

Case Number:	CM15-0135072		
Date Assigned:	08/04/2015	Date of Injury:	02/08/2005
Decision Date:	09/18/2015	UR Denial Date:	07/01/2015
Priority:	Standard	Application Received:	07/13/2015

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: New York

Certification(s)/Specialty: Internal 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 43-year-old male who sustained an industrial injury on 02-08-2005. Current diagnoses include lumbar radiculopathy, chronic pain syndrome, neuropathic pain, prescription narcotic dependence, chronic pain-related insomnia, neck pain, chronic pain related to depressive anxiety, and total body pain. Previous treatments included medications, surgical interventions, NESP-R program (Nutrition, Emotional/Psychological, Social/Financial and, Physical-Revised program), and Matrix treatments. Previous diagnostic studies include urine toxicology screenings. Report dated 06-15-2015 noted that the injured worker presented with complaints that included adverse side effects from the Butrans patch, neck pain with radiation to the mid-back and both arms, and low back pain. Pain level was 6 out of 10 on a visual analog scale (VAS). Physical examination only included vital signs. Treatments performed included Nexalin deep brain stimulation, nanohyperoxygenated hydrotherapy bath, ODIN D1 cell gradient therapy, Matrix neuro-electrical stimulation, pain school, chiropractic care, physical therapy, and vital signs x4. It was noted that the injured worker had burning on urination again so the physician started him on a 10 day course of Bactrim. The injured worker reported better physical functioning and more energy with the functional restorative physical therapy, and the physician felt that this will be the key to getting him to maximum medical improvement. The treatment plan included discontinuing the Butrans patch, Bactrim DS for a urinary tract infection, requests for buprenorphine troches, multi-vitamin (MVT), Prilosec, Nattokinase for vascular related pain, inflammation, and hypertension, Vimovo for inflammation, pain, and headaches, refill Relax and Sleep for insomnia, Schisandra for anxiety, GABA for mood stabilization,

Zofran for nausea and vomiting as needed, Gaia herbs natural laxative for constipation, 5HTP for mood elevation and serotonin effect, discontinue Serrapeptase, start alpha lipoic acid for improved cognition, vitamin B12 intramuscular (IM) for myofascial pain and nerve health, and return to center on Wednesday for follow up and treatment. Disputed treatments include Gaba 500mg 2, Schisandra, Bactrim DS #20, MVT 1 daily duration 2 months, Nattokinase 100mg #60, Vimovo #30, Relax and Sleep for 2 months, Zofran 4mg for 2 months, Gaia herbs, alpha lipoic acid #60, 5HTP 100mg for 2 months, vitamin B12 IM x 1, retro vitamin B12 IM, (DOS 6-15-15), and Restorative physical therapy.

IMR ISSUES, DECISIONS AND RATIONALES

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

GABA 500mg 2: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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 Chapter -- Medical Food.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. 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 specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. There is no peer-reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. GABA does not cross the blood-brain barrier so this supplement will not replace drugs that work in the brain by a GABA-related mechanism. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Based on the currently available medical information for review, there is no documentation about the composition of this medical food. The medical necessity for Gabadone has not been established.

Schisandra: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain Chapter -- Medical Food.

Decision rationale: The California MTUS does not address Schisandra. Schisandra is a medical food. The Official Disability Guidelines do not recommend medical foods 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. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Therefore the request for Schisandra is not medically necessary.

Bactrim DS #20: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Infectious Diseases Chapter--Bactrim.

Decision rationale: The MTUS is silent regarding Bactrim DS. The Official Disability Guidelines recommend Bactrim as first-line treatment for diabetic foot infections, osteomyelitis, chronic bronchitis, and cellulitis. The prescribing physician did not provide a urinalysis to support that the injured worker has a urinary tract infection (UTI). Also, there is a lack of any clinical data to support the relationship of this diagnosis with the industrial injury of this worker. Therefore, the request for Bactrim DS #20 is not medically necessary.

MVT 1 daily duration 2 months: 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 Chapter-B vitamins & vitamin B complex and Other Medical Treatment Guidelines Uptodate.

