

Case Number:	CM15-0047218		
Date Assigned:	03/19/2015	Date of Injury:	01/12/2009
Decision Date:	04/24/2015	UR Denial Date:	02/17/2015
Priority:	Standard	Application Received:	03/12/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 36 year old male who sustained an industrial injury on 1/12/09 resulting in neck and left arm pain. He had a left ulnar nerve release and left shoulder surgery without improvement of symptoms. He then underwent a C6-7 anterior cervical discectomy and fusion (8/12) and continued with persistent pain. Imaging report revealed hardware failure (913) and then underwent revision C6-7 anterior cervical discectomy and fusion. Currently he complains of dull, achy neck pain with radiation into the left shoulder, arm, hand and thumb with paresthesia. In addition he has pain and swelling on the left anterior aspect of the neck causing him to choke while eating. He also complains of headaches. The pain is worsening. Medications include Oxycontin-Acetaminophen, Prilosec, Percocet, Anaprox, Cyclobenzaprine, Protonix, Sumatriptan and Zofran. Diagnoses include degeneration of the cervical intervertebral disc; cervical disc displacement; cervical radiculitis; diabetes; status post C5-6 artificial disc replacement and C6-7 anterior cervical discectomy and fusion (2012) and revision (2013); pseudoarthritis of C6-7; C6 radiculopathy; anterior neck swelling; severe contusion of the dorsal left hand; left biceps tendinitis. Treatments to date include left shoulder steroid injection which elevated his blood sugars, ice, non-steroidal anti-inflammatory medications, rest, and heat. Diagnostics include x-rays of cervical spine (9/30/14), right and left shoulders, right and left elbows, right and left wrists; computed tomography of the left wrist and electromyography/nerve conduction study of the upper extremities (1/19/10); ultrasound of bilateral wrists; bilateral elbow ultrasound, bilateral shoulder ultrasound (2/2/10). In the progress note dated 1/13/15 the

treating provider requests refills of current medications but does not mention Restone, Proteolin or Cartivisc. There was no mention of these medications noted in the records reviewed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Restone 3mg/100mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Dietary Supplement and Health Education Act of 1994 (Dshea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Insomnia; Mental Stress, Insomnia, and Medical food and Other Medical Treatment Guidelines <http://bioportal.bioontology.org/ontologies/RXNORM?p=classes&conceptid=http%3A%2F%2Fpurl.bioontology.org%2Fontology%2FRXNORM%2F435493>.

Decision rationale: Restone is composed of melatonin and tryptophan. ODG does recommend melatonin for insomnia. However, tryptophan is considered a medical food. ODG states that a medical food is 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. Medical documents do not establish deficiency in nutritional requirements and do not indicate how the requested medication would specifically address the deficiency. In addition the treating physician has not documented the patients sleep hygiene or improvement in sleep on set, sleep quality, and next day functioning with Restone. As such the request for Restone 3-100mg #30 is not medically necessary.

Proteolin #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disabilities Guidelines (ODG) Treatment in Workers Compensation (TWC).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)) Chronic Pain, Curcumin and Medical foods and Other Medical Treatment Guidelines <http://www.webmd.com/drugs/drug-152698-Proteolin+oral.aspx?drugid=152698&drugname=Proteolin+oral&pagenumber=5>.

Decision rationale: Proteolin contains Tumeric and is considered a medical food. The MTUS and ODG are silent on Proteolin. A search on WebMD came up with some of the compounds included in Proteolin, including turmeric (also known as Curcumin). The MTUS does not recommend Curcumin (turmeric) for the treatment of chronic pain. In addition ODG states that a medical food is 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 eternally 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. As such, the request Proteolin #60 is not medically necessary as its use is not supported in the MTUS and ODG.

Cortivisc 500/200/150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain, Medical Food. Decision based on Non-MTUS Citation <http://www.webmd.com/drugs/2/drug-155108/cartivisc-oral/details>.

Decision rationale: Cartivisc contains Coumadin Anticoagulants/Glucosamine-Chondroitin and is a medical food. ODG states that a medical food is 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 eternally 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 medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, Coumadin is not recommended per guidelines and increases the risk of bleeding. As such, the request for Cartivisc 500/200/150mg #90 is not medically necessary.