

Case Number:	CM15-0206054		
Date Assigned:	10/22/2015	Date of Injury:	01/11/2005
Decision Date:	12/07/2015	UR Denial Date:	10/12/2015
Priority:	Standard	Application Received:	10/20/2015

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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 45 year old female who sustained an industrial injury when she fell on 1-11-05. A review of the medical records indicates she is undergoing treatment for joint pain in the lower leg, pain in the pelvis and thigh, lumbosacral spondylosis, osteoarthritis, and osteoarthritis of the knee. Medical records (9-2-15) indicate complaints of pain in her knees, as well as right hip and low back pain. She rates her pain "8-10 out of 10" without pain medication and "4-5 out of 10" with pain medication. The physical exam reveals diminished range of motion in all planes of the thoracic and lumbar spine. Tenderness to palpation is noted over the right greater trochanter. Range of motion is "greatly decreased" of bilateral knees. Diagnostic studies have included MRIs of the lumbar spine as well as the "knee". Treatment has included physical therapy, occupational therapy, aqua therapy, Synvisc injections, and medications. Her medications include Tramadol, Nucynta, and Norco. The treatment plan indicates an increase in Norco, discontinuation of Tramadol, and a trial of Voltaren gel 1%, 5 tubes. She has been receiving Norco 10-325mg since, at least, 4-21-15. The utilization review (10-12-15) includes requests for authorization of Voltaren gel 1%, Tizanidine 4mg #60, and Zohydro 20mg #60. Voltaren gel was denied. Tizanidine was modified to a quantity of 20 and Zohydro was modified to a quantity of 30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren gel 1% gel: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Voltaren gel.

Decision rationale: Voltaren gel is a topical analgesic containing diclofenac, a nonsteroidal anti-inflammatory (NSAID) drug. The MTUS recommends topical analgesics primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics have been shown to have some benefit in the first 2 weeks of treatment for osteoarthritis but with diminishing effect after that. The efficacy in clinical trials for this treatment modality 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Topical analgesics containing nonsteroidal anti-inflammatory agents are recommended only as a short-term option for chronic musculoskeletal pain associated with arthritis and tendinitis but there is little evidence for use in osteoarthritis or musculoskeletal pain involving the spine, hip or shoulder. It is also not recommended for neuropathic pain. Efficacy in clinical trials have been inconsistent with most studies being small and of short duration. There are no long-term studies of their effectiveness or safety. The FDA has approved Voltaren Gel 1% (diclofenac) with indications for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert). Additional adverse effects for NSAIDs include GI symptoms, cardiovascular risk, hypertension and impaired renal function. The ODG guidelines note that Voltaren Gel is not recommended as a first-line treatment. Voltaren Gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to FDA MedWatch, postmarketing surveillance of Voltaren Gel has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. In this case the use of Voltaren gel was initiated on 9-2-15. It is recommended for short-term use and chronic musculoskeletal pain associated with arthritis and tendinitis. In this case there is a history of chronic knee pain with osteoarthritis, which is an indication for Voltaren gel. Future treatment notes must address efficacy for the trial of this medication. The request for Voltaren gel 1% is medically necessary.

Tizanidine 4mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Tizanidine.

Decision rationale: The MTUS notes that muscle relaxants are recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases they show no benefit beyond nonsteroidal anti-inflammatory drugs in pain and overall improvement. Efficacy does appear to diminish over time. Sedation as the most commonly reported adverse effect of muscle relaxant medications. The ODG guidelines state that Tizanidine (Zanaflex, generic available) is a centrally acting alpha₂-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with subacute and chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007) Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs should be monitored baseline, 1, 3, and 6 months). (See, 2008) Dosing: 4 mg initial dose; titrate gradually by 2 - 4 mg every 6 - 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. This medication is related to clonidine and should not be discontinued abruptly. Weaning should occur gradually, particularly in patients that have had prolonged use. (Zanaflex-FDA, 2008) In this case the medical records document that Tizanidine has been used since 9-2-15. The records do not document muscle spasm or spasticity and there is no diagnosis of myofascial pain. The utilization review on 10-12-15 modified the request to allow 20 tablets. There is no documentation of efficacy or functional improvement related to the initial use of Tizanidine. As such the request for Tizanidine 4 mg #60, is not consistent with recommendations in the MTUS and ODG guidelines and is not medically necessary.

Zohydro 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, criteria for use, Opioids for chronic pain, Opioids for osteoarthritis, Opioids, dealing with misuse & addiction, Opioids, dosing, Opioids, long-term assessment, Opioids, pain treatment agreement, Opioids, specific drug list. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Zohydro (Hydrocodone).

Decision rationale: The ODG guidelines state that Zohydro (hydrocodone) is not recommended. 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 recommended against approval of Zohydro for the treatment of moderate to severe chronic pain. Zohydro is not recommended as a first line drug in ODG. In 2015 FDA approved a new formulation of Zohydro with abuse-deterrent properties. Transition from the current to the new formulation is expected to occur in the second quarter of 2015. (FDA, 2015) It is still not recommended in ODG for first-line use for treatment of acute or chronic non-malignant pain because short-acting opioids are recommended prior to use of long-acting opioids. In this case there is documentation for long-term use of short acting opioids and treatment failures for MS Contin and Nucynta. The use of Zohydro would appear to be consistent with the ODG guidelines as a second line agent. The utilization review on 10-12-15 did approve quantity of 30 for initial trial or weaning. Additional use will require documentation of efficacy with decreased pain and functional improvement. There should be a pain contract, a pain assessment, documentation of side effects, medication compliance. and aberrant pain behaviors. Without the additional documentation the request for Zohydro 20mg #60 is not medically necessary.