MAXIMUS Federal Services

Case Number:	CM14-0131487		
Date Assigned:	09/03/2014	Date of Injury:	06/13/2012
Decision Date:	11/04/2014	UR Denial Date:	07/31/2014
Priority:	Standard	Application Received:	08/18/2014

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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

Patient is a 23-year-old female who has submitted a claim for bilateral knee instability and chondromalacia patella associated with an industrial injury date of 6/13/2012. Medical records from 2014 were reviewed. Patient complained of low back pain and bilateral knee pain, rated 1/10 in severity. Physical examination showed tenderness and limited motion of both knees. Gait was antalgic. X-rays of both knees (undated) showed no progression of degenerative changes. Progress report from 4/2/14 cited that patient had gastritis history. Treatment to date has included right knee surgery in 2013, left knee arthroscopy in April 2014, physical therapy, cold/heat modality, and medications such as Orphenadrine / Caffeine, Gabapentin / Pyridoxine, Omeprazole / Flurbiprofen, and topical creams (since July 2014). Utilization review from 7/31/2014 denied the request for Orphenadrine/Caffeine 50/10mg cap #60 because long-term use was not recommended; denied Gabapentin/Pyridoxine 250mg/10mg #60 because of no neuropathy diagnosis; denied Flurbiprofen/Cyclo/Menth cream 20%/10%/4% #180gm and Keratek analgesic gel #4oz because of limited published studies concerning its efficacy and safety; denied Hydrocodone/APAP/Ondan 10/300/2mg #40 because of no subjective or objective benefit from medication use; and denied Omeprazole 10mg/Flurbiprofen 100mg #60 because of absence of gastrointestinal risk factors.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orphenadrine/Caffeine 50/10mg cap #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 Page(s): 63.

Decision rationale: As stated on page 63 of the California MTUS Chronic Pain Medical Treatment Guidelines, muscle relaxants are used as a second line option for short course treatment of muscle spasticity and spasms. In this case, the patient has been prescribed Orphenadrine-Caffeine since July 2014. However, there has been no documentation to justify the need for this specific combination. Furthermore, medical records submitted did not include evidence of muscle spasm to warrant use of Orphenadrine. Therefore, the request for Orphenadrine/Caffeine 50/10mg cap #60 is not medically necessary.

Gabapentin/Pyridoxine 250mg/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 Anti-Epilepsy Drugs Page(s): 16-17.

Decision rationale: As stated on pages 16 - 17 of CA MTUS Chronic Pain Medical Treatment Guidelines, antidepressants, such as Pregabalin and gabapentin, are recommended as a first line option for neuropathic pain, i.e., painful polyneuropathy. In this case, the patient has been prescribed Gabapentin-Pyridoxine since July 2014. The combination of Gabapentin and Pyridoxine was not mentioned in the guidelines. Furthermore, medical records submitted did not include evidence of neuropathy. Therefore, the request for Gabapentin/Pyridoxine 250mg/10mg #60 is not medically necessary.

Flurbiprofen/Cyclo/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 Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Topical NSAIDs formulation is only supported for Diclofenac in the California MTUS. In addition, there is little to no research as for the use of Flurbiprofen in compounded products. Cyclobenzaprine is not recommended for use as a topical analgesic. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical

OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Flurbiprofen and cyclobenzaprine, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for Flurbiprofen/Cyclo/Menth cream 20%/10%/4% #180gm is not medically necessary.

Keratek analgesic 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 Salicylate, Topical Analgesics Page(s): 105, 111 - 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates

Decision rationale: An online search indicates that Keratek contains menthol and methyl salicylate. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Page 105 of CA MTUS Chronic Pain Medical Treatment Guidelines states that topical salicylates (e.g., Ben-Gay, Aspercream, methyl salicylate) are significantly better than placebo in chronic pain. These products are generally used to relieve minor aches and pains. With regard to brand name topical salicylates, these products have the same formulation as over-the-counter products such as BenGay. It has not been established that there is any necessity for a specific brand name topical salicylate compared to an over the counter formulation. Therefore, the request for Keratek analgesic gel #4oz is not medically necessary.

Hydrocodone/APAP/Ondan 10/300/2mg #40: 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 Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Antiemetics (for opioid nausea) and Ondansetron

Decision rationale: As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related 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. ODG states that Ondansetron is indicated for prevention of nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery. It is not recommended for nausea and vomiting secondary to chronic opioid use. In this case, the initial date of opioid prescription is unknown due to lack of documentation. Moreover, the medical records do not clearly reflect

continued analgesia, continued functional benefit, or a lack of adverse side effects. Urine drug screen is likewise not available for review. MTUS Guidelines require clear and concise documentation for ongoing management. Moreover, there is no discussion why Ondansetron should be prescribed when there are no complaints of nausea and vomiting. The guideline also does not recommend Ondansetron use to address opioid side effects. Therefore, the request for Hydrocodone/APAP/Ondan 10/300/2mg #40 is not medically necessary.

Omeprazole 10mg/Flurbiprofen 100mg #60: Overturned

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 NSAIDs, NSAIDS, GI Symptoms, and Cardiovascular Risk Page(s): 46, 68.

Decision rationale: As stated on page 46 of the California MTUS Chronic Pain Medical Treatment guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. As stated on page 68 of CA MTUS Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors: age > 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed proton pump inhibitors (PPI). In this case, there is no prior use of this compound medication. Progress report from 4/2/14 cited that patient had gastritis history; hence, a PPI may be prescribed. There is likewise continued bilateral knee pain, thus, NSAID is a reasonable treatment option at this time. Therefore, the request for Omeprazole 10mg/Flurbiprofen 100mg #60 is medically necessary.