

Case Number:	CM15-0210323		
Date Assigned:	10/29/2015	Date of Injury:	10/31/2003
Decision Date:	12/10/2015	UR Denial Date:	10/02/2015
Priority:	Standard	Application Received:	10/26/2015

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, Indiana, New York
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 62 year old female, who sustained an industrial injury on 10-31-03. The injured worker was diagnosed as having carpal tunnel syndrome, cervical disc disorder with myelopathy, lumbar intervertebral disc disorders with myelopathy, and sprain of cruciate ligament of the right knee. Treatment to date has included medication such as Voltaren gel, Ambien, and FCL. Physical examination findings on 10-1-15 included tenderness in the cervical area upper thoracic area, lumbar spine, bilateral sacroiliac joints, bilateral shoulders, and bilateral knees. The injured worker had been taking Voltaren gel, Ambien and FCL since at least October 2015. On 10-1-15, the injured worker complained of pain in the neck, upper thoracic area, low back, bilateral sacroiliac joints, sacral area, left knee, and bilateral shoulders rated as 8 of 10. On 10-1-15 the treating physician requested authorization for Voltaren gel 1% #1, Ambien 5mg #30, and FCL (Flurbiprofen 10%-Baclofen 2%-Dexamethasone 2%-Menthol 2%-Camphor 2%- Capsaicin 0.0375%-Hyaluronic acid 0.2%) 180g. On 10-2-15 the requests were non-certified by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren gel 1% #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics.

Decision rationale: Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, Voltaren (Diclofenac) gel 1%, #1 is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The only available FDA approved topical analgesic is diclofenac. However, diclofenac gel is indicated for relief of osteoarthritis pain in the joint that lends itself 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 injured workers working diagnoses are carpal tunnel syndrome; cervical disc disorder with myelopathy unspecified cervical region; intervertebral disc disorders with myelopathy, lumbar region; and sprain of unspecified cruciate ligament right knee. Date of injury is October 31, 2003. Request for authorization is October 1, 2015. According to a progress note dated in October 1, 2015, subjective complaints include cervical, left cervical dorsal, right cervical dorsal, upper thoracic, lumbar left sacroiliac and right sacroiliac, sacral, left anterior knee, right anterior shoulder and left anterior shoulder. Pain score is 8/10. Objectively, there was palpable tenderness at the cervical region, thoracic and lumbar region, left and right sacroiliac regions and bilateral buttocks, shoulders and left anterior and right anterior knee. Cervical range of motion is decreased. Cervical MRI showed straightening of the normal cervical lordosis compatible with muscle spasm. Right shoulder range of motion is decreased. Lumbar spine range of motion is decreased. The lumbar spine has tenderness to palpation bilaterally. The treatment plan contains a request for Voltaren gel 1%, apply to affected area. There is no documentation of failed first-line treatment with anticonvulsants and antidepressants. Diclofenac gel is indicated for relief of osteoarthritis pain in the joint that lends itself to topical treatment (ankle, elbow, foot, hand, knee and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. The specific areas for application are not enumerated in the progress note. Based on clinical information in the medical record, peer-reviewed evidence-based guidelines, no specific anatomical region for application, guideline non- recommendations for the spine, hip and shoulder and no fail first-line treatment, Voltaren (Diclofenac) gel 1%, #1 is not medically necessary.

Ambien 5mg 1 po qhs #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Ambien.

