

Case Number:	CM14-0044114		
Date Assigned:	07/02/2014	Date of Injury:	04/16/2003
Decision Date:	08/05/2014	UR Denial Date:	03/17/2014
Priority:	Standard	Application Received:	04/11/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in California. 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:

The injured worker is a 48-year-old male smoker who reported a low back injury on 04/16/2003. The mechanism of injury is unknown. On 03/12/2014, he complained of chronic low back pain interfering with his activities of daily living. An examination of his back revealed mild muscle spasms in the thoracic spine greater on the right side than on the left. The lower thoracic spine exhibited mild tenderness to palpation and percussion. The lumbosacral region exhibited severe tenderness to palpation. There was a well-healed, nontender surgical scar on the lumbosacral spine. His ranges of motion values measured in degrees were, T12 flexion 15/105, sacral hip flexion 0/45, lumbar flexion 15/60, lumbar extension 5/25, right lateral bending 15/25, left lateral bending 15/25, right supine straight leg raising 30/65, and left supine straight leg raising 30/65. On a noted dated 03/17/2014, it was documented that he had had a right radiofrequency rhizotomy which had been significant in pain reduction, but the date was unknown. Upon examination, the right paravertebral region was significantly colder than the left. Swelling was noted from L4-S1 along the posterior spine. It was noted that an MRI of the lumbar spine obtained in August of 2008 revealed an unremarkable L1-2, a disc protrusion of 1 mm at L2-3, with an annular fissuring disc protrusion of 2 mm at L3-4, annular fissuring with a subtle annular bulge at L4-5, with early facet degenerative changes and a focal high intensity zone along the posterior annular margin consistent with an annular tear at L5-S1. He was diagnosed with chronic lower back pain with bilateral lower extremity radiculopathy. It was also noted that on unknown dates he had received trigger point injections and a spinal cord stimulator implantation. His medications included Nucynta IR 50 mg for severe pain, Cymbalta 20 mg for neuropathic pain, Lyrica 25 mg for radiating nerve pain to his legs, Cialis 20 mg for erectile dysfunction, and tizanidine 2 mg for muscle spasms. Requests for authorization were found for all of the medications requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta IR 50mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-95. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Tapentadol (Nucynta).

Decision rationale: CA MTUS attests that opioid drugs are considered the most powerful class of analgesics that may be used to manage chronic pain. Recommendations include a psychosocial assessment by the treating doctor and a possible second opinion by a specialist to assess whether a trial of opioids should occur. Ongoing reviews and documentation of pain relief, functional status, appropriate medication use and side effects should be documented. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain and 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Opioids should be continued if the patient has returned to work or if the patient has improved functioning and pain. There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. For chronic back pain, opioids appear to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (greater than 16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. A major concern for the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (less than 70 days). Long-term use may result in immunological and endocrine problems. Short-acting opioids: also known as normal-release or immediate-release opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. The ODG Recommended Tapentadol (Nucynta) as second line therapy for patients who develop intolerable adverse effects with first line opioids. There is no documentation in the submitted chart to attest to previous failed trials with first line opioids, appropriate long-term monitoring, evaluations, including psychosocial assessment, side effects, failed trials of NSAIDS, aspirin, antidepressants or anticonvulsants, quantified efficacy, concordant drug screens, or collateral contacts. Additionally, there is no frequency specified in the request. Therefore, this request for Nucynta IR 50 mg #120 is not medically necessary.

Tizanidine 2mg #60: 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 Muscle Relaxants (for pain).

Decision rationale: CA MTUS recommends that non-sedating muscle relaxants be used with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain cases, they show no benefit beyond NSAIDs and no additional benefit when used in combination with NSAIDs. Tizanidine (Zanaflex), is a centrally acting alpha₂-adrenergic agonist that is FDA approved for management of spasticity, with an unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. Per the submitted documentation, this worker has been using tizanidine for more than 4 months. Tizanidine is not recommended for long-term usage and shows no benefit beyond NSAIDs. He does not have a diagnosis of chronic myofascial pain syndrome. Additionally, the request does not specify frequency of administration. Therefore, this request for Tizanidine 2 mg #60 is not medically necessary.

Cialis 20mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Rxlist.com.

Decision rationale: Per rxlist.com, CIALIS is indicated for the treatment of erectile dysfunction (ED). When CIALIS is taken once daily for erectile dysfunction, the recommended starting dose is 2.5 mg, taken at approximately the same time every day, without regard to timing of sexual activity. The dose for once daily use may be increased to 5 mg, based on individual efficacy and tolerability. The recommended starting dose of CIALIS to be used on an as-needed basis in most patients, is 10 mg, taken prior to anticipated sexual activity. The request for 30 tablets suggests that the Cialis is being prescribed for daily use. The request for Cialis 20 mg is greater than the dosage which is recommended. Additionally, there was no frequency included in the request. Therefore, this request for Cialis 20 mg #30 is not medically necessary.

Lyrica 25mg #30: 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 Antiepilepsy drugs (AEDs) ; Pregabalin (Lyrica) Page(s): 16-20; 99.

Decision rationale: In the CA MTUS, Anti-epilepsy drugs (AEDs) (also referred to as anti-convulsants) have been 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 post-herpetic 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. Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and post-herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. Lyrica has FDA approval for treatment of diabetic neuropathy and postherpetic neuralgia. This worker does not have a diagnosis of either diabetic neuropathy or postherpetic neuralgia. Additionally, the request did not specify frequency of administration. Therefore, this request for Lyrica 25 mg #30 is not medically necessary.

Cymbalta 20mg #60: 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 Duloxetine Page(s): 43-44.

Decision rationale: CA MTUS recommends duloxetine (Cymbalta) as an option in first-line treatment option in neuropathic pain. Duloxetine 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 starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. Cymbalta has FDA approval for the treatment of pain related to diabetic neuropathy. This worker does not have a diagnosis of diabetes nor diabetic neuropathy. The guidelines further state that no advantage has been found by increasing the dose to twice a day except in cases of fibromyalgia. The request for Cymbalta 20 mg #60 appears to be a twice daily request. Additionally, there is no frequency of administration included in the request. Therefore, this request for Cymbalta 20 mg #60 is not medically necessary.