

Case Number:	CM14-0037206		
Date Assigned:	07/25/2014	Date of Injury:	06/09/2011
Decision Date:	12/17/2014	UR Denial Date:	03/06/2014
Priority:	Standard	Application Received:	03/27/2014

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 Family Medicine and is licensed to practice in 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 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 members injury was reportedly sustained on or about 9Jun11. The diagnoses listed as being treated included the following: Lumbar discopathy, DJD of the L hip and L shoulder impingement with partial rotator cuff tear. No plain film, CT or MRI reports are available for review, the mechanics of the injury are not detailed. The note from 17Sep13 indicated that the members issues with the injured workers L shoulder, lumbar spine and L hip were unchanged. He is reported to have been battling chronic symptomatology for a prolonged time. There is no quantification of the pain on an analogue scale and there is no mention of medication being used. The treatment plan was to be PT for the L hip, referral to a shoulder specialist and a trial of TENS. The worker is reported to be working full time without limitations and was to continue to do so. The next available record dates from 26Feb14 which essentially represents an RFA for the following: Naproxen 550mg bid, 100, for inflammation and pain, Cyclobenzaprine 7.5mg q8h, 120, up to 3 times per day for acute spasm in short courses only, Ondansetron 8mg bid prn 30 X 2 reported by the provider for nausea associated with headaches resulting from chronic cervical spine pain, Omeprazole 20mg bid, 120, this was to be taken in conjunction with the NSAID to protect the stomach, in the RFA the provider reported that the patient described a history of some epigastric pain and stomach upset while using NSAID's in the past for chronic pain, Tramadol ER 150mg qd 90, prn for pain, the provider indicated that the member suffered from an acute exacerbation of severe pain related to a chronic orthopedic condition and had benefited in the past for previous acute flare-ups and finally Terocin Patch 30 to assist the patient with treatment of mild to moderate acute or chronic aches or pain. This IMR is to review the Non-Certification for all of the above medications from the 26Feb14 RFA.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Sodium tablets 550MG #100: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 2 Page(s): 67-73.

Decision rationale: Naproxen is a member of the NSAID class of agents. NSAID's have a place as second line agents after Acetaminophen for acute exacerbations of chronic pain. They are recommended to be taken at the lowest dose for the shortest period of time. NSAID's appear to be superior to Acetaminophen for moderate to severe pain with osteoarthritis but a Cochrane review suggested they were no better than any other agent for low back pain and showed inconsistent evidence in neuropathic pain. They pose serious risks to the gastro-intestinal track for bleeding as well as negatively impact renal function and raise the risks for acute cardiovascular events. Relief of pain is generally temporary and measures of lasting benefit should consider the impact of pain relief on improvements in function and increase in activity, sleep quality and side effects. The RFA from 26Feb14 appears to be based on the examination accomplished 17Sep13. At that time there were no reports on medication usage current or previous or any trial of first line agents. Additionally per the request for Omeprazole the member reported having had epigastric pain and stomach upset while using NSAID's in the past. The request is based on an examination over 60 days prior, there is an absence of evidence of a functional assessment or detail on the results or prior use of a first line agent as well as side effects from past use of NSAID's. The Naproxen Sodium tablets 550MG #100 is not medically necessary.

Cyclobenzaprine Hydrochloride Tablets 75 mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 2 Page(s): 60, 63.

Decision rationale: The general class of agents used as muscle relaxants are generally recommended for short term use only and with caution due to side effects. They represent second line agents for patients with exacerbations of back pain. There is no evidence that they will show a benefit beyond that of NSAID's or that there is any additional benefit in combination with NSAID's. Efficacy appears to diminish with time and maximal benefit appears to decline after approximately 4 days. Sedation is the most common class effect and needs to be considered in those having to drive or operate heavy equipment. Records indicated the member was working full time without restrictions. There is no mention of an acute exacerbation of pain. The request appears to be based on an examination well in excess of 60 days in the past. No additional benefit would be anticipated in combination with Naproxen and in this case we had no evidence

that the Naproxen had been trialed yet. Medical necessity cannot be supported. The Cyclobenzaprine Hydrochloride Tablets 75 mg #120 is not medically necessary.

