

Case Number:	CM15-0174477		
Date Assigned:	09/16/2015	Date of Injury:	07/30/2009
Decision Date:	10/19/2015	UR Denial Date:	08/26/2015
Priority:	Standard	Application Received:	09/04/2015

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: 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 55-year-old female, with a reported date of injury of 07-30-2009. The diagnoses include displaced cervical intervertebral disc and brachial neuritis and radiculitis. Treatments and evaluation to date have included Cymbalta, Gabapentin, Norco (since at least 12-2014), psychotropic medications, Lunesta (since at least 03-2015), Flector patch (since at least 05-2015), and functional restoration program. The diagnostic studies to date have not been included in the medical records. The progress report dated 08-14-2015 indicates that the injured worker was there for follow-up of her upper extremity symptoms. Norco was taken as necessary and Lunesta at bedtime. The injured worker continued to have chronic discomfort through the right shoulder and entire right upper extremity. She stated that her pain was rated 7-8 out of 10. The pain was associated with numbness and tingling. The injured worker also complained of tingling and discomfort in the auxiliary area. The objective findings include diffuse tenderness in the right upper extremity (05-11-2015 to 08-14-2015), intact strength and deep tendon reflexes, tenderness with palpation over the medial and lateral epicondyles, tenderness down the forearm into the wrist, pain with movements of the wrist in all directions, no focal weakness, and pain with movements involving the elbow, wrist, and hand. The treatment plan included Norco, Lunesta, and Flector patches. The injured work status included permanent work restrictions for the upper extremities. The request for authorization was dated 08-18-2015. The treating physician requested Norco 10-325mg #60, Lunesta 2mg #90, and Flector 1.3% transdermal #180. On 08-26-2015, Utilization Review (UR) non-certified the request for Flector 1.3%

transdermal #180, and modified the request for Norco 10-325mg #60 to Norco 10-325mg #50; and Lunesta 2mg #90 to Lunesta 2mg #15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain, Opioids, dealing with misuse & addiction, Opioids, indicators for addiction, Opioids, long-term assessment.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids, including Norco. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the 4 A's for Ongoing Monitoring. These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the 4 A's for Ongoing Monitoring. The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Ongoing treatment with Norco is not considered as medically necessary.

Lunesta 2mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness & Stress, FDA.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Chronic Pain Section: Insomnia Treatment.

Decision rationale: The Official Disability Guidelines comment on the treatment for insomnia. These guidelines recommend that treatment be based on the etiology, with the medications recommended below. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; & (4) Over-the-counter medications. The majority of studies have only evaluated short-term treatment (i.e., 4 weeks) of insomnia; therefore more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. In this case, there is insufficient documentation to indicate that the patient has undergone an evaluation for the underlying cause of insomnia. As noted in the above cited guidelines, treatment should be based on the etiology. Further, there is insufficient evidence that psychiatric and/or medical illness have been adequately addressed for their impact on the sleep disorder. Finally, the request for 90 tablets suggests that the use of Lunesta is intended as a long-term treatment of this patient's insomnia. As noted in the above cited guidelines, medications such as Lunesta are only recommended for short-term treatment. For these reasons, Lunesta is not medically necessary.

Flector 1.3% transdermal #180.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, including Flector (topical diclofenac). Diclofenac is a NSAID. Topical analgesics are considered as 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. 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 topical non-steroidal antiinflammatory agents (NSAIDs) these guidelines state the following: 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. 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. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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. In this case, the records indicate that Flector is being used as a long-term treatment strategy for this patient's symptoms. As noted in the above cited guidelines, only short-term use is recommended. Further, it is unclear what condition is being addressed by the use of topical diclofenac (Flector). As stated in the above cited guidelines may be used short-term for the treatment of osteoarthritis and tendinitis; in particular, that of the knee and elbow or other joints. The request for Flector was not specific towards the rationale for its use. For these reasons, Flector is not considered as medically necessary.