

Case Number:	CM14-0157636		
Date Assigned:	09/30/2014	Date of Injury:	05/01/2012
Decision Date:	12/18/2014	UR Denial Date:	09/15/2014
Priority:	Standard	Application Received:	09/25/2014

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 Internal Medicine and is licensed to practice in New York and 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 injured worker is a 66-year-old male who reported an injury on 05/01/2012. The mechanism of injury was not specified. His diagnoses included rotator cuff sprain and joint pain of the shoulder region. His past treatments included physical therapy and medications. Diagnostic studies included x-rays of the left shoulder and left humerus with no progression of degenerative changes on an unspecified date. The injured worker's surgical history included a left shoulder arthroscopy and rotator cuff repair on 03/11/2014. On 07/28/2014, the injured worker indicated that he had pain to the left shoulder rated 5/10. Upon physical assessment, the injured worker presented with stiffness and limited range of motion to the left shoulder, with weak internal and external rotation. His medications included orphenadrine/caffeine 50/10mg capsules, gabapentin/pyridoxine 250/10mg, omeprazole/flurbiprofen 10/100mg, Keratek gel 4oz., flurbiprofen/cyclo//menthol 20%/10%/4% cream 180 mg, and Vicosetron 10/300/2mg. The treatment plan included an additional 12 sessions of physical therapy, prescriptions and to schedule a return visit in 6 weeks. The physician's rationale for the request for Gabapentin/Pyridoxine 250mg/10mg was for treatment of neuropathic pain, Flurbiprofen/cylo/menth cream 20%/10%/4% 180gm was to reduce pain, Ketarek Gel for pain, Hydrocodone/APAP/Ondan10/300/2mg for pain, nausea/upset stomach, Omeprazole 10mg/Flurbiprofen 100mg for increased gastrointestinal (GI) adverse effects, though no rationale for Orphenadrine/Caffeine 50/10mg was provided within this documentation. The Request for Authorization form was not submitted for review.

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Antispasmodics, Orphenadrine Page(s): 63, 65. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound drugs

Decision rationale: The request for orphenadrine/caffeine 50/10 mg #60 is not medically necessary. The California MTUS Guidelines indicate that antispasmodics are often used in the treatment of musculoskeletal conditions whether or not a spasm is present. Additionally non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic lower back pain, with no benefits when used in combination with non-steroidal anti-inflammatory drugs (NASID's). Effectiveness appears to decrease over time and can lead to dependence. The documentation is lacking as to the efficacy of the use of the medication, presence or absence of side effects or duration of use. Therefore, it is unclear whether the request is for initial therapy or ongoing treatment. Additionally The Official Disability Guidelines do not recommend compound drugs as a first-line therapy, and FDA approved drugs should be given and adequate trial. No evidence was submitted to show a trial of approved FDA drugs. Furthermore the request, as submitted, failed to indicate a frequency of use. The request for orphenadrine/caffeine 50/10 mg #60 is not medically necessary.

Gabapentin/Pyridoxine 250mg/10mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), Specific Anti-Epilepsy Drugs, Gabapentin Page(s): 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound drugs, Vitamin B

Decision rationale: The request for gabapentin/pyridoxine 250mg/10mg #60 is not medically necessary. The California MTUS Guidelines have shown gabapentin to be effective for diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first line treatment for neuropathic pain. Also pyridoxine also called vitamin B is not recommended for the treatment of chronic pain and is frequently used for treating peripheral neuropathy but its efficacy is not clear. Additionally The Official Disability Guidelines do not recommend compound drugs as a first-line therapy, and FDA approved drugs should be given and adequate trial. The documentation is lacking in duration of use and efficacy of the medication in relation to pain. Additionally, the request, as submitted, failed to indicate a frequency of use. As such, the request for gabapentin/pyridoxine 250 mg/10 mg #60 is not medically necessary.

Omeprazole 10mg/Flurbiprofen 100mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, non-steroidal anti-inflammatory drugs and GI symptoms & cardiovascular risk; Flurbiprofe. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound drugs

Decision rationale: The request for Omeprazole 10mg/Flurbiprofen 100mg #60 is not medically necessary. The California MTUS recommends with precautions as clinicians should determine the indications for NSAIDs against both gastrointestinal (GI) and cardiovascular risk factors. Determination of gastrointestinal events includes patients over the age of 65, history of peptic ulcer, GI bleed or perforation; and use in adjunction with aspirin, corticosteroids, and/or anticoagulants; or multiple high doses of NSAIDs. The California MTUS Guidelines recommend the lowest dose of an NSAID for the shortest period in patients with moderate to severe pain. The documentation has no evidence of gastrointestinal events by the injured worker and no indication of efficacy of the use of the medication and/or duration of relief. The Official Disability Guidelines do not recommend compound drugs as a first-line therapy, and FDA approved drugs should be given and adequate trial. No evidence was submitted to show a trial of approved FDA drugs. Additionally, the request, as submitted, failed to indicate a frequency of use. As such the request for omeprazole 10 mg/flurbiprofen 100 mg #60 is not medically necessary.

Flurbiprofen/cylo/menth cream 20%/10%/4% 180gm: 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, Non-steroidal ant inflammatory agents NSAIDs Page(s): 111.

Decision rationale: The request for flurbiprofen/cylo/menth cream 20%/10%/4% 180 gm is not medically necessary. The California MTUS Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine their efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. There is little evidence to utilize topical NSAIDs to treat osteoarthritis of the spine, hip, or shoulder. No evidence to support failed antidepressants and anticonvulsants or neuropathic pain was documented. As topical NSAIDs are not recommended for treatment of osteoarthritis of the shoulder, the request for flurbiprofen/cylo/menth cream 20%/10%/4% 180 gm is not supported. Additionally, the request, as submitted, failed to indicate a frequency of use and is not supported. As such, the request is not medically necessary.

Keratek gel 4oz: 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; Salicylate topicals Page(s): 111; 105.

Decision rationale: The request for Keratek gel 4 oz. is not medically necessary. According to the California MTUS Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Topical Salicylate, for example ben-gay, is better than a placebo for chronic pain. As Keratek gel is a compound of menthol and methyl salicylate, there is no documentation indicating the failure of use of 1 of the compounds to validate the use of the compounded medication. No evidence to support failed antidepressants and anticonvulsants or neuropathic pain was submitted. Additionally, the request, as submitted, failed to indicate a frequency of use. As such, the request for Keratek gel 4 oz is not medically necessary.

Hydrocodone/APAP/Ondan10/300/2mg #40: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetics (for opioid nausea)

Decision rationale: The request for hydrocodone/APAP/Ondan 10/300/2 mg #40 is not medically necessary. CA MTUS states Hydrocodone/Acetaminophen is indicated for moderate to moderately severe pain. CA MTUS also states a recommendation for the 4 A's for Ongoing Monitoring. These four domains for monitoring have been summarized as the "4 A's" and include monitoring for include 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 for documentation of the clinical use of these controlled drugs. The Official Disability Guidelines do not recommend compound drugs as a first-line therapy, and FDA approved drugs should be given and adequate trial. Additionally, antiemetics, such as ondansetron, are not recommended for nausea and vomiting secondary to chronic opioid use. No supportive evidence was submitted for review as to the efficacy of this medication with quantified numeric pain scales prior to or after use, improved ability to undertake activities of daily living or to address any abhorrent drug taking behaviors or side effects of the medications. Furthermore, there was no documentation of duration of use as the injury had occurred greater than 2 and one half years ago. The request, as submitted, failed to indicate a frequency of use; therefore, the request for hydrocodone/APAP/Ondan 10/300/2 mg #40 is not medically necessary.