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| Case Number: | CM13-0025622 | | |
| Date Assigned: | 11/20/2013 | Date of Injury: | 09/29/2011 |
| Decision Date: | 01/23/2014 | UR Denial Date: | 08/07/2013 |
| Priority: | Standard | Application Received: | 09/17/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Pulmonary Diseases is licensed to practice in California, Florida, and New York. 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 physician 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 patient is a 45-year-old male who reported an injury on 09/29/2011. The notes indicate that the patient currently has complaints related to neck pain which is aggravated by repetitive motion of the neck and prolonged positioning of the neck as well as pushing, pulling, lifting, forward reaching, and working at or above the shoulder level. This patient was evaluated on 06/18/2013 with examination findings of cervical spine tenderness at the paravertebral muscles and upper trapezium muscles with spasm. Axial loading with compressing testing and Spurling's maneuver were positive and it was painful in restricted cervical range of motion as well as dysesthesia of the left upper extremity. Per clinical notes on this date, the patient was prescribed and dispensed omeprazole delayed release capsules 20 mg, ondansetron ODT tablets 8 mg, cyclobenzaprine 7.5 mg, and tramadol extended release capsules 150 mg as well as Medrox pain relief 120 grams times 2 to be used topically for relief of minor aches and muscle pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

120 Omeprazole DR 20mg: Overturned

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

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

Decision rationale: CA MTUS states that patients at intermediate risk for gastrointestinal events and no cardiovascular disease should consider use of a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily or a medication such as misoprostol (200 \hat{I} ¼g four times daily); or use of a Cox-2 selective agent. Caution is given with long-term use of proton pump inhibitors as studies of use of PPI's show that use for (> 1 year) has increased the risk of hip fracture. The documentation submitted for review indicates that this patient is currently diagnosed with gastro esophageal reflux disease and other GI symptoms related to bloating and gas as well as stomach upset and diarrhea. While there is no indication in the notes of the patient being prescribed an NSAID, the patient's history of gastro esophageal reflux disease supports the recommendation for a proton pump inhibitor. Given the above, the request for 120 omeprazole DR 20 mg is medically necessary and appropriate.

60 Ondansetron ODT 8mg: Upheld

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

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, Ondansetron.

Decision rationale: The CA MTUS/ACOEM Guidelines do not specifically address Ondansetron. The Official Disability Guidelines state Zofran is not recommended for nausea and vomiting secondary to chronic opioid use. Antiemetic is not recommended. Nausea and vomiting is common with the use of opioids and these side effects should diminish over days to weeks of continued exposure. Zofran is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment and has also been FDA-approved for postoperative use. There is a lack of documentation submitted for review indicating that the patient currently suffers from nausea and vomiting. Furthermore, there is no indication that the patient is currently utilizing opioids. Given the above, the request for 60 ondansetron ODT 8 mg is not medically necessary and appropriate.

120 Cyclobenzaprine Hydrochloride 7.5mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

Decision rationale: CA MTUS guidelines states that Cyclobenzaprine (Flexeril \hat{A} ®) is recommended for a short course of therapy. Flexeril is more effective than placebo in the management of back pain; however, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Therefore, treatment should be brief. While the documentation submitted

for review indicates that the patient was evaluated on 06/18/2013 and found to have cervical spine muscle spasms, this medication is recommended only for a short course of therapy. Therefore, the request for 120 cyclobenzaprine hydrochloride 7.5 mg is not medically necessary and appropriate.

2 Prescriptions of Medrox Ointment: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Medrox (methyl salicylate, menthol, capsaicin) ointment - Daily Med

Decision rationale: CA MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. CA MTUS states Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations of Capsaicin are generally available as a 0.025% formulation and a 0.075% formulation. However, 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. CA MTUS states that salicylate topicals are recommended as significantly better than placebo in chronic pain. While the documentation submitted for review indicates that the patient is currently prescribed topical Medrox ointment for the treatment of minor aches and muscle pain, the guidelines do not support the recommendation for the use of Medrox as capsaicin is contained within Medrox at a 0.0375% formulation. The guidelines do support the recommendation for the use of methyl salicylate topicals; however, the current concentration of capsaicin in Medrox ointment has no demonstrated indication that this increase in the formulation over a 0.025% formulation provides any further efficacy. Given the above, the request for 2 prescription of Medrox ointment is not medically necessary and appropriate.