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| Case Number: | CM15-0047389 | | |
| Date Assigned: | 04/14/2015 | Date of Injury: | 11/12/2013 |
| Decision Date: | 05/14/2015 | UR Denial Date: | 02/26/2015 |
| Priority: | Standard | Application Received: | 03/12/2015 |

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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 39 year old male patient who sustained an industrial injury on 11/12/2013. The initial evaluation dated 11/12/2013 described the patient status post fall with resulting foot pain. A follow up visit dated 12/03/2013 reported the patient with complaint of ongoing left foot pain. He reports inability to bear weight on the left foot and it is noted with a red hue to the foot. Current medications are: Tramadol. He is using crutches, and a walker. Previous diagnostic testing has included radiographic study and magnetic resonance imaging. The plan of care involved application of a ACE wrap supporting the foot, continue with walker and crutches, may bear weight as tolerated, and return for follow up. His primary complaint is of left heel pain. He was given Oxycodone/APAP 5/325mg, placed in a posterior splint. He was discharged to home with contusions of heel, hip, and mechanical fall.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Topical Analgesic comprised of Caffeine Citrated Powder, Fluticasone Powder, Levocetirizine Powder, Gabapentin Powder, Lidocaine Powder, Alpha Lipoic Acid Powder, Pentoxifyl Powder, Prilocaine Powder, Tamoxifen Citrate Powder, Tranilast Powder, Propylene Glycol, Freedom Gel #360: 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: The MTUS states that topical Analgesics are recommended as an option as indicated below. They are 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. (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. 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required.

Non-steroidal antiinflammatory 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.) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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. 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)

Lidocaine Indication: Neuropathic pain 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). 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.

Gabapentin: Not recommended. There is no peer-reviewed literature to support use.

Other antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product. In this case the compounded topical medication contains components that are not recommended and others that

are not addressed by the MTUS. The request for Compounded Topical Analgesic comprised of Caffeine Citrated Powder, Fluticasone Powder, Levocetirizine Powder, Gabapentin Powder, Lidocaine Powder, Alpha Lipoic Acid Powder, Pentoxifyl Powder, Prilocaine Powder, Tamoxifen Citrate Powder, Tranilast Powder, Propylene Glycol, Freedom Gel #360 is not medically necessary.

Compounded Topical Analgesic comprised of Flurbiprofen Powder, Tramadol Powder, Propylene Glycol, Baclofen Powder, Cyclobenzaprine Powder, Lipopen Ultra Cream #360: 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: Topical Analgesics are 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 antidepressants and anticonvulsants 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. 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Baclofen is not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. In this case the topical analgesic contains Baclofen which is not recommended. As such, the request for Compounded Topical Analgesic comprised of Flurbiprofen Powder, Tramadol Powder, Propylene Glycol, Baclofen Powder, Cyclobenzaprine Powder, Lipopen Ultra Cream #360 is not medically necessary.

Compounded Topical Analgesic comprised of Urea Powder, Mupirocin Powder, Itraconazole Powder, Fluticasone Powder, Spira-Wash Gel Base #360: 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: The MTUS states that topical Analgesics are recommended as an option as indicated below. They are 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. (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. 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. In this case there is no evidence for efficacy of these compounded medications. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for compounded topical Analgesic comprised of Urea Powder, Mupirocin Powder, Itraconazole Powder, Fluticasone Powder, Spira-Wash Gel Base #360 is not medically necessary.