

Case Number:	CM14-0136553		
Date Assigned:	09/03/2014	Date of Injury:	09/12/2011
Decision Date:	09/30/2014	UR Denial Date:	07/30/2014
Priority:	Standard	Application Received:	08/25/2014

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 Physical Medicine and Rehabilitation 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 patient is a 55-year-old female with a date of injury of 09/12/2011. The listed diagnoses per [REDACTED] are: 1. Degeneration of cervical intervertebral disk. 2. Cervical disk displacement. 3. Cervical radiculitis. According to the earliest progress report provided for review dated 03/04/2014, the patient presents with neck and right shoulder pain that radiates into the right hand. The patient describes the neck pain as on and off and throbbing sensation, and the headache becomes worse with extension. It was noted patient is currently taking multiple medication with no adverse effects, and her pain is rated as 6/10. Examination of the cervical spine revealed slight tenderness in the right trapezius on axial compression and tenderness to palpation in the trapezius area. "Muscle spasm is not noted." Cervical spine ROM is restricted on all planes. This is a request for diclofenac sodium ER 100 mg, omeprazole 20 mg #120, ondansetron 8 mg #30, cyclobenzaprine HCl 7.5 mg, tramadol 150 mg #90, and sumatriptan succinate 25 mg. Utilization review denied the request on 07/30/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

120 Diclofenac Sodium ER (Voltaren SR) 100mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain , Anti-inflammatory medications , NSAIDs Page(s): 60,61, 22, 67, 68.

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. The physician is requesting a refill of diclofenac sodium ER 100 mg #120. The MTUS Guidelines page 22 supports the use of NSAIDs for chronic low back pain as a first line of treatment. Review of the medical file indicates the patient has been taking Diclofenac since 2013. Progress reports 08/07/2013 through 03/04/2014 were reviewed and provides no discussion regarding this medication's efficacy. MTUS page 60 requires documentation of pain assessment and functional changes when medications are used for chronic pain. 120 Diclofenac Sodium ER (Voltaren SR) 100mg is not medically necessary.

120 Omeprazole 20mg: Upheld

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

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

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. The treater is requesting a refill of omeprazole 20 mg #120. Review of the medical file indicates that the patient has been prescribed this medication concurrently with Voltaren since 08/07/2013. The MTUS Guidelines page 68 and 69 state, "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors." MTUS recommends determining risk for GI events before prescribing prophylactic PPI or omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. However, the treater does not discuss any GI risk issues. The patient has been taking NSAID on a long term basis, but the treater does not document dyspepsia or any GI issues. Routine prophylactic use of PPI without documentation of gastric issues is not supported by the guidelines without GI-risk assessment. 120 Omeprazole 20mg is not medically necessary.

Ondansetron 8mg #30: 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) ODG guidelines have the following regarding Zofran (Ondansetron):Not recommended for nausea and vomiting secondary to chronic opioid use. See Antiemetics (for opioid nausea).On Antiemetics for opioid nausea:Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks

of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005)Promethazine (Phenergan®): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus).Ondansetron (Zofran®): This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. See also Nabilone (Cesamet®), for chemotherapy-induced nausea, but not pain.

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. The treater is requesting ondansetron 8 mg #30. There is no rationale provided for prescribing this medication. The MTUS and ACOEM Guidelines do not discuss Zofran, however, ODG Guidelines has the following regarding antiemetic, "not recommended for nausea and vomiting secondary to chronic opiate use. Recommended for acute use as noted below for FDA-approved indications. Ondansetron (Zofran), this drug is a serotonin 5-HT3 receptor antagonist. It is FDA approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA approved for postoperative use. In this case, the treater has been prescribing Zofran since 08/07/2013 and ODG Guidelines do not support the use of Ondansetron for long term use. Ondansetron 8mg #30 is not medically necessary.

Cyclobenzaprine HCL 7.5mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available) Page(s): 64.

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. This patient presents with neck and right shoulder pain that radiates into the right hand. The treater is requesting a refill of cyclobenzaprine HCl 7.5 mg. The MTUS Guidelines page 64 states, "Cyclobenzaprine is recommended for short course of therapy. Limited, mixed evidence does not allow for recommendation for chronic use." Review of the medical file indicates the patient has been prescribed this medication since 2013. Furthermore, most recent

progress report from 03/04/2014 specifically states, "Muscle spasms not noted."
Cyclobenzaprine HCL 7.5mg is not medically necessary.

Tramadol 150mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
CRITERIA FOR USE OF OPIOIDS Page(s): 88-89.

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. This patient presents with neck and right shoulder pain that radiates into the right hand. The treater is requesting a refill of tramadol 150 mg #90. Utilization review denied the request stating "there is no first line analgesic that was utilized." It appears that this is an initial request for Tramadol as there are no prior discussions of this medication. The MTUS guidelines pg 76-78, criteria for initiating opioids recommends that reasonable alternatives have been tried, consider patient's likelihood of improvement, likelihood of abuse, etc. MTUS goes on to state that baseline pain and functional assessments should be made. Once the criteria have been met a new course of opioids may be tried at that time. The treater does not provide baseline pain or any functional assessments to necessitate a start of a new opioid. Tramadol 150mg #90 is not medically necessary.

Sumatripton Succinate 25mg: 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) ODG guidelines have the following regarding Triptans for headaches: Recommended for migraine sufferers. At marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex[®]) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. A poor response to one triptan does not predict a poor response to other agents in that class. (Adelman, 2003) (Ashcroft, 2004) (Belsey, 2004) (Brandes 2005) (Diener, 2005) (Ferrari, 2003) (Gerth, 2001) (Mannix, 2005) (Martin 2005) (McCrary, 2003) (Moschiano, 2005) (Moskowitz, 1992) (Sheftell, 2005) Rizatriptan (Maxalt[®]) has demonstrated, in a head-to-head study, higher response rates and a more rapid onset of action than sumatriptan, together with a favorable tolerability profile. Meta-analyses of double-blind placebo-controlled studies have confirmed the superior efficacy of rizatriptan. (Gäbel, 2010) While the Maxalt brand of rizatriptan therapy is more expensive than other triptans, the economic value of rizatriptan depends on the payer's perspective, as the greatest savings can be expected to be achieved in terms of reduced migraine-related loss of work productivity compared with less effective treatments. (Mullins, 2007) (McCormack, 2005) According to the FDA Orange Book, equivalent generics have been approved for Maxalt, so generic rizatriptan would be recommended. (FDA, 2013) See also Migraine pharmaceutical treatment.

Decision rationale: This patient presents with neck and right shoulder pain that radiates into the right hand. The treater is requesting sumatriptan succinate 25 mg for patient's continued headaches. Utilization review denied the request stating "guidelines only recommend this medication for patients with migraines." ODG guidelines have the following regarding triptans for headaches: "Recommended for migraine sufferers. At marketed doses, all oral triptans (e.g., Sumatriptan, brand name Imitrex are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients." As medical records document, this patient has "headaches with extension." In this case, the patient suffers from cervicogenic headaches and not migraines for which this medication is indicated for. Sumatripton Succinate 25mg is not medically necessary.