

Case Number:	CM15-0121332		
Date Assigned:	07/02/2015	Date of Injury:	12/04/2014
Decision Date:	08/25/2015	UR Denial Date:	05/26/2015
Priority:	Standard	Application Received:	06/23/2015

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: California
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 52 year old male, who sustained an industrial injury on 12/04/2014. On provider visit dated 03/03/2015 the injured worker has reported low back pain with pain radiating to his left leg. On examination of the lumbar spine revealed a decreased of motion and sensory examination revealed diminished sensation to light touch in the L5 to S1 nerve root distribution of the left lower extremity, otherwise intact to light touch for L1 to S2. The diagnoses have included lumbar radiculopathy. Treatment to date has included medication. The provider requested physical therapy 2 times for 4 weeks to improve range of motion and increased strength and flexibility of the lumbar spine, injections of vitamin B12 and medical food: Trepadone and Theramine for pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

Physical therapy 2 times a week for 4 weeks: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical medicine Page(s): 98-99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98, 99.

Decision rationale: The patient was injured on 12/04/14 and presents with low back pain with pain radiating to his left leg. The request is for physical therapy 2 times a week for 4 weeks "to improve range of motion and increase strength and flexibility of the lumbar spine musculoligamentous structure." There is no RFA provided and the patient is currently working modified work duties, with restriction of no bending and no lifting in excess of 10 pounds. Review of the reports provided indicates that the patient has already had physical therapy from 01/22/15 to 02/06/15. The 02/06/15 physical therapy states that the "patient comes to therapy with 4-5/10 low back pain but states that it has gotten better since last therapy treatment." The 03/03/15 report states that the patient "received six sessions of physical therapy; however, his low back pain did not improve." MTUS pages 98 and 99 have the following: "Physical medicine: Recommended as an indicated below. Allow for fading of treatments frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine." MTUS Guidelines pages 98 and 99 state that for myalgia, myositis, 9 to 10 visits are recommended over 8 weeks, and for neuralgia, neuritis, and radiculitis, 8 to 10 visits are recommended. He has a limited lumbar spine range of motion, diminished sensation to light touch in the L5 to S1 nerve root distribution of the left lower extremity. The patient is diagnosed with lumbar radiculopathy. The patient has had prior physical therapy; however, there is no numerical assessment to indicate how the patient "has gotten better since last therapy treatment." There is no indication of any recent surgery the patient may have had, and there is no discussion regarding why the patient is unable to establish a home exercise program to manage his pain. Furthermore, an additional 8 sessions of therapy to the 6 sessions the patient has already had exceeds what is allowed by MTUS guidelines. Therefore, the requested physical therapy IS NOT medically necessary.

Injection Vitamin B-12 Cyanocobalamin, up to 1000mcg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain, B Vitamins & Vitamin B complex.

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

Decision rationale: The patient was injured on 12/04/14 and presents with low back pain with pain radiating to his left leg. The request is for injection vitamin B-12 cyanocobalamin, up to 1000 mcg into the gluteus muscle. There is no RFA provided and the patient is currently working modified work duties, with restriction of no bending and no lifting in excess of 10 pounds. There is no indication of any prior B-12 injections the patient may have had. MTUS or ACOEM does not discuss vitamins ODG does not recommend Vitamin B for chronic pain condition. ODG, Pain Chapter, under Vitamin B states, "Not recommended for treatment of chronic pain. Vitamin B is frequently use for treating peripheral neuropathy, but its efficacy is not clear." ODG under the pain chapter further discusses B vitamins and vitamin B complex and states, "Not recommended for treatment of chronic pain unless this is associated with documented vitamin deficiency." Treater does not discuss the request other than saying that it is for the gluteus muscle. He has a limited lumbar spine range of motion, diminished sensation to

light touch in the L5 to S1 nerve root distribution of the left lower extremity. The patient is diagnosed with lumbar radiculopathy. The treater does not provide any discussion as to why the patient needs B12 injections. There is no indication that this patient has a vitamin deficiency and ODG states that Vitamin B is not recommended for chronic pain. Therefore, the request IS NOT medically necessary.

Medical food Trepadone #120 tablets: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain online version, Medical Food.

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)' Chapter under 'Trepadone'.

Decision rationale: The patient was injured on 12/04/14 and presents with low back pain with pain radiating to his left leg. The request is for medical food Trepadone #120 tablets for pain and inflammation associated with joint disorders. There is no RFA provided and the patient is currently working modified work duties, with restriction of no bending and no lifting in excess of 10 pounds. ODG guidelines, chapter 'Pain (chronic)' and topic 'Trepadone', states that the medical food is "Not recommended. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa." The guidelines also state that "There is insufficient evidence to support use for osteoarthritis or for neuropathic pain." He has a limited lumbar spine range of motion, diminished sensation to light touch in the L5 to S1 nerve root distribution of the left lower extremity. The patient is diagnosed with lumbar radiculopathy. Although the patient would be using Trepadone for pain and inflammation associated with joint disorders, ODG guidelines states that Trepadone is "not recommended." Due to lack of support from guidelines, the requested Trepadone IS NOT medically necessary.

Medicial foods- Theramine #120 tablets: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain online version, Medical Food.

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)' Chapter under 'Medical Foods' and Other Medical Treatment Guidelines www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf.

Decision rationale: The patient was injured on 12/04/14 and presents with low back pain with pain radiating to his left leg. The request is for medical food Theramine #120 tablets for chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. There is no RFA provided and the patient is currently working modified work duties, with restriction of no bending and

no lifting in excess of 10 pounds. MTUS and ACOEM guidelines are silent on medical foods. However, ODG guidelines, chapter 'Pain (Chronic)' and topic 'Medical Foods', state that medical foods such as Theramine are "Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes." Theramine is a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>. While the ODG guidelines do not discuss every ingredient found in Theramine, they state that L-arginine is "not indicated in current references for pain or inflammation." Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." Regarding GABA, the guidelines state that "This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety." Additionally, the guidelines do not recommend medical foods for the treatment of chronic pain. Thus, Theramine IS NOT medically necessary.