

Case Number:	CM15-0160913		
Date Assigned:	08/27/2015	Date of Injury:	01/30/2012
Decision Date:	10/28/2015	UR Denial Date:	07/27/2015
Priority:	Standard	Application Received:	08/17/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 59 year old male, who sustained an industrial injury on 1-30-2012. Diagnoses include lumbar spondylosis, sciatica, lumbar herniated disc and post laminectomy syndrome lumbar region. Treatment to date has included surgical intervention (lumbar fusion), diagnostics, medications and epidural steroid injections. Per the Primary Treating Physician's Progress Report dated 2-03-2015, the injured worker reported low back pain in the lumbar region, sacral region and flank on the right. He reports his usual pain level as 8 out of 10. He has numbness and tingling in the L5 and S1 dermatomal areas. Objective findings of the lumbar spine included mild tenderness of the midline bilaterally in a symmetrical distribution in the paraspinal muscles. There was tenderness in the hip area bilaterally. This was the only medical record submitted for review. On 7-27-2015, Utilization Review non-certified a request for Tramadol ER 150mg #30, Cyclobenzaprine 7.5mg #30, Terocin lotion 120gm #30, Promolaxin #60, Omeprazole 20mg #30, Flurbiprofen 20% cream #2, Sentra AM #60, Sentra PM #60, Theramine #180, Chiropractic therapy, Functional restoration Program (FRP) Narcosoft #60, and Lidocaine patch 5% #30 due to lack of documented medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150 mg, thirty count: 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 Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain, Opioids, specific drug list.

Decision rationale: Tramadol is a centrally acting opioid agonist and also inhibits the reuptake of serotonin and norepinephrine. On July 2, 2014, the DEA published in the Federal Register the final rule placing tramadol into schedule IV of the Controlled Substances Act. This rule will become effective on August 18, 2014. The CPMTG specifies that this is a second line agent for neuropathic pain. Given its opioid agonist activity, it is subject to the opioid criteria specified on pages 76-80 of the CPMTG. With regard to this request, the California Chronic Pain Medical Treatment Guidelines state the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the '4 A's' (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Guidelines further recommend discontinuing opioids if there is no documentation of improvement in function and reduction in pain. In the progress reports available for review, the primary treating physician did not adequately document monitoring of the four domains. Improvement in function was not clearly outlined. This can include a reduction in work restrictions or significant gain in some aspect of the patient's activities. Furthermore, there was no discussion regarding possible aberrant drug-related behavior. There was no documentation of a signed opioid agreement, no indication that a periodic urine drug screen (UDS) was completed, and no recent CURES report was provided to confirm that the injured worker is only getting opioids from one practitioner. Based on the lack of documentation, medical necessity of this request cannot be established at this time. Although tramadol is not medically necessary at this time, it should not be abruptly halted, and the requesting provider should start a weaning schedule as he or she sees fit or supply the requisite monitoring documentation to continue this medication.

Cyclobenzaprine 7.5 mg, thirty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Regarding the request for cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of nonsedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that cyclobenzaprine specifically is recommended for a short course of therapy. Within the

documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. Given this, the current request is not medically necessary.

Terocin lotion 120 grams, thirty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding the request for Terocin, Terocin is a combination of methyl salicylate, menthol, lidocaine and capsaicin. Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical nonsteroidal anti-inflammatory, guidelines state that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the 1st 2 weeks of treatment osteoarthritis, but either not afterwards, or with the diminishing effect over another two-week period. Regarding use of capsaicin, guidelines state that it is recommended only as an option for patients who did not respond to or are intolerant to other treatments. Regarding the use of topical lidocaine, guidelines state that it is recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Within the documentation available for review, there is no documentation of localized peripheral pain with evidence of failure of first-line therapy as recommended by guidelines prior to the initiation of topical lidocaine. Furthermore only topical lidocaine in patch form as Lidoderm is recommended per CPMTG, and thus this component is not recommended. Therefore, the currently requested Terocin is not medically necessary.

Promolaxin, sixty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on pages 77-78 recommend prophylactic treatment of opioid related constipation. Specifically, the following is state with regard to initiating Opioid Therapy: "(d) Prophylactic treatment of constipation should be initiated." In the case of this injured worker, there is documentation of opioid use. However, there is no indication of any subjective complaints of constipation. The frequency of bowel movements were not documented. Therefore, the use of this agent is not appropriate.

Omeprazole 20 mg, thirty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Regarding the request for omeprazole (Prilosec), California MTUS states that proton pump inhibitors are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. In light of the above issues, the currently requested omeprazole (Prilosec) is not medically necessary.

