

Case Number:	CM15-0137372		
Date Assigned:	07/31/2015	Date of Injury:	01/30/2012
Decision Date:	09/15/2015	UR Denial Date:	06/12/2015
Priority:	Standard	Application Received:	07/15/2015

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: Pediatrics, 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 58-year-old male who sustained an industrial injury on 01-30-2012 resulting in injury to the bilateral knees. Treatment provided to date has included: 6 sessions of physical therapy for the low back with some pain relief; right knee surgery (2012) with 6 sessions of post-op physical therapy resulting in good relief; cortisone injection to the left knee (2012) with temporary relief for one month; lumbar right-sided hemilaminectomy and discectomy (2013) with 6 sessions of post-op physical therapy resulting in minimal relief; lumbar epidural steroid injections (x3 in 2013) resulting in 2 weeks of pain relief; posterior lumbar spinal fusion at L4-S1 and revision bilateral laminectomies (2014) with post-op physical therapy resulting in minimal relief; right S1 injection; multiple medications; chiropractic treatments; and conservative therapies and care. Diagnostic tests performed include: MRI of the right knee (2011) showing small tears of the posterior horns of the medial menisci and a popliteal cyst with small knee effusion (per progress reports); MRI of the left knee (2012) showing discoid lateral meniscus with small free edge radial tear and horizontally oriented signal within the medial meniscus possibly representing a horizontal cleavage tear versus mucoid degeneration (per progress reports); CT scan of the lumbar spine (2014) showing no displacement of hardware or clear cause of nerve root impingement per CT scan report). Other noted dates of injury documented in the medical record include: low back 2012, Comorbidities included cardiac disease (heart attack) with stent placement and use of blood thinners. On 05-28-2015, physician progress report (PR) noted complaints of continued low back pain. The pain was rated 5-6 out of 10 in severity, and was noted to be worse in the afternoons after activity. The injured worker

stated that the buttocks become numb after prolong sitting and radiating burning pain radiates in the legs. Additional complaints included lower extremity weakness (right worse than left), numbness in the tailbone area, and numbness in the lower extremities when lying flat on the back. Current medications listed on this report include Lyrica and Soma, which were also listed as current medications for several months. However, the plan of care indicates that the injured worker has also been taking Sentra PM with improved sleep habits; Sentra AM resulting in less fatigue, more energy and improved mental acuity; Flexeril which was planned to be decreased; flurbiprofen cream and Lidocaine patches which were helping to reduce pain and help with sleep; and Norco which was planned to be tapered. The injured worker reported that his medications were helping a little and requested chiropractic treatment to help with low back pain. The PR noted, "Need for pain medications and muscle relaxant medications. The physician reported that the injured worker would benefit from a functional restoration program (FRP) and continued physical therapy. The physical exam revealed bilateral tenderness and spasms of the L3-5 paraspinal muscles, tenderness over the trochanteric areas, 5+ motor strength in the lower extremities, pain in the lumbar facets with extension of the back, pain upon palpation of the bilateral sacroiliac (SI) joints, positive Faber sign, decreased range of motion (ROM) in the lumbar spine, right greater than left SI compression test, decreased sensation to pin-prick along the right lateral leg, and right greater than left allodynia. The provider noted diagnoses of lumbar disk disease and lumbar radiculopathy. Plan of care includes continued Sentra PM, Sentra AM, flurbiprofen cream Lidocaine patches, Narcosoft, and tapering of Flexeril and Norco; new prescriptions of Prilosec for NSAID drugs, Tramadol ER and theramine; chiropractic treatments (unknown amount or number of sessions); FRP evaluation; and continued home exercise program. The injured worker's work status permanently partially disabled. The request for authorization and IMR (independent medical review) includes: Chiropractic treatment (unspecified), FRP evaluation, retrospective Prilosec 20mg #30 (DOS: 05-28-2015), 20% flurbiprofen cream #2, 5% Lidocaine patches #30, retrospective Tramadol ER 150mg #30 (DOS: 05-28-2015), Narcosoft #60 with 3 refills, theramine #180, Sentra PM #60 and Sentra AM #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Chiro, unspecified: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-60.

