

Case Number:	CM14-0047995		
Date Assigned:	08/08/2014	Date of Injury:	05/10/2011
Decision Date:	12/18/2014	UR Denial Date:	03/19/2014
Priority:	Standard	Application Received:	04/15/2014

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 Neurology, has a subspecialty in Neuromuscular Medicine, and is licensed to practice in New Jersey. 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 man who sustained a work-related injury on May 10, 2011. Subsequently, he developed chronic neck and low back pain. According to a progress report dated July 2, 2013, the patient reported persistent pain in the low back and continued symptoms in the cervical spine. Examination of the cervical spine revealed tenderness over the cervical paravertebral muscles, pain with terminal motion, and positive axial loading compression and Spurling's maneuver. There was painful and restricted cervical range of motion. There was dysesthesia at the C5 and C6 dermatomes. Examination of the lumbar spine revealed tenderness from the mid to distal lumbar segments. There was pain with terminal motion. Seated nerve root test was positive. There was dysesthesia at the L5 and S1 dermatomes. The provider requested authorization for Naproxen Sodium , Cyclobenzaprine Hydrochloride, Odansetron ODT, Omeprazole Delayed-Release, Tramadol Hydrochloride , and Sumatriptan Succinate.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Sodium 550 mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NON SELECTIVE NSAIDS Page(s): 72.

Decision rationale: Naproxen (Naprosyn): delayed release (EC-Naprosyn), as Sodium salt (Anaprox, Anaprox DS, Aleve [otc]) Generic available; extended-release (Naprelan): 375 mg. Different dose strengths and formulations of the drug are not necessarily bioequivalent. Dosing Information: Osteoarthritis or ankylosing spondylitis: Dividing the daily dose into 3 doses versus 2 doses for immediate-release and delayed-release formulations generally does not affect response. Morning and evening doses do not have to be equal in size. The dose may be increased to 1500 mg/day of naproxyn for limited periods when a higher level of analgesic/anti-inflammatory activity is required (for up to 6 months). Naprosyn or naproxyn: 250-500 mg PO twice daily. Anaprox: 275-550 mg PO twice daily. (total dose may be increased to 1650 mg a day for limited periods). EC-Naprosyn: 375 mg or 500 mg twice daily. The tablet should not be broken, crushed or chewed to maintain integrity of the enteric coating. Naprelan: Two 375 mg tablets (750 mg) PO once daily or two 500 mg tablets (1000 mg) once daily. If required (and a lower dose was tolerated) Naprelan can be increased to 1500 mg once daily for limited periods (when higher analgesia is required). Pain: Naprosyn or naproxyn: 250-500 mg PO twice daily. The maximum dose on day one should not exceed 1250 mg and 1000 mg on subsequent days. Anaprox: 275-550 mg PO twice daily. The maximum dose on day one should not exceed 1375 mg and 1100 mg on subsequent days. Extended-release Naprelan: Not recommended due to delay in absorption. (Naprelan Package Insert)> There is no documentation of the rationale behind the long-term use of Naproxen. NSAID should be used for the shortest duration and the lowest dose. There is no documentation from the patient file that the provider titrated Naproxen to the lowest effective dose and used it for the shortest period possible. Naproxen was used without clear documentation of its efficacy. Furthermore, there is no documentation that the provider followed the patient for NSAID adverse reactions that are not limited to GI side effect, but also may affect the renal function. Therefore, the request for Naproxen 550MG #120 is not medically necessary.

Cyclobenzaprine Hydrochloride Tablets 7.5 mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Pain Last Updated 1/7/14 - Muscle Relaxants

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to MTUS guidelines, Cyclobenzaprine a non sedating muscle relaxant is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic spasm and pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The guidelines do not recommend to be used for more than 2-3 weeks. The patient in this case does not have clear significant functional improvement with prior use of muscle relaxants. There is no indication of recent evidence of spasm. Cyclobenzaprine was previously used without clear documentation of efficacy. Therefore, the request for Cyclobenzaprine Hydrochloride Tablets 7.5 Mg Qty: 120 is not medically necessary

Ondansetron ODT Tablets 8 mg #30 Refills x2: 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) Last Updated 1/7/14: Pain - Ondansetron Mosby's Drug Consult Zofran/Ondansetron

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Moon, Y. E., et al. (2012). "Anti-emetic effect of ondansetron and palonosetron in thyroidectomy: a prospective, randomized, double-blind study." Br J Anaesth 108(3): 417-422.

Decision rationale: Ondansetron is an antiemetic drug following the use of chemotherapy. Although MTUS guidelines are silent regarding the use of Ondansetron, there is no documentation in the patient's chart regarding the occurrence of medication induced nausea and vomiting. Therefore, the prescription Ondansetron 8MG #30 is not medically necessary.

Omeprazole Delayed-Release Capsules 20 mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs - GI Symptoms and Cardiovascular Risk.

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

Decision rationale: According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAID to develop gastroduodenal lesions. There is no documentation that the patient have GI issue that requires the use of prilosec. There is no documentation in the patient's chart supporting that he is at intermediate or high risk for developing gastrointestinal events. Therefore, Omeprazole 20mg#120 is not medically necessary.

Tramadol Hydrochloride E 150 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

Decision rationale: According to MTUS guidelines, Ultram (Tramadol) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single

pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. In this case, there is no clear evidence of objective and recent functional and pain improvement from previous use of narcotics. There is no recent objective documentation of pain severity level to justify the use of narcotics in this patient. There is no clear documentation of the efficacy/safety of previous use of opioids. There is no recent evidence of objective monitoring of compliance of the patient with her medications. Therefore, the prescription of Tramadol Hydrochloride ER 150# 90 is not medically necessary

Sumatriptan Succinate Tablets 25 mg #9, Refills x2: 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): Head Procedure Summary, Last Updated 11/18/13

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Balaguer-Fernandez, C., et al. (2008). "Sumatriptan succinate transdermal delivery systems for the treatment of migraine." J Pharm Sci 97(6): 2102-2109.

Decision rationale: Sumatriptan Succinate is a treatment for migraine headache. The patient's record did not document a clear history of headache or migraine induced and occurring during the course of his employment or prior to that. There is no recent documentation of migraine headaches. The patient headaches are most likely related to the patient cervical condition. Although MTUS guidelines are silent regarding the use of Sumatriptan Succinate, there is no specific documentation to support the need for this medication. Therefore, the request for Sumatriptan Succinate Tablets 25 mg #9, Refills x 2 is not medically necessary.