

Case Number:	CM15-0114612		
Date Assigned:	06/22/2015	Date of Injury:	09/10/2004
Decision Date:	09/22/2015	UR Denial Date:	05/29/2015
Priority:	Standard	Application Received:	06/15/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 62-year-old female, who sustained an industrial injury on September 10, 2004. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. Currently, the injured worker complains of pain in her low back, right ankle and right foot. She describes her pain as sharp, tingling, electric shock, stabbing, annoying, tiring, pins/needles, shooting, cold/hot, cramping, punishing and exhausting. She rates her pain an 8 on a 10-point scale and indicates the pain is intermittent and unpredictable. Her medications provide pain control. The diagnoses associated with the request include chronic pain syndrome, causalgia of the lower limb, thoracic/lumbar neuritis/radiculitis, lumbago and pain in foot/ankle. The treatment plan includes Gabapentin, Hydrocodone acetaminophen, right knee ASO braces, ZohydroER, Voltaren and follow-up evaluation.

IMR ISSUES, DECISIONS AND RATIONALES

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

One right knee ASO brace: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 340. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee & Leg (Acute & Chronic): Knee brace (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg (Acute & Chronic) Chapter under Knee Brace.

Decision rationale: This patient presents with pain in her low back, right ankle and right foot. The current request is for one right knee ASO brace. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. The patient's work status is not addressed. ODG guidelines, Knee & Leg (Acute & Chronic) Chapter under Knee Brace, provides following criteria for the use of knee brace "re-fabricated knee braces may be appropriate in patients with one of the following conditions: 1. Knee instability; 2. Ligament insufficiency/deficiency; 3. Reconstructed ligament; 4. Articular defect repair; 5. Avascular necrosis; 6. Meniscal cartilage repair; 7. Painful failed total knee arthroplasty; 8. Painful high tibial osteotomy; 9. Painful unicompartmental osteoarthritis; 10. Tibial plateau fracture." According to progress, report 04/23/15, the patient presents with chronic low back and right foot/ankle pain. She reported worsening of pain in her right ankle/foot. Physical examination revealed she uses a walker for ambulation, and no evidence of trauma or deformity. Under treatment plan, the treater states, "the patient is indicated for a right knee ASO brace." In this case, there is no subjective complaints of knee pain and no physical examination findings that would warrant the need of a knee brace. The medical necessity of the knee brace has not been established. This request is not medically necessary.

Gabapentin 300mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18.

Decision rationale: This patient presents with pain in her low back, right ankle and right foot. The current request is for Gabapentin 300mg #60. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. The patient's work status is not addressed. MTUS chronic pain guidelines have the following regarding Gabapentin on pages 18 and 19: "Gabapentin-Neurontin, Gabarone, generic available- 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." According to progress, report 04/23/15, the patient presents with chronic low back and right foot/ankle pain. She reported worsening of pain in her right ankle/foot. Physical examination revealed she uses a walker for ambulation, and no evidence of trauma or deformity. The treater started the patient on Gabapentin on 03/24/15 to help control the pain. In this case, the patient presents with chronic back and ankle/foot pain with no indication of neuropathic pain. Gabapentin is recommended, per MTUS, as a first-line treatment for neuropathic pain. Given the patient does not meet the indication for this medication, this request is not medically necessary.

Hydrocodone/Acetaminophen 10/325mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone (Vicodin, Lortab); Opioids, criteria for use; Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Criteria for use of Opioids Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: This patient presents with pain in her low back, right ankle and right foot. The current request is for Hydrocodone/Acetaminophen 10/325mg #120. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. The patient's work status is not addressed. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS page 77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." According to progress, report 04/23/15, the patient presents with chronic low back and right foot/ankle pain. She reported worsening of pain in her right ankle/foot. She reports "Norco is helping her. She is able to be out of bed and able to walk." The patient states that her pain level is an 8 out of 10 and report that "pain is moderately controlled with the current pain regimen." The patient had a UDS on this date, which was inconsistent. The patient states that it is a mistake. The patient has been utilizing this medication since at least 01/28/15. In this case, recommendation for further use cannot be supported as there are no before and after pain scales to denote a decrease in pain and no discussion regarding possible adverse side effects. All the 4A's have not been addressed, as required by MTUS for opiate management. This request is not medically necessary and recommendation is for slow weaning per MTUS.

Zohydro ER 10mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain (Chronic): Zohydro (hydrocodone) (2015).

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

Decision rationale: This patient presents with pain in her low back, right ankle and right foot. The current request is for Zohydro ER 10mg #60. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. The patient's work status is not addressed. ODG Pain chapter, under Zohydro has the following: "Not recommended. See Hydrocodone. Zohydro ER () is the first single-entity extended-release (ER) formulation of hydrocodone approved by the FDA; unlike Vicodin, Lortab and Norco, it is not buffered with acetaminophen or some other OTC medication. Each pill will be very potent, but Zohydro initially did not have abuse-deterrent technology. According to the

FDA, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective. FDA's Drug Advisory Committee of independent experts voted 11 to 2 to recommend against approval of Zohydro for the treatment of moderate to severe chronic pain. Zohydro is not recommended as a first line drug in ODG." According to progress report 04/23/15, the patient presents with chronic low back and right foot/ankle pain. She reported worsening of pain in her right ankle/foot. She reports "Norco is helping her. She is able to be out of bed and able to walk." The patient states that her pain level is an 8 out of 10 and report that "pain is moderately controlled with the current pain regimen." The patient had a UDS on this date, which was inconsistent. The patient states that it is a mistake. This appears to be an initial request for Zohydro, as prior reports do not discuss this medication. In this case, ODG supports the use of Zohydro in patients for whom alternative treatments have been ineffective and the treater has not provided such discussion. The treater is concurrently requesting Norco stating that this medication is effective. The medical necessity has not been established for initiating this medication. This request is not medically necessary.

Voltaren 1% gel #5 tubes: Upheld

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

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

Decision rationale: This patient presents with pain in her low back, right ankle and right foot. The current request is for Voltaren 1% gel #5 tubes. Treatment to date has included physical therapy, TENS unit, spinal cord implant, assistive devices and medications. The patient's work status is not addressed. MTUS Chronic Pain Medical Treatment Guidelines page 111 states the following regarding topical analgesics: "largely experimental and used with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents." Regarding topical NSAIDs, page 111-113 states, "indications: Osteoarthritis and tendonitis, in particular that of the knee, and elbow or other joints that are amenable to topical treatment: Recommended for short term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Neuropathic pain, not recommended as there is no evidence to support use." According to progress, report 04/23/15, the patient presents with chronic low back and right foot/ankle pain. She reported worsening of pain in her right ankle/foot. Physical examination revealed she uses a walker for ambulation, and no evidence of trauma or deformity. The patient was started on Voltaren gel on 04/22/15. The treater does not specify where the topical gel is to be applied. MTUS states that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. The request cannot be substantiated without documenting which injured body part the NSAID topical gel is to be applied. This request is not medically necessary.