

Case Number:	CM15-0046299		
Date Assigned:	03/18/2015	Date of Injury:	01/02/2014
Decision Date:	04/24/2015	UR Denial Date:	03/03/2015
Priority:	Standard	Application Received:	03/11/2015

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: 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:

The injured worker is a 68 year old male who sustained a work related injury January 2, 2014. Diagnoses include left shoulder rotator cuff tear with surgical repair in May 2014, and cervical radiculopathy. Treatment has included physical therapy, medications, and surgery. According to a primary treating physician's progress report, dated February 12, 2015, the physician requests authorization for medications, physical therapy treatment, and urinalysis for toxicology. The handwritten subjective and objective findings are not legible; a partially legible notation suggests a diagnosis of lumbar spine strain/herniated nucleus pulposus. Several prior progress notes from the primary treating physician were also illegible. Several urine drug screens were submitted; the results were not addressed. An orthopedic report from November 2014 notes prescriptions for clinoril and tizanidine. An orthopedic evaluation and report dated February 23, 2015 notes the injured worker has been working, performing his regular duty. He reported some left shoulder pain. Examination showed no tenderness of the cervical spinous processes, and no tenderness or spasm of the paravertebral musculature. Cervical range of motion was decreased. Sensation, strength and deep tendon reflexes of the upper extremities were normal. Left shoulder exam showed tenderness in the anterior shoulder, good stability, positive impingement sign and negative apprehension sign. Diagnoses are documented as rotator cuff tear, left shoulder; status post left shoulder rotator cuff repair and cervical radiculitis. On 3/3/15, Utilization Review non-certified or modified requests for multiple medications, citing the MTUS and ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Capsaicin/Camphor cream 120gm: 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 Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The documentation submitted does not show that trials of antidepressants and anticonvulsants have been utilized and failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Topical NSAIDs are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Although the site of application was not specified, the injured worker's diagnoses were related to the cervical spine and shoulder. Topical non-steroidals are not recommended for neuropathic pain. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The treating physician has also prescribed a second topical NSAID as well as an oral NSAID, which is duplicative and potentially toxic. Capsaicin has some indications, in the standard formulations readily available without custom compounding. The MTUS also states that capsaicin is only recommended when other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of conventional treatments. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS is silent with regards to camphor. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. The site of application and directions for use of this compounded topical medication were not specified. As none of the products in this compound are recommended, the compound is not recommended. As such, the request for Flurbiprofen/Capsaicin/Camphor cream 120gm is not medically necessary.

Ketoprofen/Cyclobenzaprine/Lidocaine 120gm: 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 topical analgesics Page(s): 111-113.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not

recommended. Ketoprofen, a non-steroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photo contact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. As topical ketoprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The treating physician has also prescribed a second topical NSAID as well as an oral NSAID, which is duplicative and potentially toxic. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. The treating physician has also prescribed oral cyclobenzaprine, which is duplicative and potentially toxic. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch forms are generally indicated as local anesthetics or anti-pruritics. The site of application and directions for use of this compound were not specified. As none of the products in this compound are recommended, the compound is not recommended. As such, the request for Ketoprofen/Cyclobenzaprine/Lidocaine 120gm is not medically necessary.

Theramine #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 chapter: theramine.

Decision rationale: Theramine is medical food intended for use in the management of chronic pain syndromes which 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%). Per the ODG, theramine is not recommended for the treatment of chronic pain. The documentation indicates that this injured worker has chronic neck and shoulder pain. Due to lack of recommendation by the guidelines, the request for theramine 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 Official Disability Guidelines (ODG) 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 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 documentation indicates that this injured worker had chronic neck and shoulder pain. As this medical food is not recommended by the guidelines, the request for sentra AM is not medically necessary.

Gabadone #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) chronic pain chapter: Gabadone, insomnia treatment, medical food.

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 specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. There was no documentation of insomnia or sleep disturbance. 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. Due to lack of indication and lack of recommendation by the guidelines, the request for gabadone is not medically necessary.

Naproxen 550mg #60: 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 Page(s): 67-73.

Decision rationale: Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. This injured worker has diagnosis of rotator cuff repair with shoulder pain, and cervical radiculopathy. There is a possible diagnosis of lumbar strain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood

pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. NSAIDs should be used for the short term only. The quantity prescribed is not consistent with short term use. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. The specific indication for naproxen was not discussed. The treating physician is prescribing oral and transdermal NSAIDs. This is duplicative, potentially toxic, and excessive, as topical NSAIDs are absorbed systemically. Due to lack of specific indication, and potential for toxicity, the request for naproxen is not medically necessary.

Omeprazole 20mg #60: 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 and cardiovascular risk Page(s): 68-69.

Decision rationale: This injured worker has been prescribed naproxen, a NSAID, and omeprazole, a PPI. Per the MTUS, co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDs such as NSAID plus low dose aspirin). Other than age, none of the additional risk factors were documented. There are no medical reports which describe signs and symptoms of possible GI (gastrointestinal) disease. There is no examination of the abdomen on record. The associated NSAID has been determined to be not medically necessary. Due to lack of indication, the request for omeprazole is not medically necessary.

Cyclobenzaprine 7.5mg #60: 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 cyclobenzaprine muscle relaxants Page(s): 41-42, 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. It is not clearly documented that this injured worker had low back pain; multiple progress notes were illegible but one suggests a diagnosis of lumbar spine strain/herniated nucleus pulposus. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. Per the MTUS

chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Multiple additional medications were prescribed. Limited, mixed evidence does not allow for a recommendation for chronic use. The treating physician has also prescribed topical cyclobenzaprine, which is duplicative and potentially toxic. Due to quantity requested in excess of the guideline recommendation for a brief course of use, and potential for toxicity, the request for cyclobenzaprine is not medically necessary.

Tramadol 150mg #60: 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 opioids 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. The MTUS outlines criteria for prescription of opioids, which include specific functional goals, random drug testing, and opioid contract. The reason for prescription of tramadol was not documented. This injured worker was noted to have a work status of full duty, without restrictions; impairment in activities of daily living were not discussed. No functional goals were discussed. Prior prescription of opioids was not made clear in the records submitted. Several urine drug screens were submitted but the reason for these screens was not discussed and the results were not addressed. No opioid contract was discussed. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Failure of non-opioid analgesics was not documented. Due to lack of specific indication, and lack of prescribing in accordance with the MTUS guidelines for use of opioids, the request for tramadol is not medically necessary.