Decision rationale: As per Uptodate vitamin supplementation is not necessary for most adults who eat a balanced diet and get regular sun exposure or drink vitamin D "fortified dairy products. However, many people take multivitamins, and common formulations, generally containing 0.5- to 1.5-times the daily reference intakes of individual vitamins, are likely safe in nearly all people. Because some vitamins in larger doses can be harmful in some people, high-dose vitamin recommendations should be tailored to individual patients. ODG state B vitamins & vitamin B complex are not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. However, ODG do not discuss use of multivitamin. The treating provider does not provide any rationale for the request. Submitted medical records do not indicate any deficiency in this injured worker. The requested treatment: MVT 1 daily duration 2 months is not medically necessary.

Nattokinase 100mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

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 Chapter -- Medical Food.

Decision rationale: MTUS is silent regarding Vimovo. The Official Disability Guidelines "do not recommend as a first-line therapy. In May 2010, FDA approved Vimovo, a fixed-dose tablet combination of delayed-release enteric-coated naproxen and immediate-release esomeprazole magnesium (Nexium). The NSAID/PPI combo is indicated to relieve signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis while decreasing the risk for NSAID-related gastric ulcers in susceptible patients. As with Nexium, a trial of omeprazole and naproxen or similar combination is recommended before Vimovo therapy." Currently the injured worker is diagnosed with lumbar radiculopathy, chronic pain syndrome, neuropathic pain, prescription narcotic dependence, chronic pain-related insomnia, neck pain, chronic pain related to depressive anxiety, and total body pain. This medication is approved for symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis while decreasing the risk for NSAID-related gastric ulcers in susceptible patients. There is no documentation to support that the injured worker has tried and failed other medications such as omeprazole and naproxen. Therefore the request for Vimovo #30 is not medically necessary.

Vimovo #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.

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

Decision rationale: MTUS is silent regarding Vimovo. The Official Disability Guidelines "do not recommend as a first-line therapy. In May 2010, FDA approved Vimovo, a fixed-dose tablet combination of delayed-release enteric-coated naproxen and immediate-release esomeprazole magnesium (Nexium). The NSAID/PPI combo is indicated to relieve signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis while decreasing the risk for NSAID-related gastric ulcers in susceptible patients. As with Nexium, a trial of omeprazole and naproxen or similar combination is recommended before Vimovo therapy." Currently the injured worker is diagnosed with lumbar radiculopathy, chronic pain syndrome, neuropathic pain, prescription narcotic dependence, chronic pain-related insomnia, neck pain, chronic pain related to depressive anxiety, and total body pain. This medication is approved for symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis while decreasing the risk for NSAID-related gastric ulcers in susceptible patients. There is no documentation to support that the injured worker has tried and failed other medications such as omeprazole and naproxen. Therefore the request for Vimovo #30 is not medically necessary.

Relax and Sleep for 2 months: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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 Chapter -- Melatonin.

Decision rationale: Relax and Sleep contains Valerian root, Chamomile, Melatonin. ODG states Melatonin is recommended for delayed sleep phase syndrome and rapid eye movement sleep behavior disorders. There is also some suggestion that it can have an analgesic effect, but current research is largely in the experimental phases. Melatonin appears to reduce sleep onset latency to a greater extent in people with delayed sleep phase syndrome than in people with insomnia. Delayed sleep phase syndrome is characterized by late sleep onset and wake up time. It results in late wake up time, resulting in excessive daytime sleepiness, insomnia and daytime functional impairment. This may indicate that this substance re-sets the endogenous circadian pacemaker rather than as a direct action of somnogenic structures of the brain. Individuals with delayed sleep phase syndrome are distinguished from individuals with insomnia by the presence of circadian abnormality. Melatonin is also used for treatment of rapid eye movement sleep behavior disorder. This is characterized with motor activity during sleep, acting out of dreams, and polysomnography showing increased muscle tone. There is no evidence that melatonin is effective in treating secondary sleep disorders accompanying sleep restriction, such as jet lag and shift work disorder. The literature reporting treatment of chronic insomnia disorder with melatonin remains inconclusive. Submitted medical records provide no discussion of its ingredients and there is no clear rationale to support the necessity of this treatment. The Requested Treatment: Relax and Sleep for 2 months is not medically necessary.

Zofran 4mg for 2 months: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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-- Ondansetron (Zofran).

Decision rationale: The California MTUS is silent regarding Ondansetron (Zofran). The Official Disability Guidelines recommend "Ondansetron (Zofran) to prevent nausea and vomiting that may be caused by anesthesia/surgery, or chemotherapy or radiation therapy. It is also approved for use acutely with gastroenteritis. Ondansetron is not used and is ineffective for nausea associated with narcotic analgesics. The medical records submitted do not indicate that the injured worker is having surgery, chemotherapy or radiation therapy." Therefore, the request for Zofran 4mg for 2 months is not medically necessary.

