MAXIMUS Federal Services

Case Number:	CM14-0208873		
Date Assigned:	02/03/2015	Date of Injury:	10/08/2008
Decision Date:	03/03/2015	UR Denial Date:	12/01/2014
Priority:	Standard	Application Received:	12/14/2014

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: Pennsylvania
Certification(s)/Specialty: Internal 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 52 year old male with a date of injury of 10/8/08. Diagnoses include lumbar disc herniation with radiculitis/radiculopathy. The primary treating physicians report of 7/24/14 notes that the injured worker was scheduled for posterior lumbar interbody fusion on July 30, 2014. Examination of the lumbar spine showed decreased range of motion, straight leg raise 75 degrees bilaterally, hypoesthesia at the anterolateral aspect of the foot and ankle, and weakness in dorsiflexor and plantar flexor of the big toe bilaterally. A diskographic study of March 22, 2013 was noted to show marked reproduction of pain at L4-L5 and L5-S1. Prior treatments were not discussed and medications were not noted or discussed. No additional medical records were provided; however the Utilization Review determination notes that prior treatments included physical therapy, acupuncture, biofeedback, chiropractic treatment, use of heating pads, modified duty, and medications. On 12/1/14, Utilization Review non-certified requests for multiple topical medications, citing the MTUS and noting the lack of documentation of failure of trial of oral antiepileptics and antidepressants.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gab/Ket/Lido 7/10/5% VC 120 grams, provided on April 20, 2009: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Compounded Drugs Section

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

Decision rationale: Gab/Ket/lido is a compounded topical medication containing gabapentin (a form of antiepileptic medication), ketoprofen (a nonsteroidal anti-inflammatory agent or NSAID), and lidocaine. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Gabapentin is an antiepileptic drug and is not recommended in topical form; there is no peer-reviewed literature to support use. Ketoprofen is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch forms are generally indicated as local anesthetics or anti-pruritics. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. There was no documentation of a diagnosis of post-herpetic neuralgia. In addition, this compounded product contains topical gabapentin, which is not recommended by the MTUS; therefore the compound is not recommended. The request for Gab/Ket/Lido 7/10/5% VC 120 grams, provided on April 20, 2009 is not medically necessary.

Cyclo/Keto 10/3% VC, 120 grams, provided on April 20, 2009: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation ODG, Compound Drugs Section

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

Decision rationale: Cyclo/keto is a compounded topical medication containing cyclobenzaprine (a muscle relaxant) and ketoprofen (a nonsteroidal anti-inflammatory agent or NSAID). Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Ketoprofen is not currently FDA approved for topical

application. It has a high incidence of photocontact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. The request for Cyclo/Keto 10/3% VC, 120 grams, provided on April 20, 2009 is not medically necessary.

Cap 0.37%/Men 10%/Camp 2%, provided on April 20, 2009: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation ODG, Compound Drugs Section

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

Decision rationale: Cap/Men/Camp is a compounded topical medication containing capsaicin, menthol, and camphor. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS and ODG are silent with regard to menthol and camphor. They may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. There was no documentation to support the high dose of capsaicin requested. No specific indication for camphor and menthol was provided, and these agents have a risk of serious adverse reaction. The request for Cap 0.37%/Men 10%/Camp 2%, provided on April 20, 2009 is not medically necessary.

Gab/Ket/Lid 7/10/5% VC 120 grams, provided on December 22, 2008: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation ODG, Compound Drugs Section

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

Decision rationale: Gab/Ket/lido is a compounded topical medication containing gabapentin (a form of antiepileptic medication), ketoprofen (a nonsteroidal anti-inflammatory agent or NSAID), and lidocaine. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product

contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Gabapentin is an antiepileptic drug and is not recommended in topical form; there is no peer-reviewed literature to support use. Ketoprofen is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch forms are generally indicated as local anesthetics or anti-pruritics. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. There was no documentation of a diagnosis of post-herpetic neuralgia. In addition, this compounded product contains topical gabapentin, which is not recommended by the MTUS; therefore the compound is not recommended. The request for Gab/Ket/Lido 7/10/5% VC 120 grams, provided on December 22, 2008 is not medically necessary.

Cyclo/Keto 10/3% VC 120 grams, provided on December 22, 2008: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation ODG, Compound Drugs Section

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

Decision rationale: Cyclo/keto is a compounded topical medication containing cyclobenzaprine (a muscle relaxant) and ketoprofen (a nonsteroidal anti-inflammatory agent or NSAID). Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Ketoprofen is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. The request for Cyclo/Keto 10/3% VC, 120 grams, provided on December 22, 2008 is not medically necessary.

Cap 0.36%/Ment 10%/Camp 2%, provided on December 22, 2008: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113. Decision based on Non-MTUS Citation ODG, Compound Drugs Section

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Lexicomp Online 2015: Camphor and Menthol: Drug information

Decision rationale: Cap/Men/Camp is a compounded topical medication containing capsaicin, menthol, and camphor. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had a diagnosis of lumbar radiculopathy, but the specific indication for the use of the requested compounded topical medication was not provided in the records submitted. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS and ODG are silent with regard to menthol and camphor. They may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. There was no documentation to support the high dose of capsaicin requested. No specific indication for camphor and menthol was provided, and these agents have a risk of serious adverse reaction. The request for Cap 0.37%/Men 10%/Camp 2%, provided on December 22, 2008 is not medically necessary.