

Case Number:	CM14-0005203		
Date Assigned:	01/24/2014	Date of Injury:	08/29/2012
Decision Date:	06/02/2014	UR Denial Date:	12/24/2013
Priority:	Standard	Application Received:	01/14/2014

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 Family Medicine, has a subspecialty in Pain Management and is licensed to practice in California. 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:

A 58 yr. old male claimant sustained a work injury on 8/29/12 resulting in a right tibial fracture. He had undergone physical therapy and used analgesics during the rehabilitation process. A progress note on 11/13/12 noted that the claimant continued to have weakness in the knees. Examination was notable for tenderness on the medial aspect of the left knee. Physical therapy was ordered along with continuation of anti-inflammatory medications and muscle relaxants. A letter from the treating physician on 11/28/12 indicated a request for Voltaren (Diclofenac XR), Dendracin ointment and Ultracet (Acetaminophen/Tramadol).

IMR ISSUES, DECISIONS AND RATIONALES

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

DENDRACIN 120ML #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105,112-113.

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

Decision rationale: According to the MTUS guidelines for topical analgesics: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of

antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, $\hat{I}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, $\hat{I}\beta$ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, Dendracin contained Capsaicin .0375%. According to the guidelines: Capsaicin, topical Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. In this case, the capsaicin quantity in Dendracin exceeds the amount recommended by the guidelines. Any compounded that is not recommended is not recommended for the entire topical formulation. Dendracin is not medically necessary.

HYDROCODONE/ACETAMINOPHEN 5/500 #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 82-92.

Decision rationale: Hydrocodone is a short acting opioid used for breakthrough pain. According to the MTUS guidelines it is not indicated at 1st line therapy for neuropathic pain, and chronic back pain. It is not indicated for mechanical or compressive etiologies. It is recommended for a trial basis for short-term use. Long Term-use has not been supported by any trials. In this case, the claimant has been on Hydrocodone with no documentation of pain scale or specific medication response. As a result, it is not medically necessary.

ACETAMINOPHEN/TRAMADOL HCl 325/37.5MG #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 (ODG), Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94.

Decision rationale: Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain

relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain. Tramadol is a synthetic opioid affecting the central nervous system. The immediate release formulation is recommended at a dose of 50 to 100mg PO every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER®: Patient currently not on immediate release Tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release Tramadol, calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (Max dose 300mg/day). Treatment of chronic lumbar root pain: A limitation of current studies is that there are virtually no repeated dose analgesic trials for neuropathy secondary to lumbar radiculopathy. A recent study that addressed this problem found that chronic lumbar radicular pain did not respond to either a tricyclic antidepressant or opioid in doses that have been effective for painful diabetic neuropathy or postherpetic neuralgia. Morphine was the least effective treatment (reducing leg and back pain by 1-7% compared to placebo). Sample size and dropout rate was a limitation. (Khoromi, 2007). Not recommended as a first-line therapy for osteoarthritis. Short-term use: Recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/Acetaminophen, Hydrocodone and Codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (Oxycodone, Oxycodone, Hydromorphone, Fentanyl, Morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). (Stitik, 2006) (Avouac, 2007) (Zhang, 2008) In this case, there is no documentation of failure of 1st line treatment such as NSAIDs or Tylenol alone. In addition, the documentation does not support the reason for combining this with Hydrocodone (another opioid). Based on the guidelines, Acetaminophen/Tramadol HCl 325/37.5MG #60 (Ultram) is not medically necessary.