MAXIMUS Federal Services

Case Number:	CM14-0203168		
Date Assigned:	01/28/2015	Date of Injury:	10/10/2007
Decision Date:	03/30/2015	UR Denial Date:	11/24/2014
Priority:	Standard	Application Received:	12/04/2014

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. 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, Arizona, Maryland
Certification(s)/Specialty: Psychiatry

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 35-year-old female who suffered a work related injury on 10/10/07. Per the physician notes from 11/06/14, she is in a residential treatment facility. She has received equine therapy, bio-neural feedback, eye movement desensitization and reprocessing, and cognitive behavioral therapy. On 11/24/14, the Claims administrator non-certified the equine therapy citing non-MTUS guidelines. The Claims Administrator also non-certified the psychiatric sessions, lidocaine topical and Traurmeel topical, citing MTUS guidelines and non-certified Zofran, citing ODG guidelines. The Claims Administrator non-certified vortioxetine, Vitamin D3, Gaba Calm, Chamomile, Brain Vitale, Lactobacillus, Lavela, L-Theanine, Magnesium Citrate, Melatonin, Meriva, Plantizyme, Pro--Omega, Wobenzyme, Sadaplex, Rescue Pastiles, Thiamine, ElectroMix, Calms Forte, Curaphen, and L-Thearine citing MTUS guidelines not approving medical foods. The non-certified treatments were subsequently appealed for Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Equine Therapy (8 sessions): 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 PubMed Database

Decision rationale: According to the study quoted above, The evidence suggests that HBRT and hippotherapy are individually efficacious, and are both medically indicated as therapy for gross motor rehabilitation in children with CP. Recommendations for future research are discussed. The use of equine therapy is not indicated by MTUS or ODG. There is no indication for use of Equine therapy in this case or any evidence based improvement with its use. Thus, the request is not medically necessary at this time.

Psychiatric Sessions (every 2 weeks for 8 weeks then every month): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 19-23.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter, Office visits

Decision rationale: ODG states "Office visits are recommended as determined to be medically necessary. The need for clinical office visit with a health care provider is individualized based upon the review of patient concerns, signs, symptoms, clinical stability and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medications such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from health care system through self care as soon as clinically feasible." The request for Psychiatric sessions every 2 weeks for 8 weeks then every month is excessive and not medically necessary. The injured worker is not on any medications that would require such close monitoring as every 2 weeks for 8 weeks and the every 4 week visits for an unidentified amount of time. The request is excessive and not medically necessary.

Zofran 4mg #30 per month, q day,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Anti-emetics for opioid nausea

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), Antiemetics

Decision rationale: The MTUS is silent on the use of ondansetron. With regard to antiemetics, the ODG states "Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications." Specifically, "Ondansetron (Zofran): This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis." As the injured worker is not postoperative or experiencing nausea and vomiting secondary to chemotherapy and radiation treatment, or gastroenteritis, ondansetron is not recommended. There was no documentation suggesting the ongoing necessity of the medication or its efficacy. The request is not medically necessary.

Vortioxetine 20mg #30 per month, qhs,: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Stress & Mental Illness Chapter, Antidepressants for treatment of MDD (major depressive disorder); FDA.gov-Vortioxetine/BRINTELLIX

Decision rationale: Per FDA.gov- BRINTELLIX is indicated for the treatment of major depressive disorder (MDD). The injured worker has been diagnosed with major depressive disorder (MDD) and is being continued on Brintellex as well. There is no rationale of why 2 antidepressants are being prescribed. There is no documentation regarding past treatments with antidepressants such as SSRI;s or SNRI;s. Based on the above information and lack of any objective improvement with these medications, The request for Vortioxetine 20mg #30 per month, qhs is not medically necessary.

Lidocaine Topical 5% (Watson) film, #30, 1 film prn q 12 hrs,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Lidoderm Patches

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines states "Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The medical records submitted for review do not indicate that there has been a trial of first-line therapy (tri-cyclic or

SNRI antidepressants or an AED). There is also no diagnosis of diabetic neuropathy or post-herpetic neuralgia. As such, lidocaine topical is not recommended at this time. The request for Lidocaine topical 5% (Watson) film, #30, 1 film prn q 12 hrs is not medically necessary.

Vitamin D3 2000 IU #30, 1 capsule q AM,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA.gov-Vitamin D3

Decision rationale: Cholecalciferol (Vitamin D3) Vitamin D is used for treating hypoparathyroidism, vitamin D resistant rickets, and low vitamin D levels. Over-the-counter Vitamin D preparations are commonly used for low Vitamin D levels. The injured worker does have any of the above mentioned issued for which Vitamin D3 is indicated. The request for Vitamin D3 2000 IU #30, 1 capsule q AM is excessive and not medically necessary.