Decision rationale: Per the MTUS, manual therapy/manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine 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. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. The MTUS recommends a trial of 6 visit of 2 weeks,

and with evidence of objective functional improvement up to 18 visits over 6-8 weeks. Elective or maintenance care is not medically necessary, recurrences or flare-ups require re-evaluation of treatment success, and if return-to-work has been achieved then 1-2 visits every 4-6 months are recommended. Per the ACOEM Guideline citation above, manipulation is a treatment option during the acute phase of injury, and manipulation should not be continued for more than a month, particularly when there is not a good response to treatment. After review of the medical documentation submitted, it was determined that the injured worker had previously undergone an unknown number of sessions of chiropractic manipulation. The current request for additional chiropractic manipulation does not specify the reason for additional chiropractic treatment, targeted area of the body to be treated, and number of sessions being requested. Therefore, the request for unknown chiropractic manipulation is not a valid request, and is not medically necessary.

Functional restoration program evaluation: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management and Chronic pain programs (functional restoration programs) Page(s): 30-32, 49-50.

Decision rationale: According to the MTUS, Functional Restoration Programs are recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk of delayed recovery. These pain rehabilitation programs combine multiple treatments, and at the least, include psychological care along with physical therapy & occupational therapy. Patients should also be motivated to improve and return to work, and meet all the patient selection criteria which are required to meet medical necessity, including: "an adequate and thorough evaluation has been made, including baseline functional testing so follow-up with the same test can note functional improvement; (2) Previous methods of treating chronic pain have been unsuccessful and there is an absence of other options likely to result in significant clinical improvement; (3) The patient has a significant loss of ability to function independently resulting from the chronic pain; (4) The patient is not a candidate where surgery or other treatments would clearly be warranted (if a goal of treatment is to prevent or avoid controversial or optional surgery, a trial of 10 visits may be implemented to assess whether surgery may be avoided); (5) The patient exhibits motivation to change, and is willing to forgo secondary gains, including disability payments to effect this change; and (6) Negative predictors of success above have been addressed." Upon review of the medical records available, it has been determined that there is insufficient evidence that: 1) the injured worker has tried and or failed all other methods of treatment that could likely result in functional improvement; 2) the injured worker has significant loss of ability to function independently as a result of chronic pain; 3) that the injured worker exhibits motivation to change, forgoing secondary gains, including disability payments to effect this change, and 4) negative predictors of success have been addressed. Additionally, there is no indication that the injured worker is working or plans to return to work despite restrictions of no lifting over 20 pounds or repetitive bending. Therefore, the requested FRP evaluation is not medically necessary.

Retro Prilosec 20mg #30, DOS: 5/28/15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), GI symptoms & cardiovascular risk Page(s): 68.

Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter, Proton Pump Inhibitors.

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. 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. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Upon review of the clinical documentation, the injured worker is not over the age of 65. Additionally, there is no evidence of NSAID use, or complaints of gastrointestinal symptoms. Given the increased risk associated with PPI medications and lack of GI risk factors or symptoms, the medical necessity for Omeprazole (Prilosec) has not been established. Therefore, Omeprazole 20mg #30 is not medically necessary.

Flurbiprofen cream 20% #2: 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): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter; Flurbiprofen (Ansaid®).

Decision rationale: According to the MTUS guidelines: "Topical Analgesic are recommended as an option as indicated below. 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." Flurbiprofen is classified as a NSAID. NSAIDs, in the topical form, are not recommended for neuropathic pain, as there is no evidence to support use. The ODG also states: Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor); however, there is little to no research to support the use of many these agents. Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. At this time, the only available FDA-approved topical NSAID is diclofenac. In regards to the topical analgesic 20% flurbiprofen cream #2, Flurbiprofen is not FDA approved for topical application and is not recommended for

neuropathic pain. Diclofenac is the only approved topical NSAID. As a result, this topical analgesic, 20% flurbiprofen cream #2, is not medically necessary.

Lidocaine patches 5% #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine Patch).

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

Decision rationale: According to the California MTUS Guidelines (2009), Topical Analgesics, such as the Lidoderm 5% Patch, 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, for example, NSAIDs, opioids or antidepressants. Lidoderm is the brand name for a lidocaine patch. The FDA for neuropathic pain has designated the Lidoderm patch for orphan status (granting special status approval to a drug or biological product). Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Additionally, this medication is not generally recommended for treatment of myofascial pain/trigger points. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, medical necessity of the Lidoderm patch has not been established as there is no diagnosis or evidence of post-herpetic neuralgia. Additionally, this medication is not recommended for myofascial pain or trigger points. Although, the injured worker has exhibited evidence of neuropathic pain and has previously been prescribed Lyrica, this medication is only recommended for the treatment of localized peripheral pain. The location or treatment area was not specified. As such, the requested 5% Lidocaine patches #30 are not medically necessary.

