

Case Number:	CM13-0035261		
Date Assigned:	12/13/2013	Date of Injury:	03/11/2011
Decision Date:	11/03/2014	UR Denial Date:	09/16/2013
Priority:	Standard	Application Received:	10/16/2013

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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:

According to the medical records, the patient is a 53 year old female who sustained an industrial injury on 3/11/2011. The prior peer review dated 9/16/2013 certified the retrospective requests for Naproxen sodium 550mg #120 and cyclobenzaprine 7.5mg #120; DOS 8/15/2013. The retrospective requests for DOS 8/15/2013 Omeprazole delayed-release 20mg #120, Ondansetron ODT 8mg #30 x 2, Medrox patch #30, Sumatriptan succinate 25mg #9 x2, and Tramadol ER 150mg #90, were non-certified. The medical necessity of the requests was not established. According to the PTP PR-2 dated 5/6/2014, which is handwritten and not entirely legible, the patient is s/p c/s reconstruction. Patient doing well, has stiffness, requesting more PT, + headaches/migraines. On examination, decreased c/s ROM to left, + spasm and tenderness, and no neurological deficits. Medications refilled. C-spine x-rays with flexion/extension indicate solid fusion C4-7, no hardware failure, excellent position. According to the PTP request for authorization report dated 6/14/2014, Naproxen 550 #100, Orphenadrine Citrate ER 100mg #120, Sumatriptan 25mg #9 x2, Ondansetron ODT 8mg #30 x 2, Omeprazole delayed-release 20mg #120, tramadol ER 150mg #90, and Terocin Patch qty 30, are being prescribed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Omeprazole 20mg #120 DOS: 8/15/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

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

Decision rationale: The guidelines state PPIs such as Omeprazole may be indicated for patients at risk for gastrointestinal events, which are: 1) age over 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). However, the medical records do not establish any of these criteria apply to this patient. The medical records do not establish any of these potential significant risk factors apply to this patient. The ODG states PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. The medical records do not document supportive correlating subjective/objective findings documented in a medical report that would establish Omeprazole DR is medically indicated. The medical necessity of Omeprazole DR has not been established. The request is not medically necessary.

Retrospective request for Ondansetron ODT 8mg #60 DOS: 8/15/13: 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, Antiemetics (for opioid nausea)

Decision rationale: According to the Official Disability Guidelines, Ondansetron (Zofran) is not recommended for nausea and vomiting secondary to chronic opioid use. This medication is recommended for acute use as noted, per FDA-approved indications. Ondansetron is a serotonin 5-HT₃ receptor antagonist that is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also approved for postoperative use and acute use is FDA-approved for gastroenteritis. Chronic use of this medication is not recommended. The medical record do not demonstrate this medication is prescribed for its FDA-approved use. The medical records do not establish Ondansetron is appropriate and medically indicated for treatment of this patient. The request is not medically necessary.

Retrospective request for Tramadol Hydrochloride ER 150mg #90, DOS: 8/15/13: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram), Opioids Page(s): 74-96.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line

oral analgesic, it is indicated for moderate to severe pain. The guidelines state continued opioid treatment requires documented pain and functional improvement and response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. The medical records do not establish these requirements have been met. The re-evaluation progress reports do not include quantified pain level nor clinical examination findings. The subjective complaints are unchanged and do not appear to support the need for this opiate nor provide any indication that ongoing use of tramadol ER has been of notable benefit. In addition, the medical records do not document an opioid contract, and other related requirements for opioid management has been met as required by the guidelines. Chronic use of opioids for non-malignant pain is not generally supported. The medical necessity of the request for Tramadol ER has not been established in accordance with the guidelines. The request is not medically necessary.

Retrospective request for Sumatriptan Succinate 25mg #18 DOS: 8/15/13: 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), Head, Imitrex® (sumatriptan), Triptans

Decision rationale: According to the Official Disability Guidelines, Triptans are recommended for migraine sufferers. At marketed doses, all oral Triptans (e.g., Sumatriptan, brand name Imitrex) are effective and well tolerated. The medical records do not include any clinical evidence of migraines. The medical records do not establish this patient has migraine headaches. Furthermore, objective functional improvement with use of Sumatriptan has not been demonstrated. Consequently, this medication would not be indicated or considered medically necessary for this patient. The request is not medically necessary.

Retrospective request for Medrox patches #30 DOS: 8/15/13: 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), Topical Analgesics

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to the CA MTUS guidelines, topical analgesics are considered to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. According to the references, Medrox patch is a product that contains methyl salicylate 5%, menthol 5%, and capsaicin 0.0375%. Per the guidelines, Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The medical records do not establish that to be the case of this patient, as it is documented that she is prescribed oral medications, and is able to tolerate other treatments. The guidelines also state

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. Clinically significant benefit with use of Medrox, such as reduction in pain, improved function and reduction in pain medication use has not been demonstrated. Consequently, Medrox patch is not medically necessary. The request is not medically necessary.