

Case Number:	CM14-0194004		
Date Assigned:	12/01/2014	Date of Injury:	08/23/2005
Decision Date:	01/31/2015	UR Denial Date:	11/04/2014
Priority:	Standard	Application Received:	11/19/2014

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 Family Practice and is licensed to practice in California. 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 is a 63 year old male patient who sustained a work related injury on 8/23/2005. Patient sustained the injury due to slip and fall incident. The current diagnoses include strain/sprain of the cervical and lumbar spines, anxiety and depressed mood. Per the doctor's note dated 10/3/14, patient has complaints of neck and back pain at 7-8/10. Physical examination of the cervical region revealed limited range of motion, positive Head compression sign, Spurling's maneuver, muscle spasm, and decreased strength and sensation. Physical examination of the lumbar region revealed antalgic gait, tenderness on palpation, decreased strength and sensation, limited range of motion, positive SLR and Sciatic nerve compression. The current medication lists include Norco, Prilosec, Celebrex, Tylenol #3 and Apprim. The patient has had Polysomnogram on 5/24/14 that revealed severe Obstructive Sleep Apnea; on 10/3/14 Cervical and Lumbar x-rays that revealed a C5-C6 listhesis and L5 S1 disc has a bit more collapse and degeneration; on 6/3/11 MRI Cervical Spine that revealed C6-7 intervertebral disc space minimal anterolisthesis, degenerative in nature with mild central and mild bilateral neuroforaminal stenosis; on 6/3/11 Lumbar Spine MRI that revealed Mild central and moderate bilateral neuroforaminal stenosis at L5-S1, herniated nucleus pulposus, and mild central and mild bilateral neuroforaminal stenosis at L3-4 and L4-5; 4/26/06 EMG/NCS that revealed Peripheral sensory motor polyneuropathy. The patient's surgical history include on 8/30/06 right shoulder arthroscopy with subacromial decompression; appendectomy in approximately 2006. The patient has received an unspecified number of the PT visits for this injury.

IMR ISSUES, DECISIONS AND RATIONALES

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

AppTrim D (Unknown Quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, 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), Treatment Index, 8th Edition (web), Chapter- Pain (updated 12/31/14)

Decision rationale: Apptrim is a medical food which contains Tyrosine, Choline Bitartrate, 5-Hydroxytryptophan, Hydrolyzed Whey protein, Histidine, Serine, Glutamic A, Grape seed Extract, Cocoa and Caffeine. Apptrim is used for the dietary management of obesity or morbid obesity. California Medical Treatment Utilization Schedule (MTUS) does not address this request. According to the Official Disability Guidelines, 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." Official Disability Guidelines quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria:... (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements;...." Per the Official Disability Guidelines, "Choline: 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. (AltMedDex, 2008) (Clinical Pharmacology, 2008) Glutamic Acid: This supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. (AltMedDex, 2008) (Lexi-Comp, 2008) 5-hydroxytryptophan: This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. (De Benedittis, 1985) (Klarskov, 2003) (AltMedDex, 2008) (Lexi-Comp, 2008) Gamma-aminobutyric acid (GABA): 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. Dose reductions are indicated for a creatinine clearance > 60 ml/min. (AltMedDex, 2008) In this low quality RCT, with no description for the actual sleep disorder, an amino acid preparation containing both GABA and 5-hydroxytryptophan reduced time to fall asleep, decreased sleep latency, increased the duration

of sleep, and improved quality of sleep. (Shell, 2009)L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement."A detailed history of insomnia or obesity in this patient is not specified in the records provided. A detailed psychiatric evaluation is not specified in the records provided. The response to non-pharmacological measures for treatment of insomnia and obesity is not specified in the records provided. There is no documented dietary deficiency of any of the components of this product. Therefore, there is no medical necessity for any medication containing these food supplements. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The medical necessity of the request for AppTrim D (Unknown Quantity) is not fully established in this patient. Therefore, this request is not medically necessary.

Acupuncture QTY: 9 (visits): Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: Per the California MTUS Acupuncture medical treatment guidelines cited below state that, "Acupuncture is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery." The medical records provided did not specify a plan to reduce pain medications, or any intolerance to pain medications that patient is taking currently. The patient has received an unspecified number of the physical therapy visits for this injury. Response to any prior rehabilitation therapy including physical therapy/acupuncture/pharmacotherapy since the date of injury was not specified in the records provided. The records submitted contain no accompanying current physical therapy/acupuncture evaluation for this patient. Prior conservative therapy visit notes were not specified in the records provided. Any evidence of diminished effectiveness of medications was not specified in the records provided. The medical necessity of 9 acupuncture visits is not fully established. Therefore, this request is not medically necessary.

Gabapentin/Cyclobenzaprine/Ketoprofen/Capsaicin/Menthol/Camphor10/4/10/.0375/5/2% 240gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 113.

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

Decision rationale: According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed.... There is little

to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended... Gabapentin: Not recommended. There is no peer-reviewed literature to support use...Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted....." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Any trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Any intolerance or contraindication to oral medications was not specified in the records provided. Cyclobenzaprine is a muscle relaxant. Per the cited guidelines, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." The muscle relaxant Cyclobenzaprine in topical form is not recommended by MTUS. As per cited guideline, "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Gabapentin and Cyclobenzaprine are not recommended in this patient for this diagnosis as cited. The medical necessity of the request for Gaba/Cyclo/Keto/Cap/Men/Cam 240gm is not fully established in this patient. Therefore, this request is not medically necessary.

RETRO: Urinalysis (DOS 10/3/14) QTY: 1: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43.

Decision rationale: Per the California MTUS guideline cited above, drug testing is "Recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs." Per the guideline cited below, drug testing is "The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment..... Frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument.... Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results." As per records provided medication lists includes Norco and Tylenol #3. It is medically appropriate and necessary to perform a urine drug screen to monitor the use of any controlled substances in patients with chronic pain. It is possible that the patient is taking controlled substances prescribed by another medical facility or from other sources like - a stock of old medicines prescribed to him earlier or from illegal sources. The presence of such controlled substances would significantly change the management approach. The retrospective request for urinalysis (DOS 10/3/14) is medically appropriate and necessary for this patient.

Tylenol #3, QTY: 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids - Therapeutic Trial of Opioids Page(s).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Therapeutic Trial of Opioids Page(s): 76-80.

Decision rationale: Tylenol #3 is an opioid analgesic. According to California MTUS guidelines cited below, "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." The records provided do not specify that patient has set goals regarding the use of opioid analgesic. A treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: "The lowest possible dose should be prescribed to improve pain and function. Continuing review of the overall situation with regard to nonopioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs."The records provided do not provide a documentation of response in regards to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by MTUS a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. Whether improvement in pain translated into objective functional improvement including ability to work is not specified in the records provided. MTUS guidelines also recommend urine drug screen to assess for the use or the presence of illegal drugs in patients using opioids for long term. Recent urine drug screen report is not specified in the records provided. With this, it is deemed that, this patient does not meet criteria for ongoing continued use of opioids analgesic. The medical necessity of Tylenol #3, quantity 60 is not established for this patient. Therefore, this request is not medically necessary.