MAXIMUS Federal Services

Case Number:	CM15-0078527		
Date Assigned:	05/06/2015	Date of Injury:	11/06/2006
Decision Date:	09/17/2015	UR Denial Date:	04/15/2015
Priority:	Standard	Application Received:	04/24/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: California
Certification(s)/Specialty: Emergency Medicine

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 51 year old male, who sustained an industrial injury on 11/6/06. The injured worker has complaints of bilateral low back pain. The diagnoses have included chronic pain syndrome; back pain, lumbar and back pain, thoracic region. The documentation noted that there was a decreased range of motion in the lumbar spine secondary to pain. Treatment to date has included physical therapy; kadian; vicoprofen (Hydrocodone, Ibuprofen); nortriptyline HCL: ibuprofen; doxazosin mesylate; colace; gabapentin and mirtazapine. The request was for kadian 60mg XR24HCAP (Morphine Sulfate) quantity 3 month supply; vicoprofen (Hydrocodone, Ibuprofen) 7.5/200mg quantity 3 months supply; nortriptyline HCL 25mg QTY 3 months supply; ibuprofen 600mg QTY 3 month supply; doxazosin mesylate 4mg QTY 3 month supply; colace 100mg quantity 3 month supply; gabapentin 300mg quantity 3 month supply and mirtazipine 15mg quantity 3 month supply.

IMR ISSUES, DECISIONS AND RATIONALES

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

Kadian 60mg XR24HCAP (Morphine Sulfate) QTY 3 month supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Vicoprofen (Hydrocodone, Ibuprofen) 7.5/200mg QTY 3 months supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Nortriptyline HCL 25mg QTY 3 months supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Antidepressants for chronic pain.

Decision rationale: Medications in the class of Tricyclic antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) They are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect usually takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality/duration, and psychological assessment. Side effects can include excessive sedation and should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at a minimum of 4 weeks. It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants can be undertaken. In this case, the use of this medication is not certified for use based on the lack of documented assessment of screening measures for ongoing use. Pending submission of the required treatment efficacy and evaluation of function as well as psychological assessment, the request is not medically necessary.

Ibuprofen 600mg QTY 3 month supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
Page(s): 67-68 of 127.

Decision rationale: The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIS are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDs having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDS are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective that acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with

acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

Gabapentin 300mg QTY 3 month supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 of 127.

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. Their also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is inadequate documentation of a condition which would support the use of an anti-epileptic drug. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

Mirtazipine 15mg QTY 3 month supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Antidepressants for chronic pain.

Decision rationale: Medications in the class of antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) They are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect usually takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality/duration, and psychological assessment. Side effects can include excessive sedation and should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment

with a recommended trial of at a minimum of 4 weeks. It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants can be undertaken. In this case, the use of this medication is not certified for use based on the lack of documented assessment of screening measures for ongoing use. Pending submission of the required treatment efficacy and evaluation of function as well as psychological assessment, the request is not medically necessary.

Colace 100mg QTY 3 month supply: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician's Desk Reference 67th Edition.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2780140/.

Decision rationale: The request is for the use of Colace which is a product usually used for constipation. Its active ingredient is ducusate sodium which is a surface active agent laxative. The MTUS and ODG guidelines are silent regarding this topic and as such, an alternative source was used. Ducusate is an effective agent and can be used safely for chronic constipation. In this case, there is inadequate documentation of a full evaluation delineating the etiology of the patient's symptoms as well as non-pharmacologic dietary treatment rendered. As such, the request is not medically necessary.

Doxazosin Mesylate 4mg QTY 3 month supply: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician Desk Reference 67th Edition.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation https://www.nlm.nih.gov/medlineplus/druginfo/meds/a693045.html.

Decision rationale: The request is for the use of Doxazosin. Doxazosin is used in men to treat the symptoms of an enlarged prostate, which include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and urinary frequency and urgency. It is also used alone or in combination with other medications to treat high blood pressure. Doxazosin is in a class of medications called alpha-blockers and relieves the symptoms of BPH by relaxing the muscles of the bladder and prostate. In this case, there is inadequate documentation to support its use based on the indications. As such, the request is not medically necessary.