

Case Number:	CM14-0065452		
Date Assigned:	07/11/2014	Date of Injury:	04/19/2012
Decision Date:	10/09/2014	UR Denial Date:	04/29/2014
Priority:	Standard	Application Received:	05/08/2014

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 Occupational Medicine and is licensed to practice in Texas. 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 currently a 61 year old man involved in a work related injury from 4/19/12. The injured worker was carrying a heavy pipe when he slipped and fell, fracturing the right ankle and sustaining a low back injury. The injured worker was surgically treated for the ankle fracture. He had ongoing low back pain that was treated with epidural steroid injections which did not help. He had been recommended for surgical intervention which had not initially been approved.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xoten-C lotion 0.002%/10%/20%- 120 ml: 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 Topical Analgesics Page(s): 111-113.

Decision rationale: Xoten-C lotion contains Methyl Salicylate, Menthol and Capsaicin. Clinical guidelines fail to support the use of topical analgesics, particularly with substances of questionable utility such as Methyl Salicylate and Menthol, along with extremely low concentrations of Capsaicin. The Chronic Pain Medical Treatment Guidelines states that topical

analgesics are "Largely experimental in use with few randomized control trials to determine efficacy or safety. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments.... 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. The utility of topical menthol is not established either. The Chronic Pain Medical Treatment Guidelines does recommend Methyl Salicylate, stating, "Topical salicylate (e.g., BenGay, methyl salicylate) is significantly better than placebo in chronic pain." The Official Disability Guidelines continues regarding Methyl Salicylate to state, "this review found evidence that was limited by the quality, validity, and size of the available studies." Therefore, the available clinical data does not support this topical compound and it is not medically necessary.

Proteolin # 60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The requested substance is a medical food. From the Official Disability Guideline pain section, we note, "Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." The injured worker is not noted to have any nutritional deficiencies and thus this request is not medically necessary or appropriate.

Hydrocodone/APA 10/325mg # 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 Opioids, criteria for use, Opioids, long-term assessment, Opioids, specific drug list Page(s): 7.

Decision rationale: The injured worker was using this drug for a long period of time. The notes indicated addition of multiple other drugs to the injured worker's treatment regimen, including non-steroidal anti-inflammatory medications along with muscle relaxants. There was no

quantification of benefit derived with this medication. Notes indicated actually worsening of status, with the pain noting burning pain in the back and progressive difficulty with prolonged standing and walking. There are no pain score reductions, or adequate, quantified descriptions of functional gains with the pain medications, and no data describing good pain relief. Therefore the requested Hydrocodone/APA 10/325mg # 60 is not medically necessary.

Tramadol ER 150mg, # 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 Opioids, criteria for use Page(s): 76-80.

Decision rationale: The injured worker was prescribed this drug for a limited period of time. Notes indicated addition of multiple other drugs to the injured workers treatment regimen, including non-steroidal anti-inflammatory medications along with muscle relaxants. There was no quantification of benefit derived with this medication. Notes indicated actually worsening of status, with the pain noting burning pain in the back, and progressive difficulty with prolonged standing and walking. There are no pain score reductions, or adequate, quantified descriptions of functional gains with the pain medications, and no data describing good pain relief. We note from Chronic Pain Medical Treatment Guidelines: The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs (Passik, 2000). The request for Tramadol extended release is not medically necessary.