

Case Number:	CM14-0156922		
Date Assigned:	09/29/2014	Date of Injury:	03/29/2002
Decision Date:	11/25/2014	UR Denial Date:	09/17/2014
Priority:	Standard	Application Received:	09/25/2014

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. The expert reviewer is Board Certified in Preventative Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 58 year old employee with date of injury of 3/9/2002. Medical records indicate the patient is undergoing treatment for cervical radiculopathy s/p cervical fusion; neck pain; cephalgia; right shoulder pain s/p right shoulder surgery; chronic pain syndrome; tension headaches; chronic pain related insomnia; chronic pain related depression and neuropathic pain. Subjective complaints include back and neck pain. Currently, her pain radiates down the left shoulder to her arm and hand. Her pain is well-controlled with her current regimen. There are no current complaints of severe neck pain or headaches at this time. She takes an average of Subutex 2mg twice a day and an average of 10-15mg of Valium a day for anxiety. She is trying to decrease her intake of Valium. Objective findings include three trigger points over the left deltoid and upper arm musculature. She is unable to move her arm due to pain. Treatment has consisted of Capsaicin/Baclofen/Ketoprofen Compounded ointment, Suboxone, Paxil, Toradol, Sentra, Gabadone, Theramine, Trepadone, Subutex, Idrasil, Taurine, Alpha Lipoic Acid, Nattokinase Nexalin and Odin DI Therapy, Xanax, Colace; Trazadone and Ibuprofen. The utilization review determination was rendered on 9/25/2014 recommending non-certification of Idrasil 25mg QTY 1; Taurine QTY 1; Alpha Lipoic Acid QTY 1; Nattokinase QTY 1; Bloodwork to assess organ function; Toradol 60mg IM injection (retro - given 8/27/14) QTY 1; Sentra AM QTY 1; Valium 10mg QTY 1; Gabadone QTY 60; Theramine QTY 120 and Trepadone QTY 120.

IMR ISSUES, DECISIONS AND RATIONALES

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

Idrasil 25mg QTY 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 Pain, Cannabinoids <http://idrasilrx.com/>

Decision rationale: MTUS is silent concerning Idrasil (Cannabis). ODG states " Not recommended for pain. Under study for epilepsy. As of August 2014, 23 states and DC have enacted laws to legalize medical marijuana (Markoff, 2014), but there are no quality studies supporting cannabinoid use, and there are serious risks. Restricted legal access to Schedule I drugs, such as marijuana, tends to hamper research in this area. It is also very hard to do controlled studies with a drug that is psychoactive because it is hard to blind these effects. At this time it is difficult to justify advising patients to smoke street-grade marijuana, presuming that they will experience benefit, when they may also be harmed. (Mackie, 2007) (Moskowitz, 2007) One of the first dose-response studies of cannabis in humans has found that mid-range doses provided some pain relief, but high doses appeared to exacerbate pain. (Wallace, 2007) Cannabis use is associated with modest declines in cognitive performance, particularly learning and recall, especially at higher doses. The finding necessitates caution in the prescribing of medical marijuana for pain, especially in instances in which learning and memory are integral to a patient's work and lifestyle. (Wilsey, 2008) Cannabinoids as analgesic agents can have an undesirable CNS impact, and, in many cases, dose optimization may not be realizable before onset of excessive side effects. (McCarberg, 2007)".

Taurine QTY 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 Chronic Pain, Medical foods <http://dslid.nlm.nih.gov/dslid/Ingredient.jsp?db=adslid%2C&item=Adipic+acid>

Decision rationale: The MTUS and ODG are silent on Taurine. A search on the Mayo Clinic web site noted that Taurine was a dietary ingredient found in energy drinks. 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." The medical records do not indicate a specific nutritional

requirement for which this medication would be used. Thus, the request for Taurine QTY 1 is not medically necessary.

Alpha Lipoic Acid QTY 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 Chronic Pain, Medical foods [http://www.webmd.com/vitamins-supplements/ingredientmono-767-alpha%20lipoic%20acid%20\(alpha-lipoic%20acid\).aspx?activeingredientid=767&activeingredientname=alpha%20lipoic%20acid%20\(alpha-lipoic%20acid\)](http://www.webmd.com/vitamins-supplements/ingredientmono-767-alpha%20lipoic%20acid%20(alpha-lipoic%20acid).aspx?activeingredientid=767&activeingredientname=alpha%20lipoic%20acid%20(alpha-lipoic%20acid))

Decision rationale: The MTUS and ODG are silent on Alpha Lipoic Acid. A search on the WebMD web site noted that Alpha Lipoic Acid was a dietary ingredient found in. 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." The medical records do not indicate a specific nutritional requirement for which this medication would be used. Thus, the request for Alpha Lipoic Acid is not medically necessary.

