MAXIMUS Federal Services

Case Number:	CM15-0132931		
Date Assigned:	07/21/2015	Date of Injury:	09/12/2014
Decision Date:	08/26/2015	UR Denial Date:	06/19/2015
Priority:	Standard	Application Received:	07/09/2015

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: New York
Certification(s)/Specialty: Emergency Medicine

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 53 year old male who sustained an industrial injury on 09/12/2014 resulting in pain to the low back and right knee. Treatment provided to date has included: physical therapy and acupuncture which provides temporary relief; psychological therapy; lumbar epidural steroid injections; medications; and conservative therapies/care. Diagnostic tests performed include: MRI of the right lower leg (2015) showing old healed fractures; cardio-respiratory testing (2015); Sudomotor function assessment (2015) with evidence of small fiber neuropathy in the hands; electrodiagnostic and nerve conduction testing of the lower extremities (2014) showing lumbar radiculopathy in the L5-S1 nerve roots. There were no noted comorbidities or other dates of injury noted. On 06/10/2015, physician progress report noted complaints of lumbar spine pain. The pain was rated 2/10 in severity and was described as cramps. Additional complaints included 2/10 knee pain. The physical exam revealed lumbar spine tenderness and tenderness along the right knee joint line with laxity. The provider noted diagnoses of lumbar spine sprain, and right knee sprain. Plan of care includes medications, physical therapy, chiropractic treatments, pending ortho and follow-up in 4 weeks. The injured worker's work status remained temporarily totally disabled. The request for authorization and IMR (independent medical review) includes: topical cream consisting of 10% Ketoprofen, 3% Cyclobenzaprine and 5% Lidocaine 120gm; topical cream consisting of 10/0.025 Flurbiprofen, 2% capsaicin and 1% camphor 120gm; and Orphenadrine ER 100mg #60 2 times daily.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 10%, Cyclobenzaprine 3%, Lidocaine 5%, 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: In regards to the topical cream consisting of 10% Ketoprofen, 3% Cyclobenzaprine and 5% Lidocaine, according to the MTUS, Topical Analgesic are recommended as an option, but are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These medications are primarily recommended for neuropathic pain once 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." Ketoprofen is not currently FDA approved for a topical application as it has an extremely high occurrence of photo-contact dermatitis, and absorption of the drug depends on the base it is delivered in. Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: Tabradol) is a centrally acting skeletal muscle relaxant. Topical Cyclobenzaprine is not recommended for use as a topical agent. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Additionally, this medication is not generally recommended for treatment of myofascial pain/trigger points. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Upon review of the available documentation, it has been determined that this topical cream contains 3 ingredients that are not recommended for topical application. As such, the requested topical cream consisting of 10% Ketoprofen, 3% Cyclobenzaprine and 5% Lidocaine 120gm is not medically necessary.

Orphenadrine ER (extended release) 100 mg Qty 60, 2 times daily: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63, 65.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

Decision rationale: The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Orphenadrine is a

muscle relaxant, which is used to treat muscle spasms, muscle rigidity, and cramping or inflammation of the muscles. Orphenadrine is similar to Diphenhydramine, but has increased anticholinergic effects (drowsiness, urinary retention, dry mouth). The method of action is not clear, but it has been reported to be abused for euphoria and to have mood-elevating effects. In this case, there was documented cramping of the muscles in the low back. Additionally, there was no evidence in the clinical notes that the injured worker has been prescribed a muscle relaxant medication in the past several months. As such, the requested Orphenadrine ER 100mg #60 2 times daily is medically necessary.

Flubiprofen 10/0.025, Capsaicin 2%, Camphor 1%, 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: In regards to the topical cream consisting of 10/0.025 Flurbiprofen, 2% capsaicin and 1% camphor, according to the MTUS, Topical Analgesic are recommended as an option, but are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These medications are primarily recommended for neuropathic pain once 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. Flurbiprofen is classified as a NSAID. NSAIDs, in the topical form, are not recommended for neuropathic pain, as there is no evidence to support use. The ODG also states: "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); however, there is little to no research to support the use of many these agents. Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." At this time, the only available FDA-approved topical NSAID is Diclofenac. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Upon review of the available documentation, it has been determined that this topical cream contains one ingredient that is not approved or recommended for topical application. As such, the requested topical cream consisting of 10/0.025 Flurbiprofen, 2% capsaicin and 1% camphor 120gm is not medically necessary.