

Case Number:	CM15-0194750		
Date Assigned:	10/09/2015	Date of Injury:	08/03/2010
Decision Date:	12/16/2015	UR Denial Date:	09/21/2015
Priority:	Standard	Application Received:	10/05/2015

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: 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 43-year-old male, with a reported date of injury of 08-03-2010. The diagnoses include abdominal pain; acid reflux, likely secondary to NSAIDs (non-steroidal anti-inflammatory drugs), rule out gastroesophageal reflux disease; sleep disorder, likely secondary to the pain, rule out obstructive sleep apnea; sexual dysfunction; orthopedic diagnosis (referred to orthopedist); dysphagia and epigastric pain; moderate hiatal hernia; and moderate gastritis. Treatments and evaluation to date have included Norco, Prilosec (since at least 03-2015), Theramine, Sentra, Tramadol, and Naproxen. The diagnostic studies to date have included esophagogastroduodenoscopy (EGD) with biopsy on 08-04-2015. The progress report dated 07-08-2015 indicates that the injured worker continued to notice unchanged daily abdominal pain, unchanged constipation, and bloating and gas. He also complained of poor sleep quality due to pain. The physical examination showed a regular heart rate and rhythm; a blood pressure of 117 over 75; a soft abdomen; and normoactive bowel sounds. The treatment plan included several medications. It was noted that the injured worker was declared permanent and stationary on 07-02-2014. His work status was deferred to his primary treating physician. The request for authorization was dated 07-08-2015. The treating physician requested Prilosec 20mg #30, Colace 100mg #60 with two refills, Simethicone 80mg #60 with two refills, Probiotics #60 with two refills, Cyclobenzaprine 10mg #90, Rapaflo 8mg #30, Medrox patches #10 with two refills, Tramadol 50mg #60 times three bottles, physical therapy, and an orthopedic consultation. On 09-21-2015, Utilization Review (UR) non-certified the request for Prilosec 20mg #30, Colace 100mg #60 with two refills, Simethicone 80mg #60 with two refills, Probiotics #60 with two

refills, Cyclobenzaprine 10mg #90, Rapaflo 8mg #30, Medrox patches #10 with two refills, Tramadol 50mg #60 times three bottles, physical therapy, and an orthopedic consultation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec 20mg #30: Overturned

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: In this request, there is controversy over whether a PPI is warranted in this worker's treatment regimen. The Chronic Pain Medical Treatment Guidelines on page 68-69 states the following regarding the usage of proton pump inhibitors (PPI): "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." In the case of this injured worker, there is documentation of gastroenterologic work-up and the patient has gastritis confirmed via EGD. The biopsy is positive for H. pylori, a bacterial agent that could lead to peptic ulcer disease. Given this, the request for a proton pump inhibitor is medically necessary. It should be further noted that while the IMR process decides medical necessity, it does not discuss industrial causation. If the claims administrator disputes the industrial coverage of this body region, then an IME can assess causation and apportionment.

Colace 100mg #60 with 2 refills: Overturned

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: With regard to the request for Colace, 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. Although the frequency of bowel movements should be documented, the empiric use of laxative and stool softeners is appropriate medical treatment. Opioids have well known constipating effects, and these side effects do not have tolerance over time. Therefore, the use of this agent is medically necessary.

Simethicone 80mg #60 with 2 refills: Overturned

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 Online, Simethicone.

Decision rationale: Regarding the request for Simethicone, the CA MTUS, ACOEM, and ODG do not address this request. Therefore, an alternative source is referenced in the Uptodate Online, an evidenced-based database. The entry on Simethicone states that this medication is indicated for the treatment of gas retention: relief of pressure, bloating, fullness, and discomfort of gastrointestinal gas. Within the submitted documentation, there is documentation of bloating and gas retention. This is noted in a progress note dated July 8, 2015. As such, this medication is medically necessary. Of note, the IMR process comments on medical necessity but not industrial causation. If the patient's gas/bloating symptoms are not felt to be industrially related, an IME can further assess the industrial relatedness of this complaint.

Probiotics #60 with 2 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 Other Evidence:
http://cid.oxfordjournals.org/content/46/Supplement_2/S96.long.

