

Case Number:	CM13-0036959		
Date Assigned:	02/19/2014	Date of Injury:	03/08/2001
Decision Date:	03/17/2015	UR Denial Date:	10/11/2013
Priority:	Standard	Application Received:	10/21/2013

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: Georgia, California, Texas

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:

This is a 65 year old male who sustained an industrial related injury on 3/8/01. The injured worker had complaints of back pain. Diagnoses included lumbar disc desiccation and bulging, left knee pain status post arthroscopy, right shoulder closed manipulation, and right knee medial meniscal tear. Prescriptions included Proteolin, Cyclobenzaprine, Tramadol ER, and Hydrocodone/APAP. The treating physician requested authorization for Xoten-C lotion 0.002%/10%/20% 120ml, Hydrocodone/APAP 10/325mg #60, Proteolin #60, and Tramadol ER 150mg #60. On 10/12/13 the requests were non-certified. Regarding Xoten-C lotion, the utilization review (UR) physician cited the Chronic Pain Medical Treatment guidelines and noted salicylate is not recommended for neuropathic pain. Capsaicin is not currently indicated in any formulation higher than 0.025%. Therefore the request was non-certified. Regarding Hydrocodone/APAP, the UR physician cited the Chronic Pain Medical Treatment guidelines and noted based on lack of improvement in pain and function with previous opioid use and lack of guideline support for opioids as a first line treatment of an exacerbation the request was non-certified. Regarding Proteolin, the UR physician cited the Chronic Pain Medical Treatment guidelines and noted there was no evidence that the injured worker could not use standard NSAIDs. Regarding Tramadol, the UR physician cited the Chronic Pain Medical Treatment guidelines and noted there was no evidence to support the injured worker had failed trials of first-line treatments. Therefore the request was non-certified.

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%/, 120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals; Topical analgesics Page(s): 105 and 111-113.

Decision rationale: The requested Xoten-C appears to be Exoten-C, an over-the-counter topical analgesic lotion manufactured by Enovachem Manufacturing. The active ingredients of Exoten-C include methyl salicylate 20%, menthol 10%, and capsaicin 0.002%. MTUS recommends use of topical capsaicin for patients for whom other treatments have failed. Failure of other treatments is not documented, and therefore medical necessity is not established for use of topical capsaicin. In addition, the concentration of capsaicin in Exoten-C lotion is much lower than the 0.025% formulation recommended by MTUS. Efficacy for the 0.002% formulation of capsaicin has not been established. MTUS supports use of topical salicylates for chronic pain. However, similar concentrations of menthol and methyl salicylate are available in other OTC preparations such as Bengay. Because of inclusion of an ingredient not recommended by MTUS in this case, medical necessity is not established for the requested Xoten-C.

Hydrocodone/APAP 10/325mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-75.

Decision rationale: Per provider, claimant has been prescribed opioids for an exacerbation of pain following a lapse of treatment of several months. It does not appear that claimant had been receiving ongoing opioids at the time of most recent office note, and therefore no information concerning symptomatic or functional response to opioid treatment would be expected. MTUS supports use of an extended release opioid along with an immediate-release opioid for treatment of episodes of breakthrough pain. Short-term use of hydrocodone is reasonable and medically necessary in this case.

Proteolin #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 Curcumin (tumeric) [DWC] Page(s): 41. Decision based on Non-MTUS Citation ODG Pain Chapter, Medical food

Decision rationale: The website for Optimed Rx (<http://www.optimedrx.com/products.asp>) describes Proteolin as a medical food which helps to manage inflammatory response, reduce pain, and promote healing. Proteolin's ingredients are listed as immunomodulatory peptides (hyperimmune milk protein concentrate), curcuminoids (Turmeric), proteolytic enzymes (Bromelain), and Piperin. The ingredients of Proteolin are derived from cow's milk protein concentrate, pineapple, black pepper, and turmeric. Manufacturer claim's that Proteolin is comparable to NSAID drugs if efficacy, but these claims have not been evaluated by the FDA and manufacturer did not cite any clinical studies evaluating the efficacy of this proprietary preparation in comparison to NSAIDs. MTUS does not recommend curcumin (turmeric) for treatment of chronic pain. ODG does not recommend medical foods for treatment of chronic pain. No nutritional deficiency has been documented in this case which would support the medical necessity for any specific medical food. In addition, no studies of this product are identified which would support the manufacturer's claim that Proteolin has comparable efficacy to NSAID drugs. Based upon lack of support by evidence-based guidelines for use of the active ingredients of Proteolin for treatment of chronic pain and lack of evidence of effectiveness of Proteolin in clinical trials, medical necessity is not established for Proteolin.

Tramadol ER 150mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-75.

Decision rationale: Per provider, claimant has been prescribed opioids for an exacerbation of pain following a lapse of treatment of several months. It does not appear that claimant had been receiving ongoing opioids at the time of most recent office note, and therefore no information concerning symptomatic or functional response to opioid treatment would be expected. MTUS supports use of an extended release opioid along with an immediate-release opioid for treatment of episodes of breakthrough pain. Short-term use of tramadol ER is reasonable and medically necessary in this case.