MAXIMUS Federal Services

Case Number:	CM15-0201597		
Date Assigned:	10/16/2015	Date of Injury:	04/03/2014
Decision Date:	12/02/2015	UR Denial Date:	09/30/2015
Priority:	Standard	Application Received:	10/13/2015

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: Texas, 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 27 year old female who sustained an industrial injury on 04-03-2014. A review of the medical records indicated that the injured worker is undergoing treatment for contusion to the left foot and sprain and strain of the left foot. According to the treating physician's progress report on 09-15-2015, the injured worker continues to experience ankle pain, difficulty with gait and weight bearing. Examination demonstrated ability to ambulate in a full weight bearing status with difficulty toe walking and standing. Ankle was overall improved with no significant ankle pain identified. Pain was noted at the 4th interspace and metatarsalgia pain to the 1st, 2nd and 3rd metatarsal heads. Left ankle magnetic resonance imaging (MRI) performed on 08-05-2015 official report was included in the review. Prior treatments have included diagnostic testing, physical therapy, Sudoscan, psychological evaluation, left foot injection on 08-18-2015 and medications. Treatment plan consists of orthotics, continuation of physical therapy and the current request for Compound FCL 20%-4%-5% 240gms 30 days and 1st Relief topical spray 354ml, 29 days. The patient sustained the injury due to a fall. The patient had used crutches for this injury. The medication list include Ibuprofen. The patient had MRI of the left ankle on 8/6/15 that revealed joint effusion. A recent detailed clinical examination of the gastrointestinal tract was not specified in the records provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound FCL 20%-4%-5% 240gms 30 days: Upheld

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

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

Decision rationale: Compound FCL 20%-4%-5% 240gms 30 days. According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is 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. MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Cyclobenzaprine is a muscle relaxant. Per the cited guidelines, other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The medication Flurbiprofen is a NSAID. As per cited guidelines 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. Per the cited guidelines, Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Evidence of post herpetic neuralgia or diabetic neuropathy is not specified in the records provided, in this patient. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Cyclobenzaprine, Lidocaine and Flurbiprofen are not recommended by MTUS. The medical necessity of the medication Compound FCL 20%-4%-5% 240gms 30 days is not fully established in this patient therefore is not medically necessary.

1st Relieve topical spray 354ml, 29 days: Upheld

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

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

Decision rationale: 1st Relieve topical spray 354ml, 29 days. According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is 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. MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Per the cited guidelines, Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Evidence of post herpetic neuralgia or diabetic neuropathy is not specified in the records provided, in this patient. There is also no evidence that menthol is recommended by the CA, MTUS, Chronic pain treatment guidelines. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical menthol and Lidocaine is not recommended in this patient for this diagnosis. The medical necessity of the medication 1st Relieve topical spray 354ml, 29 days is not fully established in this patient therefore is not medically necessary.