

Case Number:	CM14-0215001		
Date Assigned:	01/07/2015	Date of Injury:	02/12/2013
Decision Date:	02/28/2015	UR Denial Date:	12/12/2014
Priority:	Standard	Application Received:	12/22/2014

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. 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 patient is a 59-year-old male who was injured on February 12, 2013. The patient continued to experience pain in his neck radiating into his arms. Physical examination documented is limited to vital signs. Diagnoses included cervical radiculopathy, status post cervical spine surgery, cephalgia, tension headaches, myofascial syndrome, and neuropathic pain. Treatment included medications and surgery. Requests for authorization for Percura #120, Gabadone #60, Gabapentin 600 #60, Norco 10/325 mg #120, and Fluriflex ointment were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percura #120 (unspecified strength): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain, Percura, Medical Food

Decision rationale: Percura is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid, choline bitartrate, L-arginine, L-serine, and other ingredients. It is intended for dietary management of metabolic processes associated with pain, inflammation and loss of sensation due to peripheral neuropathy. Per Medical Food, Gamma-aminobutyric acid (GABA) : There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline: There is no known medical need for choline supplementation; L-Arginine: This medication is not indicated in current references for pain or inflammation; L-Serine: There is no indication for the use of this product. Until there are high quality studies of the ingredients in Percura, it is not recommended. The request should not be authorized.

Gabadone #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain, Gabadone, Medical Food

Decision rationale: Gabadone is a medical food from [REDACTED], that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. Per Medical food, it is noted that there is no peer-reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. GABA does not cross the blood-brain barrier so this supplement will not replace drugs that work in the brain by a GABA-related mechanism. There is no quality evidence to support use in anxiety. The medication is not recommended.

Gabapentin 600mg #60: 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 Guidelines Page(s): 18-19.

Decision rationale: Gabapentin is an anti-epileptic medication. 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 and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. 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, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case the patient has been using gabapentin since at least September 2014 and has not obtained analgesia. Switch to another medication is recommended if there is inadequate control of pain. The request should not be authorized

Norco 10/325mg #120: 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 Guidelines Page(s): 11, 74-96.

Decision rationale: Norco is the compounded medication containing hydrocodone and acetaminophen. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDs have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case the patient has been using opioid medication since at least September 2014 and has not obtained analgesia. In addition there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. The request should not be authorized.

FluriFlex ointment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs and muscle relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

Decision rationale: Fluriflex is a compounded topical analgesic containing flurbiprofen and cyclobenzaprine. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of cyclobenzaprine as a topical product. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.