MAXIMUS Federal Services

Case Number:	CM14-0116273		
Date Assigned:	08/04/2014	Date of Injury:	10/05/2010
Decision Date:	09/10/2014	UR Denial Date:	07/01/2014
Priority:	Standard	Application Received:	07/23/2014

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 Anesthesia, has a subspecialty in Acupuncture and Pain 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:

69 year old male injured worker with date of injury 10/5/10 with related right knee pain. Per progress report dated 5/5/14, he rated his pain 3/10 in intensity and had difficulty walking. He reported throbbing pain in the bilateral knees. Per physical examination, he had knee range of motion decreased to -10 degrees extension bilaterally, and had crepitus in bilateral knees. All lower extremity deep tendon reflexes were normal and lower extremity strength was normal except there was weakness over the left knee extensor muscle. He was status post total right knee replacement 6/19/13. X-ray of the right knee performed on 3/3/14 revealed prior right knee arthroplasty without radiographic evidence of loosening identified. X-ray of the left knee performed on 3/3/14 revealed osteoarthritic changes with atherosclerosis with vascular calcification. Treatment to date has included surgery, physical therapy, and medication management.The date of UR decision was 7/1/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Refill medication:Topical Cream TGHot 180 gm between 5/5/2014 and 5/5/2014: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112.

Decision rationale: TGHot contains Tramadol, Gabapentin, Menthol, Camphor and Capsaicin. Capsaicin may have an indication for chronic knee pain in this context. Per MTUS p 112 Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical Capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. As the injured worker has osteoarthritis of the knees, capsaicin may be indicated.Per MTUS p113 with regard to topical Gabapentin: Not recommended. There is no peer-reviewed literature to support use.The MTUS is silent on the use of Tramadol and Camphor topically. However, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p. 60 states only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually.As Gabapentin is not recommended, the compound is not medically necessary.

Refill Medication:FlurFlex 180 gram between 5/5/2014 and 5/5/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, compounded Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112.

Decision rationale: Fluriflex contains Flurbiprofen and Cyclobenzaprine.Per MTUS with regard to Flurbiprofen (p112), (Biswal, 2006) these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Flurbiprofen may be indicated.Per MTUS CPMTG p113, there is no evidence for use of any other muscle relaxant as a topical product. Cyclobenzaprine is not indicated.The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006)

There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.Regarding the use of multiple medications, MTUS page 60 states only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually.Because topical Cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.

Refill Medication:Tramadol 50 mg #60 between 5/5/2014 and 5/5/2014: 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, 93.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines page 78 regarding on-going management of opioids four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any 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.Review of the available medical records reveals no documentation to support the medical necessity of tramadol or any documentation addressing the'4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. Review of the available medical records reveals that per 5/5/14 progress report, the injured worker reported 3/10 pain in the right knee, it was not stated whether this was with or without medication. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Refill Medication: Norco 10/325mg #60 between 5/5/2014 and 5/5/2014: 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, 91.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines page 78 regarding on-going management of opioids four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any 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.Review of the available medical records reveals no documentation to support the medical necessity of Norco or any documentation addressing the'4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. Review of the available medical records reveals that per 5/5/14 progress report, the injured worker reported 3/10 pain in the right knee, it was not stated whether this was with or without medication. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Refill Medication: Prilosec 20 mg #80 between 5/5/2014 and 5/5/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System, Gastroesophageal reflux disease (GERD) Ann Arbor (MI) University of Michigan Health System; 2012 May. 12 p.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). CPMTG guidelines further specify: Recommendations:Patients with no risk factor and no cardiovascular disease: Non-

selective NSAIDs OK (e.g., Ibuprofen, Naproxen, etc.)Patients at intermediate risk for gastrointestinal events and no cardiovascular disease :(1) a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44).Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is Naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low. Additionally, at the time of the retrospective request, the injured worker was not on NSAID therapy, as such, medical necessity cannot be affirmed.