

Case Number:	CM14-0029339		
Date Assigned:	06/20/2014	Date of Injury:	02/04/2008
Decision Date:	08/19/2014	UR Denial Date:	02/12/2014
Priority:	Standard	Application Received:	03/07/2014

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 and Rehabilitation, has a subspecialty in Pain Medicine 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:

The injured worker is a 53-year-old female who reported an unknown injury on 02/04/2008. On 05/22/2014, her diagnoses included cervical spine discopathy, bilateral shoulder impingement syndrome, bilateral carpal tunnel syndrome, lumbar spine disc protrusion at L4-5 and L5-S1 and right knee degenerative arthrosis. On 01/24/2014, her complaints were neck pain that radiated bilaterally in the upper extremities and low back pain that radiated bilaterally in her lower extremities. She rated her pain at 6/10 with medications and 9/10 without medications. Her pain was increased with activity and walking. On 11/12/2013, she had an epidural steroid injection at bilateral L4-5 and L5-S1, with no results noted. On 05/17/2013, she had a normal electromyogram of both upper extremities and the cervical paraspinal muscles bilaterally. Her surgical history included left knee arthroplasty on 02/2012, arthroscopy and manipulation under anesthesia of the left knee on 12/2012, and gastric bypass surgery in 2010. As of 02/07/2014, she had participated in 6 sessions of physical therapy of her left lower extremity, with improved strength, range of motion, balance, stability, and gait. On 03/18/2014, her complaints included persistent trapezius muscle tenderness with painful range of motion of the cervical spine, guarding and tenderness with limited range of motion to the lumbar spine, with diminished sensation at L5-S1 distribution in the lower extremities, limited extension of the left knee and joint line tenderness of the right knee with crepitus as well as pain with range of motion. On 01/24/2014, her medications included Restone 3/100 mg, Senna/docusate 50/8.6 mg, Zolpidem 10 mg, Cartivisc 500/200/120 mg, Tizanidine 4 mg, and EnovaRx ibuprofen 10% kit. There was no rationale submitted for the requests for this worker. A Request for Authorization dated 02/05/2014 was included with the documents.

IMR ISSUES, DECISIONS AND RATIONALES

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

Enovarx-Ibuprofen 10% kit, apply as directed quantity one: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

Decision rationale: The MTUS Chronic Pain Guidelines refer to topical analgesics as largely experimental with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials for nonsteroidal anti-inflammatory agents (NSAIDs) has been inconsistent, and most studies are small and of short duration. Topical NSAIDs have been shown 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 of 4 to 12 weeks. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. The only FDA approved NSAID for topical application is Voltaren gel 1% (Diclofenac). Additionally, the request did not specify a body part to which this compound was to have been applied. Furthermore, there was no documentation of failed trials of antidepressants or anticonvulsants. Therefore, the request is not medically necessary and appropriate.

Restone 3-100 mg QHS #30: 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) TWC procedure summary.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), pain, Compound drugs and Herbal medicines.

Decision rationale: The Official Disability Guidelines do not recommend compound drugs as first line therapy for most patients, but they may be recommended as an option after a trial of first line FDA approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in the ODG. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. The criteria for compound drugs include at least 1 drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. They must include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. Among the herbal medicines that are recommended are Devil's claw and willow bark as short term treatments for the relief of acute

low back pain. The requested Restone contains 23 non-FDA approved herbal substances. It is sold over-the-counter as a restorative tonic for pubertal to postmenopausal women. There is no indication in the submitted documentation of any diagnosis or condition that this worker has that would justify the use of this compounded medication. Therefore, the request is not medically necessary and appropriate.

Senokot 50/8.6, one every 12 hours #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, INITIATING THERAPY Page(s): 77.

Decision rationale: The MTUS Chronic Pain Guidelines recommend that when initiating opioid therapy, prophylactic treatment of constipation should also be initiated. There is no documentation submitted that this injured worker suffers from constipation. Although she is not currently taking any opioids, the MTUS Chronic Pain Guidelines recommend treatment for constipation should be initiated when opioid therapy is begun. Therefore, the request is not medically necessary and appropriate.

Zolpidem 10 mg QHS #30: 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) TWC Pain Procedure Summary.

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

Decision rationale: Per the Official Disability Guidelines, Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually 2 to 6 weeks) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. This injured worker does not have a diagnosis of insomnia and has been using Zolpidem for more than 6 months, which exceeds the guideline recommendations. Additionally, the requested dose is higher than that recommended in the Official Disability Guidelines. Therefore, the request is not medically necessary and appropriate.

Tizanidine 4 mg BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MUSCLE RELAXANTS Page(s): 63-66.

Decision rationale: The MTUS Chronic Pain Guidelines recommends that non-sedating muscle relaxants be used with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain cases, they show no benefit beyond NSAIDs and no additional benefit when used in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity. This injured worker did not have spasticity in her spinal examinations, nor was there documentation of spasticity in her upper extremities. The recommendations for her low back pain included judicious use of NSAIDs and home exercise program. Additionally, there was no frequency of administration included in the request. Therefore, the request is not medically necessary and appropriate.