Decision rationale: Pursuant to the Official Disability Guidelines, Ambien 5 mg one po qhs #30 is not medically necessary. Ambien (zolpidem) is a short acting non-benzodiazepine hypnotic recommended for short-term (7-10 days) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely recommend them for will use. They can be habit forming and may impair function and memory more than opiates. The dose for Ambien and women should be lowered from 10 mg to 5 mg for immediate release products and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR). In this case, the injured workers working diagnoses are carpal tunnel syndrome; cervical disc disorder with myelopathy unspecified cervical region; intervertebral disc disorders with myelopathy, lumbar region; and sprain of unspecified cruciate ligament right knee. Date of injury is October 31, 2003. Request for authorization is October 1, 2015. According to a progress note dated in October 1, 2015, subjective complaints include cervical, left cervical dorsal, right cervical dorsal, upper thoracic, lumbar left sacroiliac and right sacroiliac, sacral, left anterior knee, right anterior shoulder and left anterior shoulder. Pain score is 8/10. Objectively, there was palpable tenderness at the cervical region, thoracic and lumbar region, left and right sacroiliac regions and bilateral buttocks, shoulders and left anterior and right anterior knee. Cervical range of motion is decreased. Cervical MRI showed straightening of the normal cervical lordosis compatible with muscle spasm. Right shoulder range of motion is decreased. Lumbar spine range of motion is decreased. The lumbar spine is tenderness to palpation bilaterally. The treatment plan contains a request for Ambien 5 mg 1 PO QHS #30. The start date is unclear and there is a single progress note in the medical record dated October 1, 2015. Ambien is recommended short-term for 7-10 days. There is no documentation demonstrating objective functional improvement. There is no documentation indicating the total duration of prescribed Ambien 5 mg. Based on the clinical information in the medical record, peer-reviewed evidence-based guidelines, a single progress note with no documentation demonstrating objective functional improvement and guideline recommendations for short-term 7 to 10 days with an unknown duration of use, Ambien 5 mg one po qhs #30 is not medically necessary.

FCL (Flurbiprofen 10% Baclofen 2% Dexamethasone 2% Menthol 2% Camphor 2% Capsaicin 0.0375% Hyaluronic acid 0.20%) 180 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics.

Decision rationale: Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, FCL (Flurbiprofen 10%, baclofen 2%, dexamethasone 2%, Menthol 2%, Capsaicin 0.0375%, hyaluronic acid 0.2%, 180 g is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Other than Lidoderm, no other commercially approved

topical formulation of lidocaine whether cream, lotions or gels are indicated for neuropathic pain. In this case, the injured workers working diagnoses are carpal tunnel syndrome; cervical disc disorder with myelopathy unspecified cervical region; intervertebral disc disorders with myelopathy, lumbar region; and sprain of unspecified cruciate ligament right knee. Date of injury is October 31, 2003. Request for authorization is October 1, 2015. According to a progress note dated in October 1, 2015, subjective complaints include cervical, left cervical dorsal, right cervical dorsal, upper thoracic, lumbar left sacroiliac and right sacroiliac, sacral, left anterior knee, right anterior shoulder and left anterior shoulder. Pain score is 8/10. Objectively, there was palpable tenderness at the cervical region, thoracic and lumbar region, left and right sacroiliac regions and bilateral buttocks, shoulders and left anterior and right anterior knee. Cervical range of motion is decreased. Cervical MRI showed straightening of the normal cervical lordosis compatible with muscle spasm. Right shoulder range of motion is decreased. Lumbar spine range of motion is decreased. The lumbar spine is tenderness to palpation bilaterally. The specific anatomical region for application is not specified in the record. Flurbiprofen is not FDA approved for topical use. Baclofen is not recommended. Capsaicin is generally available as a 0.025% formulation. There have been no studies of a 0.0375% formulation and there is no current indication that an increase over 0.025% formulation would provide any further efficacy. Any compounded product that contains at least one drug (Flurbiprofen, Baclofen and Capsaicin 0.0375%) that is not recommended is not recommended. Consequently, FCL (Flurbiprofen 10%, baclofen 2%, dexamethasone 2%, Menthol 2%, Capsaicin 0.0375%, hyaluronic acid 0.2%, 180 g is not recommended. Based on clinical information in the medical record and peer-reviewed evidence-based guidelines, FCL (Flurbiprofen 10%, baclofen 2%, dexamethasone 2%, Menthol 2%, Capsaicin 0.0375%, hyaluronic acid 0.2%, 180 g is not medically necessary.