

Case Number:	CM14-0113605		
Date Assigned:	08/01/2014	Date of Injury:	07/02/2009
Decision Date:	10/01/2014	UR Denial Date:	07/08/2014
Priority:	Standard	Application Received:	07/21/2014

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 an injured female worker. The date of injury is July 2, 2009. The patient sustained an injury to her shoulders and neck and upper back. The specific mechanism of injury was not elaborated on the notes available for review. Patient care is a current diagnosis of adhesive capsulitis of the shoulder. The patient currently complains of neck upper back pain and shoulder pain. The patient is maintained on the multimodal pain medication regimen including Cymbalta, Lidoderm patch, Elavil and Norco. Request for Cymbalta, Lidoderm patch, Elavil and Norco was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

2 Retrospective Cymbalta 30mg 1 Cap every day with 1 refill #30: Upheld

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

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 (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 medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. On June 13, 2008, the FDA approved a new indication for duloxetine HCl delayed-release capsules (Cymbalta; ██████████) 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. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. 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 medical necessity has not been established.

2 Retrospective Lidoderm 5 % patches 1 patch x 12 hours with 1 refill #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain chapter

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Page(s): 56, 112.

Decision rationale: Accordingly to the MTUS "Lidoderm Patch is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics." In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical Lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. 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 medical necessity has not been established.

2 Retrospective Elavil 10mg 1 tablet every hour with 1 refill #30: 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) Pain, Chronic, TCA

Decision rationale: Tricyclic antidepressants are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant cause of fatal drug poisoning due to their cardiovascular and neurological effects. Tricyclic antidepressants have been shown in both a meta-analysis and a systematic review to be effective, and are considered a first-line treatment for neuropathic pain. This class of medications works in both patients with normal mood and patients with depressed mood when used in treatment for neuropathic pain. Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia (Argoff, 2004), painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Negative results were found for spinal cord pain and phantom-limb pain, but this may have been due to study design. Tricyclics have not demonstrated significance in randomized-control trials in treating HIV neuropathy, spinal cord injury, cisplatin neuropathy, neuropathic cancer pain, phantom limb pain or chronic lumbar root pain. (Dworkin, 2007) One review reported the NNT for at least moderate neuropathic pain relief with tricyclic's is 3.6 (3-4.5), with the NNT for amitriptyline being The NNT for venlafaxine, calculated using 3 studies, was reported to be 3.1 Another review reported that the NNT for 50% improvement in neuropathic pain was 2 to 3 for tricyclic antidepressants, 4 for venlafaxine, and 7 for SSRIs Side-effect profile: Tricyclic's are contraindicated in patients with cardiac conduction disturbances and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening ECG is recommended prior to initiation of therapy. They can create anticholinergic side effects of dry mouth, sweating, dizziness, orthostatic hypotension, fatigue, constipation, and urinary retention. (Finnerup, 2005) To minimize side effects, it is suggested that titration should be slow and based on the patient's response. An alternative choice may be a SNRI. The muscle relaxant cyclobenzaprine is closely related to the tricyclic antidepressants so caution is advised when using cyclobenzaprine. Dosing Information: Amitriptyline: Neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). Fibromyalgia: One review recommended the following dosing regimen: Start with low doses, such as 5-10 mg 1-3 hours before bedtime. Dose may be increased by 5 mg at two-week intervals; final dose is dependent upon efficacy and patient tolerability to side effects. Doses that have been studied range from 25 to 50 mg at bedtime. According to the documents available for review, the patient has

2 Retrospective Norco 7.5/325 1 tablet every day / two times per day with 1 refill #45:
Upheld

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

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 non-adherent) 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 non-opioid 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." There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.