

Case Number:	CM15-0148778		
Date Assigned:	08/12/2015	Date of Injury:	07/20/2004
Decision Date:	10/07/2015	UR Denial Date:	07/22/2015
Priority:	Standard	Application Received:	07/31/2015

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: New York, Tennessee
 Certification(s)/Specialty: Emergency Medicine

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 32 year old male, who sustained an industrial injury on 07-20-2004 secondary to tripping over uneven carpeting resulting in left ankle injury. On provider visit dated 07-08-2015 the injured worker has reported ongoing depression due to pain and disability and continued left ankle-foot pain. Objective findings were noted as having an anxious affect. The diagnoses have included unspecified site of ankle sprain, ankle sprain and chronic pain syndrome. Treatment to date has included psychological treatment, TENS, and medication. The provider requested Nucynta, Lyrica, Gym membership due to foot pain, TENS unit and ongoing supplies for non-pharmaceutical pain control, Lidoderm, Flector and Celebrex.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta 75mg #100: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Tapentadol (Nucynta).

Decision rationale: MTUS does not comment on Nucynta. Nucynta is Tapentadol, a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. Nucynta was made a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Nucynta may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with Oxycodone, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. Nucynta is recommended as a second line therapy when patients develop intolerable adverse effects to first line opioids. In this case there is no documentation that the patient has failed treatment or developed adverse effects with first line opioids. Medical necessity has not been established. The request should not be medically necessary.

Lyrica 75mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: Lyrica is Pregabalin, an anti-epilepsy drug. It is has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. It is recommended in neuropathic pain conditions and fibromyalgia. In this case documentation does not support the diagnosis of neuropathic pain. In addition the patient has been taking the medication since at least January 2015 and has not obtained analgesia. The request should not be medically necessary.

Gym membership due to foot pain: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle & Foot.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Exercise.

Decision rationale: Exercise is recommended. There is strong evidence that exercise programs, including aerobic conditioning and strengthening, are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment or rehabilitation program, unless exercise is contraindicated. Such programs should emphasize education, independence, and the importance of an on-going exercise regime. A recent study of the long term impact of aerobic exercise on musculoskeletal pain found that exercise was associated with a substantial and significant reduction in pain even after adjusting for gender, baseline BMI and attrition, and despite the fact that fractures, a significant predictor of pain, were slightly more common among exercisers. A recent trial concluded that active physical treatment, cognitive-behavioral treatment, and the two combined each resulted in equally significant improvement, much better compared to no treatment. Progressive walking, simple strength training, and stretching improved functional status, key symptoms, and self-efficacy in patients with fibromyalgia. Physical conditioning in chronic pain patients can have immediate and long-term benefits. Exercise programs aimed at improving general endurance (aerobic fitness) and muscular strength (especially of the back and abdomen) have been shown to benefit patients with acute low back problems. So far, it appears that the key to success in the treatment of low back pain is physical activity in any form, rather than through any specific activity. One of the problems with exercise, however, is that it is seldom defined in various research studies and its efficacy is seldom reported in any change in status, other than subjective complaints. If exercise is prescribed a therapeutic tool, some documentation of progress should be expected. While a home exercise program is of course recommended, more elaborate personal care where outcomes are not monitored by a health professional, such as gym memberships or advanced home exercise equipment, may not be covered under this guideline. In this case there is no documentation that there will be oversight of the exercises by a health professional. The request should not be medically necessary.

TENS unit and ongoing supplies for non-pharmaceutical pain control: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle & Foot.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

Decision rationale: TENS units are not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, including reductions in medication use, for neuropathic pain, phantom limb pain, spasticity, and multiple sclerosis. Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. Functional restoration programs (FRPs) are designed to use a medically directed, interdisciplinary pain management approach geared specifically to patients with chronic disabling occupational musculoskeletal disorders. These programs emphasize the importance of function over the elimination of pain. FRPs incorporate components of exercise progression with disability management and

psychosocial intervention. In this case there is no documentation that the patient is participating in a functional restoration program. TENS units are not recommended as a primary treatment modality. The request should not be medically necessary.

Lidoderm #60: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle & Foot.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Lidoderm (lidocaine patch).

Decision rationale: Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. Criteria for use of Lidoderm patches: (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non- neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of patches. (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period. (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued. (i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued. In this case there is no documentation to support the diagnosis of postherpetic neuralgia. In addition there is no documentation the outcomes have been measured. Criteria for lidoderm patch use have not been met. The request should not be medically necessary.

Flector #60: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle & Foot.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Flector patch.

Decision rationale: Flector , the topical NSAID diclofenac, is not recommended as a first-line treatment. Flector patch is FDA indicated for acute strains, sprains, and contusions. On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Post marketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminate hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate Flector efficacy beyond two weeks. In this case the patient has been using Flector since at least January 2015. Duration of treatment exceeds the known duration of efficacy. In addition there is insufficient documentation to support the diagnosis of osteoarthritis. Medical necessity has not been established. The request should not be medically necessary.

Celebrex 100mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle & Foot.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects.

Decision rationale: Celebrex is the selective COX-2 nonsteroidal anti-inflammatory drug celecoxib. It has been useful in the treatment of osteoarthritis, anklyosing spondylitis, and rheumatoid arthritis. Chronic Medical Treatment Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". For osteoarthritis, it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be more effective than acetaminophen, and had more adverse side effects. Adverse effects for hypertension and renal function have been reported with COX-2 NSAIDs. Record of pain and function with the medication should be documented. In this case the patient has been taking Celebrex since at least March 2015. Long term use increases the risk of side effects with no documented benefit. The request should not be medically necessary.