

Case Number:	CM14-0153180		
Date Assigned:	09/23/2014	Date of Injury:	11/05/2004
Decision Date:	10/29/2014	UR Denial Date:	08/21/2014
Priority:	Standard	Application Received:	09/19/2014

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 & Rehabilitation and is licensed to practice in Illinois. 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 67-year-old female who reported an injury on 11/05/2004. The mechanism of injury was not provided. The injured worker's diagnoses included chronic low back pain, lumbar degenerative disc disease, lumbar radiculopathy, and bilateral trochanteric bursitis. The injured worker's past treatments included home exercise program, cortisone injections, and lumbar support brace, and medications. There was no relevant diagnostic testing or relevant surgery included in the documentation. On 08/15/2014, the injured worker complained of chronic low back pain radiating into the hips and lower extremities. She rated the pain to be 3/10 to 4/10 on the VAS, which can increase to 8/10 with prolonged sitting, standing, and ambulation. She reported that the use of Cymbalta twice daily helped with her radicular pain, and the Lidoderm patches and topical compounded creams have been effective in managing her low back pain. She reported that she used Norco only on rare occasions when the pain became severe. Upon physical examination, the injured worker was noted with a mildly antalgic gait, moderately limited range of motion to the lumbar spine in all planes, and mild lumbar paraspinal muscle tenderness. The injured worker's current medications included Cymbalta 30 mg, Lidoderm 5% patches, Ketoprofen 15%, Cyclobenzaprine 2%, Gabapentin 10%, and Lidocaine 2% topical compounded cream. The request was for 30 tablets of Norco 5/325 mg, topical compound cream, 60 capsules of Cymbalta 30 mg with 3 refills, and 60 patches of Lidoderm 5% with 3 refills. The rationale for the request was not provided. The Request for Authorization form was not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

30 tablets of Norco 5-325mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Opioids: On-going management, Page(s): pages 78-80..

Decision rationale: The MTUS Chronic Pain Guidelines may recommend ongoing opioid therapy for patients with ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The pain assessment should include a quantified current pain, the least reported pain over the period since last assessment, intensity of pain after taking the opioid, 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. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids to be pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug related behaviors. The guidelines note to continue opioids if the patient has returned to work and if the patient has improved functioning and pain. The injured worker reported that she used the Norco only on rare occasions when the pain became severe. There was no documented evidence of monitoring for the occurrence of any potentially aberrant drug related behaviors or appropriate medication use, like a urine drug test. The injured worker reported her pain to be 3-4/10 on the VAS, however, it was not indicated if that was with or without medication use. The documentation did not provide evidence of significant objective functional improvement or decrease in pain with the medication. In the absence of documentation with evidence of significant objective functional improvement, evidence of objective decrease in pain, and documented evidence of a urine toxicology screening, the request is not supported. Additionally, as the request was written the frequency was not provided. Therefore, the request is not medically necessary.

Topical compound cream (Ketoprofen 15 %, Cyclobenzaprine 2 %, Gabapentin 10 % and lidocaine 2%) 240 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Topical analgesics, Page(s): page(s) 111.

Decision rationale: The MTUS Chronic Pain Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific

analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. 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. They are recommended for short term use (4 to 12 weeks). Ketoprofen is not currently FDA-approved for topical application. It has an extremely high incidence of photo contact dermatitis. Topical lidocaine may be recommended for neuropathic pain after there has been evidence of a trial of first line therapy. Topical lidocaine, in the formulation of a dermal patch Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. Lidoderm has no other commercially approved topical formulations (whether creams, lotions, or gels). Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. Gabapentin is not recommended. There is no peer reviewed literature to support use. The injured worker reported that the compounded cream was effective in managing her low back pain. The documentation did not provide sufficient objective evidence of the efficacy of the medication to support her subjective claim. In the absence of documentation with sufficient objective evidence of the efficacy of the medication like increased objective function and decreased pain, and because Gabapentin is not recommended by the guidelines, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

60 capsules of Cymbalta 30 mg with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SSRIs (selective serotonin reuptake inhibitors) Page(s): 15.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Antidepressants for chronic pain, Page(s): pages 13-16.

Decision rationale: The MTUS Chronic Pain Guidelines may recommend antidepressants for chronic pain as a first line treatment option for neuropathic pain, and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation, should be assessed. It has been suggested that if pain is in remission for 3 to 6 months, a gradual tapering of antidepressants may be undertaken. Long term effectiveness of antidepressants has not been established. The effects of this class of medication in combination with other classes of drugs have not been well researched. Cymbalta is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Cymbalta is recommended as a first line option for diabetic neuropathy. No high quality evidence is reported to support the use of Cymbalta for lumbar radiculopathy. More studies are needed to determine the efficacy of Cymbalta for other types of neuropathic pain. The injured worker reported that she used Cymbalta twice daily, which helped with her radicular pain; however, there was no documented evidence of the decreased pain level objectively. In the absence of documentation with sufficient evidence of an assessment of treatment efficacy with pain outcomes, evaluation of function, changes in use of other analgesic medication, psychological assessment, and an assessment of the side effects, the request is not

supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

60 patches of Lidoderm 5% with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm, Page(s): pages 56-57..

Decision rationale: The MTUS Chronic Pain Guidelines may recommend topical lidocaine for localized peripheral pain after there has been evidence of a trial of first line therapy, such as Gabapentin or Lyrica. This is not a first line treatment and is only FDA-approved for postherpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. The injured worker reported that she used to Lidoderm patches as needed for pain and that they had been effective in managing her low back pain. The documentation did not include a complete and thorough pain assessment with objective evidence of the efficacy of the medication. In the absence of documentation with objective evidence of efficacy of Lidoderm patches and documented evidence of postherpetic neuralgia, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.