Retro Tramadol ER 150mg #30, DOS: 5/28/15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram).

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

Decision rationale: Ultram (Tramadol) is an opioid medication used to treat moderate to severe pain. The MTUS identifies criteria for a therapeutic trial of opioids as: 1) are there reasonable alternatives to treatment and have they been tried; 2) is the patient likely to improve (has the patient benefited from other opioids in the past); 3) is there likelihood of abuse or adverse outcome; 4) are there red flags indication that opioids may not be beneficial in the chronic phase which can include little to no relief with opioid therapy in the acute and sub acute phases, 5) has the patient had a psychological evaluation or been diagnosed with psychological disorders, or is there a diagnosis that has not been shown to have an adequate response to opioids; 6) before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals; 7) baseline pain and functional assessments should be made (including social, physical, psychological, daily and work activities) and should be performed

using a validated instrument or numerical rating scale; 8) pain related assessments should include history of pain treatment and effect of pain and function; 9) assess the likelihood that the patient could be weaned from opioids when there is no improvement in pain and function; and 10) patient should have at least one physical and psychosocial assessment by the treating doctor.

Additionally, MTUS discourages long-term usage unless there is evidence of ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case, the injured worker has been previously prescribed long-term use of opioids (including Tramadol per the PR dated 01-05-2015) without significant improvement in function or reduced pain. The injured worker has been taking Norco recently and the treatment plan is to taper Norco and restart Tramadol. Upon review of the progress notes, 1) there is no indication or evidence that the injured worker has undergone a psychological evaluation despite the ongoing use of opioids and lack of improvement; 2) there is no indication or evidence of set goals or ongoing review of meeting these goals. Furthermore, the treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. These are necessary to meet MTUS guidelines. As such, the request for Tramadol ER 150mg #30 (DOS: 05-28-2015) is not medically necessary.

Narcosoft #60 x 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.webmd.com/drugs.

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) Chapter; Opioid-induced constipation treatment and Other Medical Treatment Guidelines www.enovachem.us.com.

Decision rationale: Narcosoft is a Nutritional Supplement containing of a blend of soluble fibers and natural laxatives that may help to relieve symptoms of occasional constipation. The MTUS is silent in regards to Narcosoft; therefore, the ODG was consulted in the decision on this issue. The ODG states: "if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract." In this case, there is no evidence or history of constipation. However, the injured worker has been prescribed Norco, which is being tapered per the progress report. Despite the fact the injured worker is on an opioid, the Narcosoft is prescribed with 3 refills. There is no evidence to support medical necessity for a 4-month supply of Narcosoft. Additionally, the request for tramadol has been found not medically necessary. As such, the request for Narcosoft #60 with 3 refills is not medically necessary.

Theramine #180: 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) Chapter; Theramine® and Medical Food.

Decision rationale: The MTUS is silent in regards to the recommendation of Theramine; therefore, other guidelines were referenced in the decision of Theramine. Per the ODG guidelines, Theramine is "not recommended for the treatment of chronic pain. 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. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors." The ODG also states that medical food is not recommended for chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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, are established by medical evaluation." In this case, the physician prescribed Theramine without specifying its intended use. Theramine, which is a medical food, is not recommended. As such, the requested Theramine #180 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 Official Disability Guidelines (ODG) Pain (chronic); Sentra PM and Medical Food.

Decision rationale: The MTUS is silent in regards to the recommendation of Sentra PM (medical food); therefore, other guidelines were referenced in the decision of Sentra PM. Per the ODG guidelines for medical food, medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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, are established by medical evaluation." The ODG indicates that Sentra PM is a medical food that is intended for use in the treatment or management of sleep disorders associated with depression. Additionally, the ODG states "Sentra PM is not recommended". In this case, Sentra PM was prescribed by the physician without specifying its intended use. Sentra PM, which is a medical food, is not recommended. As such, the requested Sentra PM #60 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) Pain (chronic); Medical Food.

Decision rationale: The MTUS is silent in regards to the recommendation of Sentra AM (medical food); therefore, other guidelines were referenced in the decision of Sentra AM. Per the ODG guidelines for medical food, medical food is not recommended for chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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, are established by medical evaluation." In this case, Sentra AM was prescribed by the physician without specifying it's intended use. Sentra AM that is a medical food is not recommended. As such, the requested Sentra AM #60 is not medically necessary.