

Case Number:	CM14-0039244		
Date Assigned:	08/01/2014	Date of Injury:	02/23/1999
Decision Date:	09/19/2014	UR Denial Date:	03/21/2014
Priority:	Standard	Application Received:	04/03/2014

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 Anesthesiology, has a subspecialty in Pain management and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 50 year old with a date of injury February 23, 1999. The patient sustained injuries to his upper back and lower back and the mechanism of injury is unclear from the documents provided. The injured worker currently carries the following diagnoses: Chronic pain syndrome, migraines, degeneration of the thoracolumbar intravertebral disk and muscle spasms. The patient is currently being maintained on the multimodal pain medication regimen consisting of: Skelaxin, Cymbalta, Celebrex, Gabapentin, Norco and Topiramate. A request for the above-mentioned medications was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Skelaxin 800MG dos 1/31/14: 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 Antispasticity / Antispasmodic Drugs, Skelaxin Page(s): 63-66.

Decision rationale: Skelaxin is recommended with caution as a second-line option for short-term pain relief in patients with chronic LBP. However, according to the MTUS, Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of

acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. The efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to the documents available for review, the patient has been utilizing Skelaxin for long-term treatment of chronic pain condition. This is in contrast to the into US recommendations for short-term treatment of acute exacerbations. Therefore, the request is not medically necessary.

Gabapentin 600mg DOS 1/29/14: 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 Anti-epilepsy drugs (AEDs), Gabapentin Page(s): 18.

Decision rationale: 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. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007)(Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat(NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba,2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007)Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007)(Menigaux, 2005) (Pandey, 2005)Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004)CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007)Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study.(Yaksi, 2007)Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007)(Attal, 2006) Weight gain

is also an adverse effect. Dosing Information: Postherpetic neuralgia - Starting regimen of 300 mg once daily on Day 1, then increase to 300mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert) Diabetic neuropathy (off-label indication) - Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonja, 2002) (Eisenberg, 2007). Gabapentin is 100% renally excreted. 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 suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007) Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) When to switch to pregabalin: If there is evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trials of the two drugs. According to the documents available for review, the patient has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and therefore is not medically necessary.

Duloxetine 60 mg HCL DOS 1/29/14: 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 Cymbalta Page(s): 43.

Decision rationale: According to the MTUS, Cymbalta is Recommended 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 medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) On June 13, 2008, the FDA approved a new indication for duloxetine HCl delayed-release capsules for the management of fibromyalgia in adults. 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. According to the documents available for review, the patient has none of the aforementioned MTUS approved

indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and is not medically necessary.

Celebrex 200mg DOS 1/29/14: 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 Pain Interventions and Treatments, NSAIDs, Specific drug list & adverse effects Page(s): 70-73.

Decision rationale: According to the MTUS, Celebrex is approved for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. According to the documents available for review, the patient has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time is not medically necessary.

Topiramate 200mg DOS 1/29/14: 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 Anti-epilepsy drugs (AEDs), Topiramate Page(s): 21.

Decision rationale: According to the MTUS, Celebrex is approved for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. According to the documents available for review, the patient has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time is not medically necessary.

Sumatriptan Succinate 6 mg DOS 1/10/14: 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) Head, headaches.

Decision rationale: According to the official disability guidelines, section on headaches, triptans are recommended for migraine sufferers. According to the documents available for review, the patient suffers from migraine headaches. Therefore at this time the requirements for treatment have be met. Therefore the request is medically necessary and appropriate.

Hydrocodone/Acetaminophen 10/325mg DOS 1/10/14: 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 Opioids, On-Going Management Page(s): 74-97.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the 4 A's (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. According to the documents available for review, there is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Additionally, according to the documents available for review, there is no evidence of a pain consultation despite the fact that the patient is being maintained on opiates for greater than three months. Therefore, at this time, the request is not medically necessary.