Flurbiprofen 20% cream, two count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding the request for topical flurbiprofen, guidelines state that topical NSAIDs are recommended for short-term use. Oral NSAIDs contain significantly more guideline support, provided there are no contraindications to the use of oral NSAIDs. Within the documentation available for review, there's no indication that the patient has obtained any specific analgesic effect from the use of topical flurbiprofen, as the patient continue to have 8/10 pain. Additionally, there is no documentation that the topical flurbiprofen is for short term use, as recommended by guidelines. In the absence of clarity regarding those issues, the currently requested topical flurbiprofen is not medically necessary.

Sentra AM, sixty count: 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, Medical food.

Decision rationale: Regarding the request for Sentra AM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid" 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. Within the documentation available for review, there is no documentation of a condition for which the components of Sentra AM would be supported. In the absence of such documentation, the currently requested Sentra AM is not medically necessary.

Sentra PM, sixty count: 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, Medical food.

Decision rationale: Regarding the request for Sentra PM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid" 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. Within the documentation available for review, there is no documentation of a condition for which the components of Sentra PM would be supported. In the absence of such documentation, the currently requested Sentra PM is not medically necessary.

Theramine, 180 count: 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: Regarding the request for Theramine, California MTUS and ACOEM Guidelines do not contain criteria for the use of medical foods. ODG states Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. As such, the currently requested Theramine is not medically necessary.

Chiropractic therapy (unspecified): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Manual therapy & manipulation.

Decision rationale: Regarding the request for chiropractic care, Chronic Pain Medical Treatment Guidelines support the use of chiropractic care for the treatment of chronic pain caused by musculoskeletal conditions. However, these guidelines specify for an initial trial of up to 6 visits. Only with evidence of objective functional improvement, can further session be supported. Given this request does not specify the number of chiropractic visits, this request is not medically necessary.

FRP Evaluation: 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) Fitness for Duty Chapter, Functional Capacity Evaluation and Other Medical Treatment Guidelines ACOEM, Chapter 7, p. 137-138.

Decision rationale: Regarding request for functional capacity evaluation, ACOEM Practice Guidelines state that there is not good evidence that functional capacity evaluations are correlated with a lower frequency of health complaints or injuries. ODG states that functional capacity evaluations are recommended prior to admission to a work hardening program. The criteria for the use of a functional capacity evaluation includes case management being hampered by complex issues such as prior unsuccessful return to work attempts, conflicting medical reporting on precautions and/or fitness for modified job, or injuries that require detailed explanation of a worker's abilities. Additionally, guidelines recommend that the patient be close to or at maximum medical improvement with all key medical reports secured and additional/secondary, conditions clarified. Within the documentation available for review, there is no indication that there has been prior unsuccessful return to work attempts, conflicting medical reporting, or injuries that would require detailed exploration. Given this, the currently requested functional capacity evaluation is not medically necessary.

Narcosoft, sixty count with three refills: 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 <https://enovachem.us.com/product/narcosoft/>.

Decision rationale: The CA MTUS, ODG, or ACOEM do not address narcosoft. Per the product website, Narcosoft is a Medical Nutritional Supplement containing of a blend of soluble fibers and natural laxatives that may help to relieve symptoms of constipation. This includes a proprietary blend of various laxatives. The suggested use of this product is "as a dietary

supplement, take two (2) capsules daily with 10 ounces of water, juice, or beverage of choice. Do not exceed four (4) capsules daily." Within the submitted documentation, it is not clear why this anti-constipation agent was utilized as opposed to well known laxatives. Furthermore, there is no documentation of constipation in review of system or subjective complaints. Because this is not a product acknowledged by guidelines and with limited peer reviewed evidence to support its efficacy, it is not medically necessary.

Lidocaine patch 5%, thirty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding request for topical Lidoderm, Chronic Pain Medical Treatment Guidelines recommend the use of topical lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Within the documentation available for review, there is no indication that the patient has failed first-line therapy recommendations as the patient has taken Lyrica without documented treatment failure. There is no documentation of analgesic effect in terms of reduction of NRS as a result of the currently prescribed Lidoderm. As such, the currently requested Lidoderm is not medically necessary.

Urine Drug Screen, provided on July 9, 2015: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing, Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, screening for risk of addiction (tests), Opioids, steps to avoid misuse/addiction. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Urine Drug Testing.

Decision rationale: Regarding the request for a urine toxicology test, CA MTUS Chronic Pain Medical Treatment Guidelines state the drug testing is recommended as an option in patients on controlled substances. Guidelines go on to recommend monitoring for the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. ODG recommends urine drug testing on a yearly basis for low risk patients, 2-3 times a year for moderate risk patients, and possibly once per month for high risk patients. There risk stratification is an important component in assessing the necessity and frequency of urine drug testing. With the documentation available for review, there is documentation of prescription of controlled substances. However, there is no notation of when the last previous urine toxicology testing was done. No risk factor assessment, such as the utilization of the Opioid Risk Tool or SOAPP is apparent in the records, which would dictate the schedule of random periodic drug testing. Given this, this request is not medically necessary.