Nattokinase QTY 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 Chronic Pain, Medical foods <http://www.webmd.com/vitamins-supplements/ingredientmono-1084-nattokinase.aspx?activeingredientid=1084&activeingredientname=nattokinase>

Decision rationale: The MTUS and ODG are silent on Nattokinase. A search on the WebMD web site noted that Nattokinase was a dietary ingredient found in vitamins. 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." The medical records do not indicate a specific nutritional requirement for which this medication would be used. Thus, the request for Nattokinase is not medically necessary.

Bloodwork to assess organ function: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects Page(s): 70.

Decision rationale: MTUS also writes regarding NSAID monitoring, "Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established." Routine blood work to monitor organ function while on multiple medical medications is a reasonable request. However, the treating physician did not specify which test was needed and the medical rationale for such test. As such, the request for Bloodwork to assess organ function is not medically necessary.

Toradol 60mg IM injection (retro - given 8/27/14) QTY 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: Decision based on MTUS Chronic Pain Treatment Guidelines Ibuprofen, NSAIDs Page(s): 67-72. Decision based on Non-MTUS Citation Official Disability Guidelines Pain, NSAIDS, Ketoralac

Decision rationale: MTUS recommends the use of NSAIDS for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. MTUS states "Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: This medication is not indicated for minor or chronic painful conditions". ODG states "Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not

be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of Ketorolac (Sprix) for short-term pain management. (FDA, 2010)." Guidelines note that Toradol is not meant for minor or chronic conditions. The treating physician has not provided documentation to meet the above guidelines at this time. As such the request for Toradol 60mg IM injection (retro - given 8/27/14) QTY 1 is not medically necessary.

Sentra AM QTY 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, Medical Food.

Decision rationale: Sentra AM is a medical food that contains Choline and Acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. 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." ODG specifically states "Choline is a precursor of acetylcholine. There is no known medical need for Choline supplementation except for the case of long-term parenteral nutrition or for individuals with Choline deficiency secondary to liver deficiency." Medical records do not indicate that the patient meets these criteria. 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, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM QTY 1 is not medically necessary.

Valium 10mg QTY 1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: MTUS states that benzodiazepine (i.e. Valium) is "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic,

anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks." The medical record does not provide any extenuating circumstances to recommend exceeding the guideline recommendations. Additionally, no documentation as to if a trial of antidepressants was initiated and the outcome of this trial. As such, the request for Valium 10 mg QTY 1 is not medical necessary.

Gabadone QTY 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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (Chronic), Gabadone and Medical Food

Decision rationale: MTUS is silent concerning Gabadone. 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". ODG comments on Gabadone directly, "Not recommended. Gabadone is a medical food from [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA)." The ODG guidelines do not support the use of Gabadone. As such the request for Gabadone QTY 60 is not medically necessary.

Theramine QTY 120: 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 Theramine and medical food

Decision rationale: 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". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric

acid [GABA] and Choline Bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for Choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." The ODG guidelines do not support the use of Theramine. As such the request for Theramine QTY 120 is not medically necessary.

Trepadone QTY 120: 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 Trepadone and Medical Food

Decision rationale: MTUS is silent concerning Trepadone. 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". ODG comments on Trepadone directly, "Trepadone is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, Choline Bitartrate, L-serine and Gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)."ODG states, "Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia." Medical records do not indicate that this medication would be used to treat epilepsy, spasticity and tardive dyskinesia.ODG states, "L-Serine: There is no indication in Micromedex, Clinical Phamacology, or AltMedDex for the use of this supplement." This component is not indicated.ODG states, "L-Arginine: This supplement is not indicated in current references for pain or "inflammation. It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome." Medical records do not indicate that this medication would be utilized for urine detoxification or for treatment off the other indicated reasons.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, there are several components of this medication that are not recommended per guidelines. As such, the request for Trepidone qty 120 is not medically necessary.