

Case Number:	CM14-0217563		
Date Assigned:	01/15/2015	Date of Injury:	10/11/2011
Decision Date:	03/03/2015	UR Denial Date:	12/12/2014
Priority:	Standard	Application Received:	12/29/2014

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: Pennsylvania
 Certification(s)/Specialty: Internal Medicine

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 70-year-old male who sustained a work-related injury dated October 11, 2011 due to a fall. Diagnoses at that time were right shoulder impingement and cervical/lumbar herniated nucleus pulposus (HNP). Additional diagnoses include post concussion syndrome with cephalgia, vertigo and insomnia, cervical and thoracic spine sprain/strain, right shoulder tendinopathy, stress, and anxiety. Treatment history had included physical therapy, manipulation therapy, steroid injections, pain medication management and extra-corporeal shock wave treatments (ESWT). The documentation submitted contained multiple authorization requests, three dates of service for ESWT, a Qualified Medical Evaluation report from 6/25/13, and physician progress notes. The QME report documented a past medical history of diabetes, hypercholesterolemia, and hypertension. The QME report also noted prior radiographic studies including x-rays and magnetic resonance imaging (MRI) studies, and electrodiagnostic studies; however, the documents submitted did not include the formal reports of these studies. The October 15, 2014 documentation reflected that the worker was experiencing decreased range of motion of the cervical and lumbar spine. Diagnoses at this visit included displacement of cervical intervertebral disc without myelopathy and other affections of the shoulder region not otherwise classified. Treatment plan included medication refills, a urine drug screen and follow up appointment in four weeks. The documentation reflected the worker had completed three treatments of ESWT, in which the worker had reported measurable improvement. A functional capacity study dated October 3, 2014 reflected the worker was experiencing pain that was rated as seven, however pain was reported to get as high as ten. Range of motion was reported

decreased in the cervical spine, lumbar spine, upper and lower extremity. Work capacity was documented as light work duties and since his job was heavy duty, he would not be able to return to work. The treating physicians progress note of 11/10/14 notes that the injured worker was instructed to remain off work. Progress notes document fatigue and insomnia, but a discussion of these complaints was not documented. Detailed medication history was not provided and current medications were not noted. There was no discussion of the outcome of prior physical therapy, and physical therapy notes were not provided. In an authorization request dated December 8, 2014, the physician requested a pain management referral, physical therapy 12 visits, an internist referral, acupuncture referral and medication refills. The utilization review (UR) decision dated December 12, 2014 non-certified the request for Tramadol 150mg, one tablet twice daily, 60 count and Cyclobenzaprine 7.5mg, 90 count. The UR rationale for non-coverage was based on the California MTUS which states opioids should be limited to short-term pain relief, and that long-term opioid efficacy is unclear beyond 16 weeks and there is limited evidence for the use of opioids for chronic low back pain. The guidelines for use of cyclobenzaprine state the medication should be used with caution as a second line option for short-term treatment of acute exacerbation in patients with chronic low back pain. UR noted the documentation did not indicate the worker was experiencing an exacerbation and therefore the request was non-certified. UR also non-certified requests for Theramine, Sentra PM, and Gabadone, noting that guidelines do not support the use of medical foods.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #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, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Chronic pain chapter: theramine

Decision rationale: Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Although the injured worker does have report of ongoing pain issues, per the ODG, Theramine is not recommended for the treatment of chronic pain. The request for Theramine #60 is not medically necessary.

Sentra PM #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, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, chronic pain chapter: insomnia treatment, sentra pm

Decision rationale: Sentra PM is a medical food from [REDACTED], [REDACTED], intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had insomnia, but no evaluation of the potential causes of sleep disturbance was documented. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. The request for Sentra PM #60 is not medically necessary.

Sentra AM #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, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Chronic pain chapter: medical food

Decision rationale: Sentra AM is a medical food 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. The injured worker did have documentation of ongoing pain issues. The ODG states that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The request for Sentra AM 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, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Chronic pain chapter: Gabadone

Decision rationale: Gabadone is a Medical food from [REDACTED], [REDACTED] 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 specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had insomnia, but no evaluation of the potential causes of sleep disturbance was documented. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. The request for Gabadone #60 is not medically necessary.

Tramadol 150mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids; tramadol Page(s): 74-96.

Decision rationale: Tramadol is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. It may also produce life-threatening serotonin syndrome. There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. There should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, mechanical and compressive etiologies, and chronic back pain. The physician progress notes did not include discussion of the medication history and outcome of treatment, nor the current medications. The current work status was noted as off work. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient has failed a trial of non-opioid analgesics. Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not include discussion of adverse side effects, and screening for aberrant drug-taking behaviors was not documented. The request for tramadol 150 mg #60 is not medically necessary.

Cyclobenzaprine 7.5mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

Decision rationale: Cyclobenzaprine is a muscle relaxant and central nervous system depressant. Nonsedating muscle relaxants are recommended with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The greatest effect of treatment with cyclobenzaprine is in the first four days of treatment. The documentation indicates the injured worker has chronic low back pain; acute exacerbation was not documented. The MTUS states that treatment with cyclobenzaprine should be brief. The number requested is not consistent with short term use. The MTUS notes that sedative effects of cyclobenzaprine may limit use. The request for cyclobenzaprine 7.5 mg #90 is not medically necessary.

Pain management consult: 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, low back chapter: office visits

Decision rationale: The ODG notes that office visits are recommended as determined to be medically necessary. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The injured worker was noted to have cervical and lumbar herniated nucleus pulposus, with chronic pain. The treating physician progress notes did not provide an adequate history of the prior treatment for chronic pain with the outcomes of specific modalities. The reason for the request for pain management consultation was not documented. There is no documentation of intent for treatment that is outside of the scope of routine treatment provided by the primary treating physician. The request for pain management consultation is not medically necessary.

Internist referral: 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, Low back chapter: office visits

Decision rationale: The ODG notes that office visits are recommended as determined to be medically necessary. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The QME report noted past medical history of diabetes, hypertension, and hypercholesterolemia. The treating physician reports, however, do not document the indication or reason for referral to an internist. No pertinent signs, symptoms,

or physical examination findings were documented. The request for internist referral is not medically necessary.