Gaia herbs: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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--

Herbal medicines.

Decision rationale: Gaia herbs is a natural laxative. As per ODG Herbal medicines are recommended as an option given low risk in patients with moderate pain, and there is no harm in having patients continue these preparations as long as they perceive benefit and cover the costs of these OTC treatments themselves; however, for all herbals and dietary supplements, there may be concerns for potential interactions with prescription and over-the-counter medications and lack of manufacturing quality controls. Caution is advised since product quality may be uncertain due to the lack of regulations. Submitted medical records do not clearly state the necessity for Gaia herbs. In the light of the guidelines the requested treatment: Gaia herbs is not medically necessary.

Alpha lipoic acid #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

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 Chapter -- Medical Food.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. 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 specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Based on the currently available medical information for review, there is no documentation about the composition of this medical food. There is no compelling evidence provided by the treating provider that will offset the guidelines. The medical necessity for Alpha lipoic acid #60 has not been established.

5HTP 100mg for 2 months: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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 Chapter -- Medical Food.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. 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 specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. There is no peer-

reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Based on the currently available medical information for review, there is no documentation about the composition of this medical food. The medical necessity for 5HTP 100mg for 2 months has not been established.

Vitamin B12 IM x 1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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-B vitamins & vitamin B complex.

Decision rationale: The prescription for Vitamin B12 is evaluated in light of the Official Disability Guidelines (ODG). ODG state B vitamins & vitamin B complex are not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. There are multiple B vitamins with specific symptoms due to deficiency: (1) vitamin B1 (thiamine) - beriberi; (2) vitamin B2 (riboflavin); (3) vitamin B3 (niacin or nicotinic acid) - pellegra; (4) vitamin B5 (pantothenic acid); (5) vitamin B6 (pyridoxine); (6) vitamin B7 (biotin); (7) vitamin B9 (folic acid) - megaloblastic anemia; (8) vitamin B12 (various cobalamins) - pernicious anemia, myelopathy, neuropathy, dementia, subacute combined degeneration of the spine, and decreased cognition. Treatment of vitamin B12 deficiency is generally parenteral. Vitamin B Complex contains the above 8 vitamins plus para-aminobenzoic acid, inositol, and choline. It is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy (diabetic and alcoholic). Evidence was insufficient to determine whether specific B vitamins or B complex for these conditions was beneficial or harmful. The treating provider's notes do not specify Vitamin B12 deficiency in this injured worker. The requested treatment: Vitamin B12 IM x 1 is not medically necessary.

Retro Vitamin B12 IM, DOS: 6/15/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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-B vitamins & vitamin B complex.

Decision rationale: The prescription for Vitamin B12 is evaluated in light of the Official Disability Guidelines (ODG). ODG state B vitamins & vitamin B complex are not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. There are multiple B vitamins with specific symptoms due to deficiency: (1) vitamin B1 (thiamine) - beriberi; (2) vitamin B2 (riboflavin); (3) vitamin B3 (niacin or nicotinic acid) - pellegra; (4) vitamin B5 (pantothenic acid); (5) vitamin B6 (pyridoxine); (6) vitamin B7 (biotin); (7) vitamin B9 (folic acid) - megaloblastic anemia; (8) vitamin B12 (various cobalamins) - pernicious anemia, myelopathy, neuropathy, dementia, subacute combined degeneration of the

spine, and decreased cognition. Treatment of vitamin B12 deficiency is generally parenteral. Vitamin B Complex contains the above 8 vitamins plus para-aminobenzoic acid, inositol, and choline. It is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy (diabetic and alcoholic). Evidence was insufficient to determine whether specific B vitamins or B complex for these conditions was beneficial or harmful. The treating provider's notes do not specify Vitamin B12 deficiency in this injured worker. The requested treatment: Vitamin B12 IM x 1 is not medically necessary.

Restorative physical therapy: Upheld

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

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

Decision rationale: The California Chronic Medical Treatment Guidelines note that active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal, visual and/or tactile instructions. Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home physical medicine. The physician request does not indicate the site (body part) for physical therapy or the amount of physical therapy being requested. Therefore, the request for restorative physical therapy is not medically necessary.