MAXIMUS Federal Services

Case Number:	CM15-0187532		
Date Assigned:	09/29/2015	Date of Injury:	11/16/2007
Decision Date:	11/10/2015	UR Denial Date:	08/18/2015
Priority:	Standard	Application Received:	09/23/2015

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: North Carolina
Certification(s)/Specialty: Family Practice

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 61 year old female, who sustained an industrial injury on 11-16-2007. She has reported subsequent neck, back, right hand and bilateral knee pain and was diagnosed with cervical, lumbar and right wrist strain and sprain and chronic pain syndrome. Treatment to date has included pain medication, acupuncture, bracing, physical therapy and a home exercise program which were noted to have failed to significantly relieve the pain. A 02-11-2015 progress note shows that Flector patches being utilized for pain and the injured worker reported that with medication, a home exercise program and acupuncture, her condition was improving. Pain was rated as 5 out of 10. Subsequent notes do not document Flector patches as being an active medication. Documentation shows that a trial of Pamelor was started on 05-04-2015 for chronic pain and pain related insomnia. In the 06-11-2015 progress note, the physician notes that the injured worker's trial of Pamelor was helpful for sleep and Pamelor was continued. The intensity of pain was rated as 6 out of 10 during the visit and after taking pain medication was rated as 1 out of 10 and pain relief was noted to last 4-6 hours. In a progress note dated 07-22-2015, the injured worker reported neck, back, right hand and bilateral knee pain that was rated as 4-9 out of 10. The injured worker's current pain was rated as 6 out of 10, the least reported pain over the period since the last assessment was rated as 5 out of 10, average pain was rated as 7.5 out of 10 and intensity of pain after taking medication was rated as 1.5 out of 10. The duration of pain relief was noted to be 2.5 hours. Objective examination findings revealed tenderness in the right greater than left cervical paraspinal muscles, trigger point in the right superior trapezius with a twitch response, decreased painful range of motion of the cervical spine and diffuse tenderness of the lumbar spine and decreased painful range of motion. The physician noted that the injured worker was sleeping better with Pamelor and had good results from past use of the Flector

patches. The physician noted that a trial of Flector patches was being requested and that Pamelor would be continued. Work status was documented as permanent and stationary. A request for authorization of Pamelor 10 mg #30 and Flector patch 1.3% #30 trial was submitted. As per the 08-18-2015 utilization review, the requests for Pamelor 10 mg #30 and Flector patch 1.3% #30 trial were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pamelor 10mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The California MTUS and the ACOEM do not specifically address this medication. Per the official disability guidelines recommend pharmacological agents for insomnia only is used after careful evaluation of potential causes of sleep disturbance. Primary insomnia is usually addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. Pharmacological treatment consists of four main categories: Benzodiazepines, Non-benzodiazepines, Melatonin and melatonin receptor agonists and over the counter medications. Sedating anti-depressants have also been used to treat insomnia however, there is less evidence to support their use for insomnia, but they may be an option in patients with co-existing depression. The patient does not have the diagnosis of primary insomnia or depression. There is no provided clinical documentation of failure of sleep hygiene measures/counseling. Therefore, the request is not medically necessary.

Flector patch 1.3% #30 trial: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of anti-depressants and anti-convulsants 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, anti-depressants, 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. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical

trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (Diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in 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. (Krummel 2000) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options but rather the diagnosis of neck and knee pain. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.