Gaba Calm (Source Naturals) 125mg #60, 1 lozenge SL q 2 hrs prn anxiety max 4 per day,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

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 Foods

Decision rationale: Gamma-aminobutyric acid (GABA): GABA is the derivative of glutamic acid and ornithine. It does not cross the blood-brain barrier so taking this orally does not increase brain levels. Therefore taking the supplement will not replicate drugs that do work by a GABA-related mechanism. In complimentary medicine settings, this supplement has been used for treatment of depression, bipolar disorder, seizures, premenstrual dysphoric disorder, and anxiety, although there is no quality evidence that GABA supplements have any effect on these conditions. It has also been suggested that GABA can improve sleep quality and improve cognitive function, but there is no scientific evidence to support these claims. There is some preliminary evidence that GABA can reduce blood pressure, but further studies are needed to allow for a recommendation for general use. When used in Medical Foods such as Theramine, it is suggested that GABA dampens pain signals in the spinal cord and brain. All studies supporting these potential mechanisms of action were performed on animals, and as noted, the supplement does not cross the blood-brain barrier. According to the guidelines, there is no scientific claim to support the above claims. Thus, the request for Gaba Calm (Source Naturals) 125mg #60, 1 lozenge sl q 2 hrs prn axniety max 4 per day is not medically necessary.

Chamomile (Natures Way) 350mg #30, 1 capsule qhs,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA- Chamomile

Decision rationale: Chamomile: It is an herbal medicine.It does not have a FDA approval. Due to the lack of scientific evidence to indicate the use of Chamomile which is an herbal product, the request for Chamomile (Natures Way) 350mg #30, 1 capsule qhs is not medically necessary.

Brain Vitale (Designs for Health) #60, 2 capsules q AM,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

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 Foods

Decision rationale: Brain Vitale: Per Manufaturer's product description "Brain Vitale is a combination of the two most powerful and beneficial brain nutrients, Phosphatidylserine and Acetyl-L-Carnitine." Per the Chronic Pain section of ODG; Medical foods section are not recommended for conditions covered by ODG. The request for Brain Vitale (Designs for Health) #60, 2 capsules q AM is not medically necessary because of lack of any research-based evidence for the use of the same.

Lactobacillus Rhamnosus (no FOS or inulin in ingredients) #60, 10 billion organisms, 2 capsules qhs,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines (ODG) Chronic Pain Chapter, Medical Foods.

Decision rationale: Lactobacillus: It does not have a FDA approval for the use of this medical food. The request for Lactobacillus Rhamnosus (no FOS or inulin in ingredients) #60, 10 billion organisms, 2 capsules qhs is not medically necessary because of lack of any research-based evidence for the use of the same.

Lavela WS 1265 80mg #60 (Integrative Therapeutics), 1 capsule bid,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com-lavela

Decision rationale: Lavela: Lavela is a product that contains Lavender oil. Per Manufaturer's product description " Lavender WS 1265 from Integrative Therapeutics provides natural relaxation support". This product is not recognized by the FDA and has insufficient evidence for its safety and use. The request for Lavela WS 1265 80mg #60 (Integrative Therapeutics), 1 capsule bid is not medically necessary because of lack of any research based evidence for the use of the same.

L-Theanine 5HTP Melatonin (Bio-Clinical Naturals), Somno-Pro 2 tablets qhs #60,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

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: Medical foods Drugs, com: L-Theanine

Decision rationale: L-Theanine is Gamma-ethylamino-L-glutamic acid: The U.S. Food and Drug Administration(FDA) has not approved L Theanine for its use, however it has generally recognized it as safe.The request for L-Theanine 5HTP Melatonin (Bio-Clinical Naturals), SomnoPro 2 tablets qhs #60 is not medically necessary because of lack of any research-based evidence for the use of the same.

Magnesium Citrate/BioCitrate Magnesium (Solaray) 135mg #30, qhs,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

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 Foods, and on Drugs.com-Magnesium Citrate

Decision rationale: According to drugs.com: Magnesium is a naturally occurring mineral that is important for many systems in the body, especially the muscles and nerves. Magnesium citrate also increases water in the intestines. Magnesium citrate is used, as a laxative to treat occasional constipation.The request for Magnesium Citrate/BioCitrate Magnesium (Solaray) 135mg #30,

qhs is not medically necessary because of lack of any research-based evidence for the use of the same.

Melatonin 10mg #30, qhs: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter, Melatonin

Decision rationale: ODG states that 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 sonmogenic 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 shiftwork disorder. The literature reporting treatment of chronic insomnia disorder with melatonin remains inconclusive." The request for Melatonin 10mg #30, qhs is not medically necessary because of lack of any research-based evidence for the continued use of the same in treatment of sleep related issues.

Meriva Turmeric 500mg #60, bid,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods and Herbal Medicines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com: Meriva Turmuric

Decision rationale: Meriva is a proprietary delivery form of curcumin. Curcumin is the yellow pigment of turmeric. Per Manufacturer's product description" Planti-Zyme contains plant enzymes for individuals desiring a vegetarian-source digestive enzyme formulation." This product is not recognized by the FDA and has insufficient evidence for its safety and use. The request for Meriva Turmuric 500mg #60, bid is not medically necessary because of lack of any research-based evidence for the use of the same.