MAXIMUS Federal Services

Case Number:	CM14-0122233		
Date Assigned:	08/06/2014	Date of Injury:	04/24/2006
Decision Date:	09/11/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	08/04/2014

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 patient is a 34 years old female with an injury date on 04/24/2006. Based on the 07/14/2014 progress report provided by Dr. [redacted], the diagnoses are: 1. Sprains and strains of ankle 2. Lumbar or lumbosacral disc degeneration 3. Reflex Sympathetic Dystrophy not otherwise specific 4. Closed ankle fracture not otherwise specified 5. Ankle Arthroscopy6. Sprains and strains of ankle not otherwise specified According to this report, the patient complains of severe increased left ankle pain, severe low back pain with spasm, and depression. Per treater, due to medications denial, the patient's pain has severely escalated and he is less functional. The patient is currently using a quad cane. The 01/08/2014 report indicates the patient's lower back pain is constant and radiates to the hip. Lumbar range of motion is restricted due to pain. Patient can't do heel walk and toes walk. The patient's current medications are Neucontin, Norco, Cymbalta and Lunesta. There were no other significant findings noted on this report. Dr. [redacted] is requesting 1. Neurontin 300mg with 2 refills #1802. Norco 10/325mg #1203. Cymbalta 60mg with 1 refill #304. Lunasta 2mg with 1 refill #30. The utilization review denied the request on 07/22/2014. Dr. [redacted] is the requesting provider, and provided treatment reports from 02/07/2013 to 07/14/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

180 Neurontin 300 mg with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. Recommended for neuropathic pain (pain due to nerve damage), but not for acute somatic pain. (Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) 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. (Attal, 2006) The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin); Pregabalin (Lyrica); Lamotrigine (Lamictal); Carbamazepine (Tegretol); Oxcarbazepine (Trileptal); Phenytoin (Dilantin); Topiramate (Topamax); Levetiracetam (Keppra); Zonisamide (Zonegran); & Tiagabine (Gabitril).

Decision rationale: According to the 07/14/2014 report by Dr. [redacted] this patient presents with severe left ankle pain, severe low back pain, and depression. The treater is requesting Neurotin 300mg with 2 refills #30. Neurotin was first noted in the 02/07/2013 report. Regarding Anti-epileptic (AKA anti-convulsants) drugs for pain, ODG Guidelines recommend for neuropathic pain (pain due to nerve damage), but not for acute somatic pain. Review of reports indicate that the patient has neuropathic pain. The ODG guidelines support the use of anti-convulsants for neuropathic pain. However, the treater does not mention that this medication is working. There is no discussion regarding the efficacy of the medication. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when used for chronic pain. Therefore, this request is not medically necessary.

120 Norco 10-325 mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of

comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not all recommended). See Anticonvulsants for chronic pain; Antidepressants for chronic pain; Anti-epilepsy drugs (AEDs); Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Buprenorphine; Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine (Flexeril); Duloxetine (Cymbalta); Gabapentin (Neurontin); Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Topical analgesics, Compounded; Uncaria Tomentosa (Cat's Claw); Venlafaxine (Effexor); White willow bark; & Ziconotide (Prialt).CRITERIA FOR USE OF OPIOIDS (MTUS pgs 88, 89)Long-term Users of Opioids (6-months or more)1) Re-assess(a) Has the diagnosis changed?(b) What other medications is the patient taking? Are they effective, producing side effects?(c) What treatments have been attempted since the use of opioids? Have they been effective? For how long?(d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life.

Decision rationale: According to the 07/14/2014 report by Dr. [redacted] this patient presents with severe left ankle pain, severe low back pain, and depression. The treater is requesting Norco 10/325mg #120. Review of report shows that the patient has been taking Norco since 03/06/2013. For chronic opiate use, MTUS Guidelines page 88 and 89 require functioning documentation using a numerical scale or validated instrument at least once every 6 months. Documentation of 4 A's (analgesia, ADLs, adverse side effects, adverse behaviors) are also required. Furthermore, under outcome measures, MTUS recommends documentation of current pain, average pain, least pain, time it takes for medication to work, duration of pain relief with medications. In this case, the report shows no documentation of pain assessment using a numerical scale describing the patient's pain. No outcome measures are provided. No specific ADL's, return to work are discussed. No discussions are provided regarding potential aberrant drug seeking behavior. Given the lack of sufficient documentation demonstrating efficacy from chronic opiate use, the patient should be slowly weaned as outlined in MTUS Guidelines. Therefore, this request is not medically necessary.

30 Cymbalta 60 mg with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CymbaltaSelective serotonin and norepinephrine reuptake inhibitors (SNRIs): (MTUS pg16,17)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%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005) Dosing: 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency.Venlafaxine (Effexor): FDA-approved for anxiety, depression, panic disorder and social phobias. Off-label use for fibromyalgia, neuropathic pain, and diabetic neuropathy.Side-effect profile: CNS: (5%) drowsiness, weakness, dizziness, dry mouth, insomnia, nervousness/anxiety (13/6% vs. 6/3%), tremor, headache, seizures. GI: N&V, constipation, weight loss (2-18%). Pre-existing hypertension should be controlled. Cholesterol may be increased (5%). Sexual dysfunction has also been noted. (Maizels, 2005) (ICSI, 2007)Dosing: Neuropathic pain (off-label indication): 37.5 mg once daily, increase by 37.5 mg per week up to 300 mg daily. (Maizels, 2005) (ICSI, 2007) 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.Duloxetine (Cymbalta) (MTUS p43,44)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 starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. 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) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the Page(s): 16-17; 43-44.

Decision rationale: According to the 07/14/2014 report by Dr. [redacted] this patient presents with severe left ankle pain, severe low back pain, and depression. The provider is requesting Cymbalta 60mg with 1 refill #30. Cymabalta was first mentioned in the 02/07/2013 report. For Cymbalta, the MTUS Guidelines page 16 and 17 states, "Duloxetine (Cymbalta) is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. It is also used for off-label neuropathic pain and radiculopathy. Duloxetine is recommended as a first line option for diabetic neuropathy." In this case, the patient is prescribed Cymbalta for depression and neuropathic pain. However, there was no discussion of the efficacy of the medication. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when used for chronic pain. Therefore, this request is not medically necessary.

30 Lunesta 2 mg with 1 refill: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)Lunesta under Insomnia, Pain chapter:Eszopicolone (Lunestaâ¿¢) has demonstrated reduced sleep latency and sleep maintenance. (Morin, 2007) The only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. (Walsh, 2007) Side effects: dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. Dosing: 1-2 mg for difficulty falling asleep; 2-3 mg for sleep maintenance. The drug has a rapid onset of action. (Ramakrishnan, 2007).

Decision rationale: According to the 07/14/2014 report by Dr. [redacted] this patient presents with severe left ankle pain, severe low back pain, and depression. The treater is requesting Lunesta 2mg with 1 refill #30. Lunesta was first mentioned in the 02/07/2013 report. Regarding Lunesta, the MTUS and ACOEM Guidelines do not discuss, but ODG Guidelines discuss Lunesta under insomnia and state "Lunesta has demonstrated reduced sleep latency and sleep maintenance. The only benzodiazepine receptor agonist FDA approved for use longer than 35 days." The only report that mentions patient sleeping issue is noted on the 12/19/2013 report, "Because of pain I have less than 2 hours of sleep." The treater does not mention what Lunesta is doing for this patient. Despite Lunesta, the patient is only getting 2 hours of sleep. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when used for chronic pain. Based on the above, this request is not medically necessary.