

Case Number:	CM15-0001905		
Date Assigned:	01/26/2015	Date of Injury:	07/10/2013
Decision Date:	03/23/2015	UR Denial Date:	12/15/2014
Priority:	Standard	Application Received:	01/05/2015

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: Anesthesiology

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 66 year old female, who sustained an industrial injury on July 10, 2013, from cumulative type trauma. She has reported sharp pain on lower and upper back, tingling, numbness, and pain in the arms and legs, pain in the neck and shoulders, and sharp pain on the heels. The diagnoses have included left foot contusion, lumbar spine disc displacement, left should partial rotator cuff tear, and cervical discopathy. Treatment to date has included chiropractic therapy, physical therapy, injections, extracorporeal shockwave therapy, and oral and topical medications. Currently, the Injured Worker complains of insomnia, fatigue, and 7/10 pain. The Primary Treating Physician's report dated November 3, 2014, noted the cervical and lumbar spine with decreased range of motion and spasms. On December 15, 2014, Utilization Review non-certified eight sessions of chiropractic therapy, one urinalysis for toxicology, Flurbi/Caps/Camp 10/0.025%/2/1% 120gm, Naproxen 550mg #60, Omeprazole 20mg #30, Ketoprofen/cyclobenzaprine/lidocaine 10/3/5% 120gm, unknown ortho shockwave therapy for the left shoulder, left foot, cervical spine, and bilateral wrists, one non-invasive DNA test, Sentra AM #60, Sentra PM #60, Theramine #90, and GABA done #60. The injured worker was noted to have been certified for twelve chiropractic sessions on July 25, 2014, without evidence of measurable functional improvement from the completed sessions, the request for eight sessions of chiropractic therapy were non-certified, citing the Chronic Pain Medical Treatment Guidelines. The UR Physician noted that as the injured worker was not utilizing opioid medications, and had no risk factors for abuse, a urinalysis for toxicology was not necessary and was non-certified, citing the Chronic Pain Medical Treatment Guidelines . The request for

Flurbi/Caps/Camp 10/0.025%/2/1% 120gm was non-certified as there was lack of evidence for the capsaicin and no guideline support for camphor, citing the Chronic Pain Medical Treatment Guidelines. The request for Naproxen was non-certified as there was lack of functional improvement from previous use documented, with the injured worker reporting upset stomach with the medications, citing the Chronic Pain Medical Treatment Guidelines. There were no current complaints of stomach upset, therefore, the Omeprazole 20mg #30 was non-certified, citing the Chronic Pain Medical Treatment Guidelines. The guidelines were noted to clearly state that topical cyclobenzaprine and topical lidocaine were not supported therefore, the request for Ketoprofen/cyclobenzaprine/lidocaine 10/3/5% 120gm was non-certified, citing the Chronic Pain Medical Treatment Guidelines. The request for unknown ortho shockwave therapy for the left shoulder was non-certified based on the lack of evidence for the effectiveness of this therapy by guideline criteria, citing the American College of Occupational and Environmental Medicine (ACOEM) Guidelines and the Official Disability Guidelines (ODG). DNA testing was noted to be not recommended by the evidence based guidelines due to lack of consistent studies, therefore the request for one non-invasive DNA test was non-certified, citing the Official Disability Guidelines (ODG). The requests for Sentra AM #60, Sentra PM #60, Theramine #90, and GABAdone #60 were non-certified as guidelines do not support the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients, citing the Official Disability Guidelines (ODG). On January 5, 2015, the injured worker submitted an application for IMR for review of eight sessions of chiropractic therapy, one urinalysis for toxicology, Flurbi/Caps/Camp 10/0.025%/2/1% 120gm, Naproxen 550mg #60, Omeprazole 20mg #30, Ketoprofen/cyclobenzaprine/lidocaine 10/3/5% 120gm, unknown ortho shockwave therapy for the left shoulder, left foot, cervical spine, and bilateral wrists, one non-invasive DNA test, Sentra AM #60, Sentra PM #60, Theramine #90, and GABAdone #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

8 Sessions of chiropractic therapy: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009) Page(s): 58-60.

Decision rationale: According to CA MTUS Guidelines (2009), Manual Therapy or Chiropractic therapy is recommended for chronic pain if it is caused by musculoskeletal conditions. The intended goal or effect is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. For the treatment of low back pain, a trial of 6 visits is recommended over 2 weeks, with evidence of objective improvement, with a total of up to 18 visits over 6-8 weeks. If manipulation has not resulted in functional improvement in the first one or two weeks, it should be stopped and the patient reevaluated. In this case, the injured worker was noted to have been certified for twelve (which exceeded the MTUS guidelines of 6) chiropractic sessions on July 25, 2014, without evidence of measurable

functional improvement from the completed sessions. Therefore, the additional requested number of sessions are not medically necessary. The requested services are not medically necessary.