Omeprazole Delayed Release Capsules 20 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 Part 2 Page(s): 68. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Manufacturers FDA defined product insert

Decision rationale: Omeprazole has an FDA approved indication for gastric ulcer prophylaxis that is NSAID associated. In this particular situation we have no evidence that first line medications had failed. As well the RFA indicated that the member had previously reported GI intolerance with NSAID use. A Cochrane review suggested NSAID's were no better than any other agent for low back pain and showed inconsistent evidence in neuropathic pain. We have no indication of functional improvement for the member's complaints with the use of NSAID's. The last physical review associated with the request is well over 60 days prior, we have no documentation of the current status for the members pain or response to first line agents or a trial of NSAID's. In light of the reported past history of GI intolerance, lack of evidence for the medical necessity for the use of Naproxen the Non-Certification for the RFA for Omeprazole is supported based on the Non-Certification for use of Naproxen. Therefore, Omeprazole Delayed Release Capsules 20 mg # 120 is not medically necessary.

Ondansetron ODT tablets 8mg #30 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain Procedure Summary

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: Manufacturers FDA defined product insert

Decision rationale: Ondansetron has FDA approval for use in N/V prevention that is chemo-related, post-op, or associated with Radiotherapy (XRT). There is no indication that the member had issues with nausea at the last examination dated 17Sep13. The listed diagnoses being treated included the L shoulder impingement syndrome, DJD of the L hip and Lumbar discopathy. The report in the RFA for nausea associated with headaches emanating from chronic cervical pain is, to say the least, confusing. Should there indeed be nausea as a result of the neck pain it still represents an off label use of the medication and cannot be supported. To assess for medical necessity there would need to have been a documented evaluation of the cervical spine that indicated a history confirming recurrent headache associated with nausea sufficient to warrant treatment. The Non-Certification for Ondansetron is upheld.

Tramadol Hydrochloride ER 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 Part 2
Page(s): 11, 60, 74-81.

Decision rationale: The notes for the most recent documented examination were well in excess of 60 days old and all recorded issues were documented as chronic and unchanged. They did not indicate any acute exacerbation of pain. Opioids are not recommended as first line agents for analgesia. For analgesia acetaminophen and NSAID's are considered to be our initial agents of choice. For short term relief opioids can be efficacious. Tramadol has been found to provide pain relief but not functional improvement. However this class of agent is associated with significant risks. These risks include tolerance, hyperalgesia and abuse. It is estimated that chronic use is associated with a risk for substance use disorder of between 36 and 56%. There is no evidence for long term benefit or improvement in function. Rather than pain, consideration of level of functioning, quality of life and activities of daily living should be evaluated. Considering that reports of the members pain are well over 60 days prior to the request, that symptoms were reported to have remained unchanged and that the member remained at work full time with no restrictions there is no support for medical necessity for the use of this medication. The Ondansetron ODT tablets 8mg #30 with 2 refills is not medically necessary.

Terocin Patch #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 2
Page(s): 111-112.

Decision rationale: Terocin is a combination of both Lidocaine and Menthol. Menthol has not been evaluated as efficacious by the FDA and where a compound contains an agent that is not recommended the compound is not recommended. Additionally the primary indication for Lidocaine when used as a patch is for neuropathic pain after use of a trial of first line agents such as antidepressants or anti-epilepsy drugs. We are dealing in this situation with chronic pain (nociceptive) rather than neuropathic pain. When used as a cream rather than a patch Lidocaine is primarily being used as an analgesic. Per guidelines Lidocaine is not recommended for non-neuropathic pain and has not been shown to be more effective than placebo. There is no evidence that other first or second line medications had failed. With these caveats this product cannot be supported. The Terocin Patch #30 is not medically necessary.