MAXIMUS Federal Services

Case Number:	CM14-0083386		
Date Assigned:	07/21/2014	Date of Injury:	01/06/1998
Decision Date:	12/04/2014	UR Denial Date:	05/22/2014
Priority:	Standard	Application Received:	06/05/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 66 year-old woman who has reported multifocal pain after she fell on 1/6/98. Painful areas include the hips, shoulder, neck, and right upper extremity. Diagnoses, which may include non-industrial conditions, have included fibromyalgia, low back pain, leg pain, radiculopathy, cervicalgia, poor sleep hygiene, depression/anxiety, myofascial pain/spasm with trigger points, obesity, hyperthyroidism, hypothyroidism, generalized deconditioning, treated breast cancer, GERD/gastritis, left shoulder pain, left shoulder partial rotator cuff tear, s/p repair. Treatment appears to have included multiple surgeries, many medications, physical therapy, and injections. Per an AME on 11/1/06, records were reviewed and diagnoses (listed above) were noted. No date for the breast cancer was given. The injured worker was using a Fentanyl patch and Norco for "regional pain", a "chronic pain syndrome". The treating physician reports range from 11/8/12 to 3/13/14. None of those reports address the functional improvement that might have occurred with any medication, and none of those reports address the specific results of taking any medication other than brief discussions of the use of opioids (generally regarding lack of efficacy), and hypnotics. Per the PR-2 of 11/8/12, Oxycodone was ineffective and the injured worker prefers Norco. Pain was severe. The medication list included the medications now under Independent Medical Review other than Abstral. A Fentora trial was initiated. Oxycodone was stopped. Per the PR-2 of 12/2/13, there was a new finding of a renal mass, and a history of uterine cancer. Back pain was increased. The medication list and symptoms were the same as on 3/13/14. Medications were continued. The PR-2 of 3/13/14 appears to be incomplete and missing a page; there are no subjective complaints noted. There was ongoing pain and tenderness in the neck, low back. She was using a cane. There were neurological deficits. Inconsistencies in a prior urine drug screen and use of opioids was noted. Oxycodone was stated to have been trialed and failed. Aciphex was stated to be for "severe gastritis". An in-house, qualitative urine drug

screen was positive for barbiturates and oxycodone. Current medications included Abstral "as needed for severe cancer pain" Aciphex daily, Ativan daily, Elavil at bedtime, Fentanyl 50mcg patch every 48 hours, Lidoderm 5% patch once a day, Metanx twice a day, Percocet 4 times a day, Rozerem at bedtime, Savella daily, and Zanaflex at bedtime. Medications were continued. The guidelines and rationales were not included in the records.

IMR ISSUES, DECISIONS AND RATIONALES

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

Metanx #180: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment in Workers Compensation

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 Foods; FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Metanx is classified as a medical food. 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 possible indications (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 in Metanx nor identified any specific indications for the ingredients in Metanx. Metanx is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Lidoderm Patches #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment in Workers Compensation

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical; Lidocaine, Lidoderm Page(s): 111-113, 57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Chapter, Lidoderm

Decision rationale: Topical Lidocaine (Lidoderm patch) is indicated for post-herpetic neuralgia, according to the manufacturer. The MTUS recommends Lidoderm only for localized peripheral neuropathic pain after trials of "tri-cyclic or SNRI anti-depressants or an anti-epilepsy drug such as Gabapentin or Lyrica". The MTUS recommends against Lidoderm for low back pain or osteoarthritis. There is no evidence in any of the medical records that this injured worker has peripheral neuropathic pain or that she has failed the recommended oral medications prior to a

trial of Lidoderm. There is no evidence in the medical records that Lidoderm has provided specific symptomatic and functional benefit. Lidoderm is not medically necessary based on the MTUS.

Abstral 300mcg #32: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment in Workers Compensation

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mec.

Decision rationale: Abstral is sublingual Fentanyl. The MTUS specifically recommends against the use of transmucosal opioids (see Fentora and Actiq citations above) for non-cancer pain. The treatment in this case appears to be for non-cancer pain. Although the injured worker is stated to have had cancer in the remote past, none of the available reports refer to any of the current chronic pain as anything other than chronic, non-malignant pain. The AME described it as "regional pain" and a "chronic pain syndrome". In addition, there is no 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. None of these aspects of prescribing are in evidence. Abstral is not medically necessary based on the MTUS.

Aciphex 20mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment in Workers Compensation

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain chapter, NSAIDs, GI symptoms and Cardiovascular Risk

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 on record. 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. Co-therapy with an NSAID is not indicated in patients other than those at high risk. This injured worker is not taking NSAIDs. If one were to presume that a patient were to have ongoing, "severe gastritis" lasting for months or years, the treating physician would be expected to change the medication regime at least on a trial basis and to pursue other diagnostic avenues to help determine causation. In this case, there is no evidence of any attempts to determine the cause of symptoms, including minimal attempts to adjust medications. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip,

wrist, and spine fractures; pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on chronic proton pump inhibitors. Aciphex is not medically necessary based on guidelines, lack of sufficient evaluation, and risk of toxicity.