

Case Number:	CM14-0169607		
Date Assigned:	10/17/2014	Date of Injury:	09/08/2005
Decision Date:	12/02/2014	UR Denial Date:	09/15/2014
Priority:	Standard	Application Received:	10/14/2014

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:

The injured worker is a represented employee who has filed a claim for chronic neck, mid back, and low back pain reportedly associated with an industrial injury of September 8, 2005. Thus far, the injured worker has been treated with the following: Analgesic medications; transfer of care to and from various providers in various specialties; and muscle relaxants. In a Utilization Review Report dated September 15, 2014, the claims administrator failed to approve a request for a tramadol-acetaminophen-ondansetron amalgam, partially approved a request for Zanaflex, denied a request for flurbiprofen-ranitidine, and denied a request for a TENS unit with associated supplies. The injured worker's attorney subsequently appealed. In a progress note dated June 9, 2014, the injured worker reported ongoing complaints of neck and low back pain. It was stated that the injured worker was working regular duty as a custodian. The injured worker was given prescriptions for tramadol-acetaminophen, ondansetron in conjunction with Zanaflex, flurbiprofen-ranitidine, and a TENS unit with continued supplies. In an earlier progress note dated April 20, 2014, the attending provider posited that the injured worker was using promethazine as tramadol had previously caused nausea. The injured worker was working, it was again acknowledged. The attending provider posited that the injured worker's pain levels were 10/10 without medications and that ongoing medication consumption was beneficial here. The injured worker was given prescriptions for tramadol-acetaminophen-ondansetron, Zanaflex, and flurbiprofen-ranitidine. It was suggested (but not clearly stated) that the injured worker was using ranitidine for gastric prophylactic purposes as opposed to for actual symptoms of reflux. The injured worker was 44 years old as of the June 9, 2014 office visit, it has been incidentally noted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol/acetaminophen/Ondansetron 100/250/2mg 390 with 3 refills 2: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management section. Page(s): 7-8. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), Ondansetron Medication Guide.

Decision rationale: The MTUS does not address the topic of ondansetron, one of the ingredients in the amalgam. However, pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines do stipulate that an attending provider using a drug for non-FDA labeled purposes has a responsibility to be well informed regarding usage of the same and should, furthermore, furnish compelling evidence to support such usage. The Food and Drug Administration (FDA) notes that ondansetron (Zofran) is indicated in the treatment of nausea and vomiting caused by cancer chemotherapy, radiation therapy, and/or surgery. In this case, however, there was no evidence that the injured worker has had any recent cancer chemotherapy, radiation therapy, and/or surgery. Rather, the attending provider appeared intent on employing ondansetron owing to the issues associated with tramadol-induced nausea. Usage of ondansetron for opioid-induced nausea is not an FDA-approved role for the same. The attending provider did not furnish any compelling injured worker -specific rationale or medical evidence which would offset the unfavorable FDA position on usage of ondansetron to prevent tramadol-induced nausea. Since the ondansetron component of the amalgam is not recommended, the entire amalgam or compound is not recommended. Therefore, the request is not medically necessary.

Zanaflex 4mg #30 with 3 refills: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine-Zanaflex section. Page(s): 66.

Decision rationale: As noted on page 66 of the MTUS Chronic Pain Medical Treatment Guidelines, tizanidine or Zanaflex is FDA approved in management of spasticity but can be employed for unlabeled use for low back pain, as is present here. The attending provider has posited that previous usage of Zanaflex has proven beneficial, as evinced by the injured worker's subjective reports of analgesia with the same and as evinced by the injured worker's successful return to and/or maintenance of regular duty work status with on going Zanaflex usage. Continuing the same is indicated, particularly in light of the fact that the injured worker is having issues tolerating tramadol owing to nausea associated with the usage of the same. Therefore, the request is medically necessary.

Flurbiprofen/Ranitidine #90 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms, and Cardiovascular Risk Topic. Page(s): 68.

Decision rationale: The attending provider indicated in his progress note that he was employing the Flurbiprofen-ranitidine amalgam for gastric prophylaxis purposes, to reduce the likelihood of the injured worker developing any adverse gastrointestinal (GI) issues or symptoms in the future. However, as noted on page 68 of the MTUS Chronic Pain Medical Treatment Guidelines, individuals who are at heightened risk for adverse gastrointestinal events and who would, by implication, qualify for prophylactic usage of proton pump inhibitors. In addition, it is indicated for those who have H2 antagonists, such as ranitidine include those individuals who are aged 65 years of age or greater and are using non-steroidal anti-inflammatory drugs (NSAIDs); who are using multiple NSAIDs, those individuals who have a history of GI bleeding or peptic ulcer disease and are using NSAID; and/or those individuals who are using NSAIDs in conjunction with corticosteroids. In this case, however, the injured worker is 44 years old and there was no mention of the injured worker having any history of prior GI bleeding and/or peptic ulcer disease. The injured worker is not using any corticosteroids and is only using one NSAID, oral Flurbiprofen. The injured worker, thus, is not a prime candidate for prophylactic usage of ranitidine, per page 68 of the MTUS Chronic Pain Medical Treatment Guidelines. Therefore, the request is not medically necessary.

Tens Unit & Supplies (Rental or Purchase): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS (Transcutaneous Electrical Nerve Stimulation).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the Use of TENS Topic. Page(s): 116.

Decision rationale: Based on the attending provider's description of events authorization was seemingly being sought for provision of a TENS unit on a purchase basis with associated supplies. However, as noted on page 116 of the MTUS Chronic Pain Medical Treatment Guidelines, provision of a TENS unit and/or purchase of associated supplies should be predicated on evidence of a favorable outcome during said one-month trial. In this case, however, it did not appear that the injured worker had undergone a successful one-month trial before the request for purchase of the TENS unit and/or associated supplies was made. Therefore, the request is not medically necessary.