1 Urinalysis for toxicology: Upheld

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

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

Decision rationale: According to CA MTUS (2009), a urine drug screen is recommended as an option to assess for the use or the presence of illegal drugs. According to ODG, urine drug testing (UDT) is a recommended tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. In this case, was not found to be medically necessary. Therefore, the requested urine drug screenings are not medically necessary.

Flurbl/Caps/Camp 10/0.025%/2/1% 120gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical Analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Flurbl/Caps/Camp 10/0.025%/2/1% topical analgesic. There is no documentation of intolerance to other previous medications. In addition, evidence-based guidelines revealed no support for the topical use of camphor. Medical necessity for the requested topical medication has not been established. The requested Flurbl/Caps/Camp topical medication is not medically necessary.

Naproxen 550mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Pain Interventions and Treatments Page(s): 67.

Decision rationale: The requested medication, Naproxen 550mg, is not medically necessary for the treatment of the patient's pain condition. Naproxen is a non-steroidal anti-inflammatory medication (NSAID). These types of medications are recommended for the treatment of chronic pain as a second line of therapy after acetaminophen. The documentation indicates the patient has been maintained on the medication and there was lack of functional improvement from previous use documented. In addition, the injured worker reported an upset stomach with this medication. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Omeprazole 20mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS, PPIs Page(s): 68. Decision based on Non-MTUS Citation PPIs

Decision rationale: According to the California MTUS (2009), Omeprazole (Prilosec), is proton pump inhibitor (PPI) that is recommended for patients taking NSAIDs, with documented GI distress symptoms, or at risk for gastrointestinal events. There is no documentation indicating the patient had any GI symptoms or risk factors. GI risk factors include: age 65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose/multiple NSAIDs. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. There were no current complaints of stomach upset, therefore, the Omeprazole 20mg #30 is not medically necessary.

Ketoprofen/Cyclobenzaprine/Lidocaine 10/3/5% 120 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical Analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Ketoprofen/cyclobenzaprine/lidocaine 10/3/5% topical analgesic. There is no documentation of

intolerance to other previous medications. Medical necessity for the requested topical medication has not been established. The requested Ketoprofen/cyclobenzaprine/lidocaine topical medication is not medically necessary.

Unknown ortho shock wave therapy for the left shoulder, left foot, cervical spine and bilateral wrists: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 14 Ankle and Foot Complaints Page(s): 203, 371. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 371. Decision based on Non-MTUS Citation Ankle and Foot Medscape Internal Medicine

Decision rationale: Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment proposed to treat refractory tendonopathies such as, plantar fasciitis and lateral epicondylitis. It has also been introduced as an alternative to surgery for patients that have not responded to other conservative therapies. ESWT is a noninvasive treatment that involves delivery of low or high energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft tissue interface. Low-energy shock wave treatments are generally given in one session and usually require some type of anesthesia. The documentation indicates the claimant has chronic neck, left shoulder, bilateral wrist pain and left foot pain. There is no indication for the use of ESWT for the treatment of these areas. There are limited large-scale, long-term references showing the safety and efficacy of the requested treatment in this patient's clinical scenario. However, medical necessity for the requested procedure has not been established. The requested service is not medically necessary.

1 Non invasive DNA test: 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 Medscape Internal Medicine, Saliva DNA Testing (2012)

Decision rationale: Guidelines state that genetic testing or DNA testing for potential abuse is not recommended. While there appears to be a strong genetic component to addictive behavior, current research is experimental in terms of the use of the saliva DNA test. DNA testing is not recommended by the evidence-based guidelines due to the lack of consistent studies. Based on the lack of guideline support, the request for a non-invasive DNA test is not recommended. Based on the available information provided, the medical necessity for this testing has not been established. The requested non-invasive DNA test is not medically necessary.

Sentra: AM #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 Sentra AM Product information

Decision rationale: Sentra AM is a Medical Food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness and memory. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item was not established. The requested medical food is not medically necessary.

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 Sentra Product information

Decision rationale: Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item was not established. The requested medical food is not medically necessary.

Theramine #90: 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 Chronic Pain

Decision rationale: Theramine is a Medical food that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. It is a proprietary blend of gamma-aminobutyric acid and choline bitartrate, L-arginine, and L-serine. There is no literature support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item was not established. The requested medical food is not medically necessary.

GABAdone #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 Medical Food, GABAdone

Decision rationale: GABAdone is a Medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG guidelines do not support the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item was not established. The requested medical food is not medically necessary.