

Case Number:	CM14-0189112		
Date Assigned:	12/09/2014	Date of Injury:	08/30/2012
Decision Date:	01/28/2015	UR Denial Date:	10/13/2014
Priority:	Standard	Application Received:	11/12/2014

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 Occupational Medicine 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:

EMG/NCV studies of the lower extremities, pain management consultation for the lumbar spine, 8 additional physical therapy sessions, 8 acupuncture sessions, tramadol, and diclofenac were denied following utilization review on 02/19/14. 04/08/14 PT note documented completion of 15 therapy sessions since 01/29/14. Improvements in lumbar range of motion were noted. Bilateral lower extremity weakness was noted and IW reported difficulty with activities of daily living and with ambulation greater than 30 minutes. The services in the current request were denied following utilization review on 10/13/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urinalysis for toxicology: 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)

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

Decision rationale: MTUS recommends urine drug testing as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. However, due to lack of documented

current or planned use of scheduled substances in this case, there is insufficient documented rationale to support the medical necessity for urine drug testing.

Additional Chiropractic x 12: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58.

Decision rationale: MTUS would support a trial of 6 sessions for chiropractic manipulation, but does not recommend additional chiropractic treatment without documented objective measurable gains in functional improvement. Due to an amount of treatment exceeding MTUS recommendations, medical necessity is not established for the requested 12 chiropractic sessions. Therefore this request is not medically necessary.

Theramine #90: 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 (Chronic), Theramine®.

Decision rationale: Concerning the medical food Theramine, ODG states: "Not recommended for the treatment of chronic pain. Theramine is a medical food from [REDACTED], [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) Theramine significantly improves chronic low back pain and reduces inflammation compared with low-dose ibuprofen, according to this RCT funded by the manufacturer. Criticisms of the study include that it was performed by the company that makes that product and conducted at commercial sites funded by the same manufacturer, the paper doesn't include the raw data on outcomes, only percentages of improvement, and doesn't discuss issues such as the success of blinding and patient adherence. Plus there is little information on the study patients and how they were recruited. (Shell, 2014) Until there are higher quality studies of the ingredients in Theramine, it remains not

recommended." Medical necessity is not established for the requested Theramine per evidence-based recommendations.

Sentra PM #60: 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 (Chronic), Sentra PM; Medical food.

Decision rationale: Per ODG, "Sentra PM is a medical food from [REDACTED], [REDACTED], intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan." Concerning the individual components of Sentra PM, ODG states: "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...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...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." No nutritional condition for which supplementation with choline or glutamate would be recommended has been identified. While ODG notes several conditions for which 5-hydroxytryptophan may be effective, none of these conditions is documented in this case. In addition, 5-hydroxytryptophan is readily available as an inexpensive single over-the-counter agent, and no rationale is documented which would support use of 5-hydroxytryptophan in a combination product. Medical necessity is not established for the requested Sentra PM.

Sentra AM: 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 (Chronic), Medical food Other Medical Treatment Guideline or Medical Evidence: Manufacturer's website: http://www.ptlcentral.com/downloads/product-sheets/Sentra_AM.pdf; WebMD, Hawthorn, Ginkgo.

Decision rationale: Ingredients of Sentra AM include L-glutamic acid, choline bitartrate, cocoa extract, acetyl L-carnitine HCl, hawthorne berry, ginkgo biloba, and dextrose. Manufacturer's website recommends use of Sentra AM in nutritional management of fatigue, memory disorders

and vascular dementia. None of these conditions is documented in this case. ODG states: "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." Concerning glutamic acid/glutamate, ODG states: "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." None of these conditions is documented in this case. WebMD states that hawthorn is used to treat diseases of the heart and blood vessels, digestive system complaints, tapeworm, boils, itching, and frostbite. None of these conditions is documented in this case. WebMD states ginkgo is used to treat memory disorders, Lyme disease, depression, and eye problems. None of these conditions is documented in this case. No condition for which use of the ingredients of Sentra AM would be appropriate is documented in this case. In addition, the individual components of this preparation are available as inexpensive over-the-counter nutritional supplements and there is no evidence that this combination is more effective than its individual ingredients alone. Medical necessity is not established for the requested Sentra AM.

Flubiprofen/Capsaicin/Camphor 120gm 10/0.025%/2%/1%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 11-113.

Decision rationale: MTUS does not recommend topical NSAIDs such as flurbiprofen for treatment of chronic back pain. MTUS recommends capsaicin for patients who have failed other treatments. No trial of other medications for back pain is documented. Medical necessity is not established for use of topical flurbiprofen or capsaicin in this case. MTUS states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, medical necessity is not established for the requested compounded topical medication.

Ketoprofen/Cyclobenzaprine/Lidocaine 120gm (10%/3%/5%):

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: MTUS does not recommend topical NSAIDs such as ketoprofen for treatment of chronic back pain. MTUS does not recommend use of topical muscle relaxants such as cyclobenzaprine. MTUS recommends topical lidocaine as a second-line agent for treatment of neuropathic pain following trial of first-line medication. Lidoderm patch is the only form of

topical lidocaine recommended by MTUS for treatment of chronic pain. No trial of first-line medications for neuropathic pain is documented. Medical necessity is not established for use of topical ketoprofen, cyclobenzaprine, or lidocaine in this case. MTUS states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, medical necessity is not established for the requested compounded topical medication.

Protonix 20mg #60 (Pantoprazole): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Proton pump inhibitors (PPIs).

Decision rationale: Protonix is a proton pump inhibitor (PPI). MTUS recommends PPIs as gastroprotective agents for at risk patients who are receiving oral NSAIDs. No oral NSAID use is documented in this case. No gastrointestinal condition for which use of a PPI would be indicated is documented. In addition, ODG considers Protonix to be a second-line PPI, and does not recommend use of this drug unless there has been a previous trial of omeprazole or lansoprazole. No previous trial of another PPI is documented. Medical necessity is not established for the requested Protonix.

Pain management consult for facet injection: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 296, 300, 309.

Decision rationale: Concerning specialty consultations for low back complaints, ACOEM Guidelines states: "Physical-examination evidence of severe neurologic compromise that correlates with the medical history and test results may indicate a need for immediate consultation. The examination may further reinforce or reduce suspicions of tumor, infection, fracture, or dislocation. A history of tumor, infection, abdominal aneurysm, or other related serious conditions, together with positive findings on examination, warrants further investigation or referral. A medical history that suggests pathology originating somewhere other than in the lumbosacral area may warrant examination of the knee, hip, abdomen, pelvis or other areas." Objective evidence of facet joint mediated pain or a red-flag condition is not documented. ACOEM Guidelines do not recommend facet joint injections. Medical necessity is not established for the requested pain management consult for facet injection.