Decision rationale: Regarding the request for probiotics, CA MTUS and ODG do not address the issue. A search of the National Library of Medicine and other online resources reveals that "Proven benefits of probiotics include the treatment of acute and antibiotic-associated diarrhea; applications with substantial evidence include the prevention of atopic eczema and traveler's diarrhea; promising applications include the prevention of respiratory infections in children, prevention of dental caries, elimination of nasal pathogen carriage, prevention of relapsing C. difficile-induced gastroenteritis, and treatment of inflammatory bowel disease; and proposed future applications include the treatment of rheumatoid arthritis, treatment of irritable bowel syndrome, cancer prevention, prevention of ethanol-induced liver disease, treatment of diabetes, and prevention or treatment of graft-versus-host disease. The use of probiotics in medical practice is rapidly increasing, as are studies that demonstrate the efficacy of probiotics. A note of caution should be applied: negative findings are being reported, as would be expected as more studies are being performed and as more applications are being sought for the use of probiotics." Within the documentation available for review, there is no clear identification of the condition(s) for which the probiotics are being utilized and evidence-based support for the use of probiotics in the management of that/those condition(s). In the absence of clarity regarding the above issues, the currently requested probiotics are not medically necessary.

Cyclobenzaprine 10mg #90: 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 non-sedating 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. This has been prescribed since at least April 2015, which exceeds the recommendation for short-term use. Given this, the current request is not medically necessary.

Rapaflo 8mg #30: 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 Online, Rapaflo.

Decision rationale: With regard to the request for Rapaflo (silodosin), the CA MTUS, ACOEM, and ODG do not address this issue. Instead, an evidence-based database is cited. Uptodate Online states that silodosin is used for the "treatment of signs and symptoms of benign prostatic hyperplasia (BPH)." Within the documentation submitted for review, it is not apparent that there is an industrial diagnosis of benign prostatic hyperplasia. Given this, this request is not medically necessary.

Medrox patches #10 with 2 refills: 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: Medrox is a compounded topical medication consisting of methyl salicylate, menthol, and capsaicin 0.0375%. The Chronic Pain Medical Treatment Guidelines on page 111 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Thus, each active ingredient should be analyzed in making a determination of medical necessity. With regard to capsaicin, the Chronic Pain Medical Treatment Guidelines states on pages 28-29: "Capsaicin is generally available as a

0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy." Given this recommendation against a 0.0375% strength of capsaicin, the Medrox is not medically necessary.

Tramadol 50mg #60 3 bottles: 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, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use, 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 requesting provider 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. Although there was documentation of periodic urine drug screening (UDS) and CURES report checked, this is only part of the required monitoring for continuing tramadol. 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.

Physical therapy: 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): Physical Medicine.

Decision rationale: In the case of this injured worker, the submitted documentation failed to indicate functional improvement from previous physical therapy. It is very likely this worker has undergone prior PT and possibly multiple courses of PT given the chronicity of this injury (with date of injury in 2010). There is no comprehensive summary of how many sessions have been attended in total over the course of this injury, and what functional benefit the worker gained from PT. This functional improvement can include a reduction in work restrictions or other clinically significant improved function in activities of daily living. According to the Chronic Pain Medical Treatment Guidelines, continuation of physical therapy is contingent on demonstration of functional improvement from previous physical therapy. Therefore additional physical therapy is not medically necessary.

Orthopedic consultation: 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 ACOEM, 2nd Edition, (2004), Independent Medical Examinations and Consultations Chapter, Page 127.

Decision rationale: In regards to the request for orthopedic consultation, the ACOEM Practice Guidelines recommend expert consultation when "when the plan or course of care may benefit from additional expertise." Thus, the guidelines are relatively permissive in allowing a requesting provider to refer to specialists. Within the submitted documentation, there is documentation of previous consultation with at least 2 different orthopedists. This is documented in the clinical narrative summary from a note on date of service 6/2/15. Therefore, there should be specific rationale as to why this is medically necessary at this juncture and what specific musculoskeletal issues the requesting provider would like to have addressed through specialty consultation. Without reference to the prior orthopedic consultation, it is not apparent as to whether the requesting provider is aware of these prior consultation and any associated recommendations or treatments to date. Given this, this request is not medically necessary.