with decreased extension and positive facet challenge on the right. A supplemental report dated 1/22/15, indicated that the injured worker had stopped oral medication use due to severe constipation around 8/22/14. The physician noted that the injured worker was now using topical compound creams for pain control. On 2/5/15, Utilization Review non-certified a request for Prednisone 10mg #25, modified a request for Gabapentin 600mg #60 to Gabapentin 600mg #60 one month supply and certified a request for Senna citing CA MTUS Chronic Pain Medical Treatment Guidelines. As a result of the UR denial, an IMR was filed with the Division of Workers Comp.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 600mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-17, 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDs) Page(s): 16-19.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Anti-Epilepsy Drugs (AEDs) such as gabapentin. These guidelines state the following: AEDs are recommended for neuropathic pain (pain due to nerve damage). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. Outcome: A good response to the use of AEDs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the trigger for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Specifically studied disease states: Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine). Postherpetic neuralgia: Gabapentin and pregabalin are recommended. Central pain: There are so few trials (with such small sample size) that treatment is generally based on that recommended for peripheral neuropathy, with gabapentin and pregabalin recommended. Lamotrigine has been found to be effective for central post-stroke pain (see below for specific drugs), and gabapentin has also been found to be effective. Chronic non-specific axial low back pain: A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. CRPS: Gabapentin has been recommended. Fibromyalgia: Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. Lumbar spinal stenosis: Gabapentin produced statistically significant improvement in walking distance, decrease in pain with movement and sensory deficit in a pilot study. Myofascial pain: Not recommended. There is a lack of evidence to demonstrate that AEDs significantly reduce the level of myofascial or other sources of somatic pain. 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. 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

suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. In this case, there is insufficient documentation of pain relief and improvement in function based on the use of gabapentin. There is insufficient documentation that the patient has received a "moderate" or "good" response to gabapentin as measured by a 30 to 50% reduction in pain. There is insufficient documentation that the patient underwent a trial period for three to eight weeks per the MTUS recommendations. For these reasons, use of gabapentin is not considered as medically necessary.

Prednisone 10mg #25`: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Oral Corticosteroids.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) and Other Medical Treatment Guidelines Low Back Complaints/Acute & Chronic: Corticosteroids for Low Back Pain.

Decision rationale: The Official Disability Guidelines comment on the use of corticosteroids, such as prednisone, for the treatment of low back complaints. These guidelines state that corticosteroids are recommended in limited circumstances as noted below for acute radicular pain, and patients should be aware that research provides limited evidence of effect with this medication. Corticosteroids are not recommended for acute non-radicular pain (i.e. axial pain) or chronic pain. Overview: Studies designed to investigate the use of oral, intramuscular, and intravenous steroids in the setting of acute low back pain are limited. Oral steroids (corticosteroids) are used by some clinicians for the treatment of patients with acute low back pain with radiculopathy. The therapeutic objective is to reduce inflammation in an attempt to promote healing and reduce pain. It is also hypothesized that the effect of corticosteroids on mood can enhance the effect of well-being. Overall it is suggested that the main effect of systemic steroids is to provide pain relief (which is reported as minimal in current research) in the early acute period. Adverse effects: Multiple severe adverse effects have been associated with systemic steroid use. This is more likely to occur after long-term use. Musculoskeletal manifestations include myopathy, impaired wound healing and osteoporosis. Prolonged use can produce edema and hypertension. Endocrine effects include Cushing's syndrome, menstrual irregularities, hyperglycemia and aggravation of diabetes. Mental disturbances including depression, anxiety, emotional liability and even psychosis have been reported. Impaired hypothalamic-pituitary-adrenal axis and withdrawal: One of the most serious problems after prolonged use of corticosteroids is secondary adrenocortical insufficiency. In patients taking any dose of steroid for less than 3 weeks duration, clinically significant suppression of the hypothalamic-pituitary-adrenal axis is rarely a problem and steroids can be withdrawn suddenly without adverse effect. Acute Radicular Pain: There is extremely limited evidence to recommend oral corticosteroid for acute radicular pain. Criteria for the Use of Corticosteroids (oral/parenteral for low back pain):(1) Patients should have clear-cut signs and symptoms of radiculopathy;(2) Risks of steroids should be discussed with the patient and documented in the record;(3) The patient should be aware of the evidence that research provides limited evidence of effect with

this medication and this should be documented in the record;(4) Current research indicates early treatment is most successful; treatment in the chronic phase of injury should generally be after a symptom-free period with subsequent exacerbation or when there is evidence of a new injury. In this case, the records do not indicate that the patient meets the above cited ODG guidelines for the use of prednisone. First, it is unclear from the records that prednisone is intended for acute radicular pain. The information in the records suggests that prednisone is being used for chronic radicular symptoms. It is unclear that the patient has undergone documented counseling as to the limited evidence in support of prednisone and has been made aware of the risks of this therapy. For these reasons, the use of prednisone is not considered as medically necessary.

Senna: Overturned

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) and Other Medical Treatment Guidelines Pain/Chronic: Opioid-Induced Constipation Treatment.

Decision rationale: The Official Disability Guidelines comment on the use of medications to mitigate constipation associated with the use of opioids, such as Tramadol. The guidelines state that, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Senna is a stimulant laxative that increases peristalsis and may help patients with opioid-induced constipation. In this case, the records indicate that the patient is on the opioid Tramadol and has experienced significant constipation from this medication. In the Utilization Review Process, Senna was certified. Certification of Senna is consistent with the ODG guidelines. Senna is therefore, medically necessary and appropriate treatment for this patient's opioid-induced constipation.