

Case Number:	CM15-0058340		
Date Assigned:	04/17/2015	Date of Injury:	11/04/2013
Decision Date:	07/15/2015	UR Denial Date:	03/17/2015
Priority:	Standard	Application Received:	03/27/2015

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 37 year old male who widespread pain, mental illness, and internal medicine conditions after a contusion and fall on November 4, 2013. The diagnoses have included brachial neuritis, radiculitis, thoracic sprain, headache, psychosexual dysfunction, dysthymic disorder and insomnia. Treatment has included medications. The primary treating physician reports during 2014 reflect ongoing high levels of pain, "temporarily totally disabled" work status, polypharmacy, and no discussion of the specific symptomatic and functional benefit from using any of the medications. Quazepam, tramadol, omeprazole, medical foods, Norco, and the topical agents have been prescribed chronically. A urine drug screen on 9/25/14 was positive for benzodiazepines, citalopram, and hydrocodone. A urine drug screen on 2/5/15 was positive for tramadol and negative for a long list of other medications, including benzodiazepines, many opioids, and cyclobenzaprine. There are no physician reports which address these results. At an office visit on December 22, 2014, there was ongoing multifocal pain, 6-8/10. Depression and insomnia were stated to be due to chronic pain. Medications were "helpful." There was no discussion of the specific benefits and functional improvement from any single medication. The medications referred for this Independent Medical Review were prescribed. Topical flurbiprofen was dispensed as a single agent. Topical tramadol and cyclobenzaprine were dispensed as a combination. Each of the medications was listed with a guideline reference but without patient-specific information. The work status was "temporarily totally disabled." On 3/17/15, Utilization Review non-certified the medications referred for this Independent Medical Review, noting the lack of indications per the cited MTUS and Official Disability Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 25% 30gram tube: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: Per the MTUS, topical non-steroidal anti-inflammatory agents (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no good evidence supporting topical NSAIDs for shoulder or axial pain. The treating physician did not provide any body part intended for this NSAID, and it appears to be prescribed for axial 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.

Cyclobenzaprine 10% 30 gram tube: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: The documentation submitted indicates that this medication is part of a compounded topical cream. The additional ingredients in the compound were not specified. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state: that "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." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The physician is prescribing both oral and topical cyclobenzaprine, which is redundant and possibly toxic. Cyclobenzaprine is a muscle relaxant. Per the MTUS citation, there is no good evidence in support of topical muscle relaxants; these agents are not recommended. As such, the request for Cyclobenzaprine 10% 30 gram tube is not medically necessary.

Tramadol 10% 120 gm tube: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications, Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials, Tramadol Page(s): 60, 111-113, 77-81, 94, 80, 81, 60, 94, 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: There is insufficient 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, opioid contract, and there should be a prior failure of non-opioid therapy. There is insufficient documentation of these aspects of prescribing opioids. The prescribing physician describes this patient as "temporarily totally disabled," which fails the "return-to-work" criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. The documentation submitted indicates that this medication is part of a compounded topical cream. The additional ingredients in the compound were not specified. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. The treating physician did not explain why topical tramadol might be needed when the injured worker is already prescribed oral tramadol. Assuming that topical tramadol is absorbed, this is redundant and possibly toxic. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "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." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. There is no good evidence in support of topical opioids for musculoskeletal pain. Topical tramadol is not medically necessary based on the cited guidelines, lack of medical evidence, and concurrent prescribing of oral tramadol.

Theramine #90 (2 bottles): 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), Pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Medical food, Theramine and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food." The Official Disability Guidelines have several recommendations and indications for certain medical foods (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. The Official Disability Guidelines recommend against Theramine for chronic pain. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Gabadone #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.gov/pubmed/1941759>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Medical food, Theramine and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food." The Official Disability Guidelines have several recommendations and indications for certain medical foods (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Cyclobenzaprine HCL 7.5mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 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. The muscle relaxant prescribed in this case is sedating. This injured worker has chronic pain with no evidence of prescribing for flare-ups. Prescribing of topical and/or oral cyclobenzaprine has occurred consistently for months at least. The quantity

prescribed implies long term use, not a short period of use for acute pain. No reports show any specific and significant improvements in pain or function as a result of prescribing muscle relaxants. Cyclobenzaprine, per the MTUS, is indicated for short term use only and is not recommended in combination with other agents. This injured worker has been prescribed multiple medications along with cyclobenzaprine. The physician is prescribing both oral and topical cyclobenzaprine, which is redundant and possibly toxic. Per the MTUS, this muscle relaxant is not indicated and is not medically necessary.

Quazepam 15mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. No reports show specific symptomatic and functional benefit for this medication. The urine drug screen of 2/5/15 was negative for benzodiazepines, raising the question of whether this injured worker is even taking this medication. The MTUS does not recommend benzodiazepines for long term use for any condition. The prescribing has occurred chronically, not short term as recommended in the MTUS. This benzodiazepine is not prescribed according the MTUS and is not medically necessary.

Omeprazole 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: There are no medical reports which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. There is no examination of the abdomen. There are many possible etiologies for gastrointestinal symptoms; the available reports do not provide adequate consideration of these possibilities. Empiric treatment after minimal evaluation is not indicated. This injured worker is not taking non-steroidal anti-inflammatory agents (NSAIDs) or other medications likely to adversely affect the acid milieu of the upper gastrointestinal tract. No reports describe the specific risk factors present in this case, as presented in the MTUS. Proton pump inhibitors (PPIs) are not benign. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures; pneumonia, Clostridium-difficile-associated diarrhea, cardiovascular disease, and hypomagnesemia in patients on proton pump inhibitors. This PPI is not medically necessary based on lack of medical necessity and risk of toxicity.