

Case Number:	CM14-0180419		
Date Assigned:	11/05/2014	Date of Injury:	09/11/2012
Decision Date:	12/10/2014	UR Denial Date:	10/07/2014
Priority:	Standard	Application Received:	10/30/2014

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 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 worker is a 41 year old male who was injured on 9/11/2012 after falling off of a ladder. He was diagnosed with a closed calcaneus (right foot/ankle) fracture and ankle/foot pain. He was treated with reconstructive surgery, physical therapy and various oral and topical medications. On 9/17/2014, the worker was seen by his orthopedic physician complaining of pain, although slightly better than the last office visit. No report on medication use, pain levels, or functional capacity was included in the progress note. Physical findings of the right ankle included mild swelling and tenderness of the lateral aspect of the calcaneus and normal sensation. A review of the prior x-ray showed that the fracture had healed. He was then recommended he continue his medications and add on topical Diclofenac/Lidocaine. A review of previous recommendations by this physician to this worker revealed that on 7/30/14, he was recommended Orphenadrine /Caffeine, Gabapentin/Pyridoxine, Omeprazole/Flurbiprofen, Flurbiprofen/Cyclobenzaprine/ Menthol, Keratek, and Hydrocodone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orphenadrine/Caffeine 50/10mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

Decision rationale: The MTUS Guidelines state that using muscle relaxants for muscle strain may be used as a second-line option for short-term treatment of acute exacerbations of chronic pain, but provides no benefit beyond NSAID use for pain and overall improvement, and are likely to cause unnecessary side effects. Efficacy appears to diminish over time, and prolonged use may lead to dependence. In the case of this worker, there was evidence that the worker had been using this medication leading up to this request; however, there was no documented evidence that he was directly receiving any benefit from it as this was not included in the documents provided for review. Also, as any muscle relaxant is not recommended for chronic use, the Orphenadrine is not medically necessary. Therefore, this request is not medically necessary.

Gabapentin/Pyridoxine 250/10mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22.

Decision rationale: The MTUS Guidelines state that Antiepilepsy drugs (or anti-convulsants) are recommended as first line therapy for neuropathic pain as long as there is at least a 30% reduction in pain. If less than 30% reduction in pain is observed with use, then switching to another medication or combining with another agent is advised. Documentation of pain relief, improvement in function, and side effects is required for continual use. Preconception counseling is advised for women of childbearing years before use, and this must be documented. The worker in this case had been taking gabapentin prior to this request for continuation. However, at the time of the request, there was no documented evidence of functional or pain-reducing benefit directly related to his gabapentin use. Also, there was no physical objective evidence of neuropathic pain related to his injury. Therefore, the gabapentin/pyridoxine is not medically necessary.

Omeprazole/Flurbiprofen 10/100mg #60: Upheld

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

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

Decision rationale: The MTUS Guidelines state that NSAIDs (non-steroidal anti-inflammatory drugs) may be recommended for osteoarthritis as long as the lowest dose and shortest period is used. The MTUS also recommends NSAIDs for short-term symptomatic use in the setting of back pain if the patient is experiencing an acute exacerbation of chronic back pain if

acetaminophen is not appropriate. NSAIDs are not recommended for neuropathic pain, long-term chronic pain, and relatively contraindicated in those patients with cardiovascular disease, hypertension, kidney disease, at risk for gastrointestinal bleeding. In the case of this worker, there was no documented evidence of functional benefit directly related to this medication. Also, NSAIDs such as Flurbiprofen are not indicated for chronic use due to their side effect profiles. Also, a combination with a proton-pump-inhibitor is not medically necessary as there was no evidence that the worker was at an intermediate or high risk for gastrointestinal events. Therefore, due to the above reasons collectively, the omeprazole/Flurbiprofen is not medically necessary.

