MAXIMUS Federal Services

Case Number:	CM13-0026423		
Date Assigned:	04/25/2014	Date of Injury:	11/14/2011
Decision Date:	07/14/2014	UR Denial Date:	07/22/2013
Priority:	Standard	Application Received:	09/19/2013

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 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 patient is a 45-year-old male who has submitted a claim for cervicalgia, lumbago, hand pain, and right shoulder arthroplasty associated with an industrial injury date of 11/14/2011. Medical records from 2012 to 2013 were reviewed. The patient complained of right shoulder pain associated with numbness, tingling, weakness, cramping, and spasms. The patient likewise complained of constant neck pain associated with headache and nausea. There was intermittent pain at both writs that resulted in difficulty with dressing, sleeping, taking a bath, carrying objects, among others. Physical examination revealed tenderness and limitation of motion of the right shoulder. Axial loading compression test was positive. There was weakness of the right shoulder flexor and abductor. Reflexes were normal and sensation was diminished at the right upper extremity. An EMG/NCV of the bilateral upper extremities, dated January 21, 2013, revealed moderately severe bilateral carpal tunnel syndrome. There was no evidence of cervical radiculopathy. Treatment to date has included right shoulder arthroscopy on May 2012, right shoulder total arthroplasty on August 16, 2013; physical therapy, and medications.Utilization review from 07/22/2013 denied the retrospective requests for naproxen, omeprazole,ondansetron, cyclobenzaprine, sumatriptan succinate, Medrox ointment, tramadol, compound keto/lidoc /cap/tram, and compound flur/cyclo/caps/lid due to lack of documentation and reasoning to support such treatment.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE NAPROXEN SODIUM PROVIDED ON 5/28/13: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46.

Decision rationale: The Chronic Pain Medical Treatment guidelines state that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. In this case, patient complained of right shoulder pain associated with weakness. He reported pain relief upon intermittent intake of naproxen. Progress report, dated May 28, 2013, prescribed Naproxen 550 mg, #120 for pain and inflammation. The guideline criteria were met. Therefore, the requested Naproxen provide on May 28, 2013 was medically necessary.

RETROSPECTIVE OMEPRAZOLE DELAYED RELEASE PROVIDED ON 5/28/13: Overturned

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 Page(s): 68.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors: age > 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed with proton pump inhibitors (PPI). In the case, patient had symptoms of acid reflux and gastrointestinal upset associated with naproxen intake. Patient reported symptomatic relief upon intake of Omeprazole. Progress report, dated May 28, 2013, cited prescription for Omeprazole delayed-release capsules 20mg, #120. The guideline criteria were met. Therefore, the requested Omeprazole Delayed Release provided On 5/28//13 was medically necessary.

RETROSPECTIVE ONDANSETRON ODT PROVIDED ON 5/28/13: 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 Chapter, Antiemetics (for opioid nausea) and Ondansetron.

Decision rationale: The ODG states that Ondansetron is indicated for prevention of nausea and vomiting caused by cancer chemotherapy, radiation therapy, and surgery. In this case, patient

complained of nausea associated with headaches and cervical spine pain. However, the guideline indicates that this is only recommended for prevention of nausea related to chemotherapy, radiotherapy, and surgery. The guideline criteria were not met. Therefore, the requested Ondansetron ODT provided on 5/28/13 was not medically necessary.

RETROSPECTIVE CYCLOBENZAPRINE HYDROCHLORIDE PROVIDED ON 5/28/13: Overturned

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

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

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In this case, patient was prescribed with Cyclobenzaprine since May 2013. Physical examination findings revealed muscle spasms at the paracervical and paralumbar areas. The patient was also educated of its short-term duration of treatment. The guideline criteria were met. Progress report, dated May 28, 2013, cited prescription for Cyclobenzaprine hydrochloride tablets 7.5mg, #120. Therefore, the requested Cyclobenzaprine Hydrochloride provided on 5/28/13 was medically necessary.

RETROSPECTIVE SUMATRIPTAN SUCCINATE PROVIDED ON 5/28/13: Overturned

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 Other Medical Treatment Guideline or Medical Evidence: FDA, Sumatriptan.

Decision rationale: The FDA states that Sumatriptan is indicated for the acute treatment of migraine attacks with or without aura in adults. Sumatriptan is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. In this case, the patient was noted to have headaches, migrainous in nature, associated with chronic cervical pain. The patient reported relief of symptoms upon intake of Sumatriptan, which allowed him to perform daily activities. Progress report, dated May 28, 2013, cited prescription for Sumatriptan Succinate tablets 25mg, #9 x 2. Therefore, the requested Sumatriptan Succinate provided on 5/28/13 was medically necessary.

RETROSPECTIVE MEDROX OINTMENT FOR DATE OF SERVICE 5/28/13: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Topical Salicylates.

Decision rationale: Medrox ointment is a compounded medication that includes 5% methyl salicylate, 20% menthol, and 0.0375% capsaicin. The Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain. According to the guideline, topical salicylate is significantly better than placebo in chronic pain. Regarding the Menthol component, the MTUS guidelines do not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. Moreover, any compounded product that contains at least one drug that is not recommended is not recommended. In this case, patient complains of chronic cervical pain radiating to bilateral upper extremities. However, this medication contains drug classes that are not recommended. The guidelines do not recommend the use of compounded topical products that contain at least one drug class that is not recommended. Therefore, the requested Medrox Ointment provided on 5/28/13 was not medically necessary.

RETROSPECTIVE TRAMADOL HYDROCHLORIDE ER PROVIDED ON 5/28/13: 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 Page(s): 78.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. he monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. The medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects associated with tramadol use. The guidelines require clear and concise documentation for ongoing management. Moreover, patient reported benefits upon intake of naproxen. It is unclear why an addition of opioid was necessary in this case. Therefore, the requested Tramadol Hydrochloride ER provided on 5/28/13 was not medically necessary.

RETROSPECTIVE COMPOUND KETO/LIDOC/CAP/TRAM PROVIDED ON 6/21/13: Upheld

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

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

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that there is little to no research as for the use of Ketoprofen in compounded products. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. Tramadol is indicated for moderate to severe pain. In this case, there is no documented rationale concerning the need for multiple topical compounded products. Furthermore, guidelines state that any compounded product with a drug class that is not recommended is not recommended. The requested drug has active ingredients that are not recommended for topical use. Therefore, the requested compound keto/lidoc/cap/tram provided on 6/21/13 is not medically necessary.

RETROSPECTIVE COMPOUND FLUR/CYCLO/CAPS/LID PROVIDED ON 6/21/13: 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 Page(s): 111-113.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that there is little to no research as for the use of Flurbiprofen in compounded products. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. Likewise, Cyclobenzaprine has no evidence for use as a topical product. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. In this case, there is no documented rationale concerning the need for multiple topical compounded products. Furthermore, guidelines state that any compounded product with a drug class that is not recommended is not recommended. The requested drug has active ingredients that are not recommended for topical use. Therefore, the requested compound flur/cyclo/caps/lid provided on 6/21/13 was not medically necessary.