Hydrocodone/APAP/Ondansetron 10/300/2mg #40: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Anti-Emetic use for Opioid-Related Nausea, Zofran

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines state that opioids may be considered for moderate to severe chronic pain as a secondary treatment, but require that for continued opioid use, there is to be ongoing review and documentation of pain relief, functional status, appropriate medication use with implementation of a signed opioid contract, drug screening (when appropriate), review of non-opioid means of pain control, using the lowest possible dose, making sure prescriptions are from a single practitioner and pharmacy, and side effects, as well as consultation with pain specialist if after 3 months unsuccessful with opioid use, all in order to improve function as criteria necessary to support the medical necessity of opioids. Long-term use and continuation of opioids requires this comprehensive review with documentation to justify continuation. The MTUS is silent on the use of Zofran. The ODG states that Ondansetron (Zofran) is not recommended for nausea and vomiting secondary to chronic opioid use and is only approved for use in chemo-therapy induced pain or malignancy-induced pain. Antiemetic's in general, as also stated in the ODG, are not recommended for nausea related to chronic opioid use, but may be used for acute short-term use (less than 4 weeks) as they have limited application for long term use. Nausea tends to diminish over time with chronic opioid use, but if nausea remains prolonged, other etiologies for the nausea must be evaluated for. Also there is no high quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. In the case of this worker, who had been taking a combination product (hydrocodone/APAP/Ondansetron), there was no documented review found in the progress note at the time of the request and particularly no evidence of functional benefit directly related to this medication. Also, there was no evidence found in the documents provided suggesting the worker had nausea which might have allowed the worker to consider this worker an exception to the guidelines on the matter of Ondansetron use. Therefore, the hydrocodone/APAP/Ondansetron is not medically necessary.

Keratek gel 4 oz.: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate, Topical Page(s): 139.

Decision rationale: Keratek gel is a topical analgesic which included the active ingredients, menthol and methyl salicylate. The MTUS Chronic Pain Treatment Guidelines state that topical salicylates are significantly better than placebo in chronic pain, and are considered recommended. However, in order to justify continuation, evidence of functional benefit needs to be present. In the case of this worker, who had been using Keratek for at least months leading up to this request, there was no documented report on how this particular medication was influencing his overall function or pain levels directly, which is required for continuation. Therefore, the Keratek gel is not medically necessary.

Flurbiprofen 20%, Cyclobenzaprine 10%, Menthol 4% cream 180 gm.: Upheld

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

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

Decision rationale: The MTUS Chronic Pain Guidelines state that topical analgesics are generally considered experimental as they have few controlled trials to determine efficacy and safety currently. Specifically muscle relaxants in topical form are not recommended due to their lack evidence. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In the case of this worker who had been taking a combination product which included Flurbiprofen, cyclobenzaprine, and menthol, the entire topical product will be considered medically unnecessary due to a muscle relaxant being an ingredient. Also, there was no documented evidence of functional benefit related to its use. Therefore, this request is not medically necessary.

Diclofenac/Lidocaine 3%/5% 180mg: Upheld

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

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

Decision rationale: The MTUS Chronic Pain Guidelines state that topical analgesics are generally considered experimental as they have few controlled trials to determine efficacy and safety currently. Topical NSAIDs, specifically, have some data to suggest it is helpful for osteoarthritis and tendinitis for at least short periods of time, but there are no long-term studies to help us know if they are appropriate for treating chronic musculoskeletal pain. Topical NSAIDs

have not been evaluated for the treatment of the spine, hip, or shoulder. Although some topical analgesics may be appropriate for trial as a secondary agent for neuropathic pain after trials of oral therapies have been exhausted, topical NSAIDs are not recommended for neuropathic pain. The only FDA-approved topical NSAID currently is Voltaren gel (diclofenac). Ketoprofen is not currently one of the topical NSAIDs available that is FDA approved, and it has a high incidence of photocontact dermatitis. All topical NSAID preparations can lead to blood concentrations and systemic effect comparable to those from oral forms and caution should be used for patients at risk, including those with renal failure and hypertension. The MTUS Guidelines for Chronic Pain state that topical lidocaine is not a first-line therapy for chronic pain, but may be recommended for localized peripheral neuropathic pain after there has been evidence of a trial of first-line therapy (including tri-cyclic, SNRI anti-depressants, or an AED such as gabapentin or Lyrica). Topical lidocaine is not recommended for non-neuropathic pain as studies showed no superiority over placebo. In the case of this worker, he was recommended a combination product which included diclofenac and lidocaine, both. The documentation provided for review did not include sufficient subjective or objective physical examination evidence that his pain was neuropathic in nature, which would be required before considering lidocaine. Therefore, the entire product will be considered medically unnecessary.