

Case Number:	CM15-0179462		
Date Assigned:	09/21/2015	Date of Injury:	07/12/2007
Decision Date:	10/23/2015	UR Denial Date:	08/17/2015
Priority:	Standard	Application Received:	09/11/2015

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: North Carolina
 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 64-year-old female, who sustained an industrial injury on July 12, 2007. The injured worker was being treated for cervical radiculopathy, pain in limbs, temporo-mandibular joint disorder (TMJ) pain, lumbar radiculopathy, bilateral carpal tunnel syndrome, left knee meniscal tear, right knee arthritis, meniscal tear, and popliteal cysts; and herniated disc and degenerative disc disease of the lumbar spine. Medical records (March 6, 2015 to May 8, 2015) indicate ongoing cervical radicular pain, lumbar radicular pain, and bilateral knee pain. There is crepitus, medial and lateral joint line tenderness, and patellofemoral tenderness of the left knee. The right knee wounds are clean and dry and the sutures are intact. The physical exam (March 6, 2015 to May 8, 2015) reveals an antalgic gait, improved lumbar range of motion, improved cervical range of motion, and tenderness to palpation along the C7 (cervical 7) and L4-5 (lumbar 4-5) spinous processes. There is claw deformity of the left hand with flexion at the proximal interphalangeal joints of the ring and small fingers and atrophy of the thenar eminence. There is a 0.5 millimeter fluctuant fixed mass and tenderness to palpation at the right hand dorsum, limited range of motion of the right thumb, right hand discoloration and hyper-sensitivity, inability to make a right fist, and decreased sensation in the median nerve root distribution. Medical records (May 19, 2015) indicate worsening of the injured worker's ongoing left greater than right craniocervical pain with bilateral occipital tenderness, TMJ pain, headaches, and pain in the wrists, hands, and thumbs. In addition, the injured worker has ongoing low back and leg pain related to 2 recent falls, with difficulty walking due to pain. Records also indicate ongoing difficulty with all activities of daily living. On May 19, 2015, the

physical exam reveals craniocervical pain with bilateral occipital tenderness and very severe tenderness at bilateral temporomandibular joints. On March 13, 2015, electromyography and nerve conduction velocity studies of the bilateral upper extremities were normal. On April 22, 2015, a CT of the cervical spine revealed postsurgical changes at C5-6 (cervical 5-6) and C6-7 (cervical 6-7) with evidence of anterior discectomy and fusion, a posterior osteophyte ridging at C5-6 and C6-7 causing anterior impression on the thecal sac, and mild bilateral foraminal narrowing. At C4-5 (cervical 4-5), there is a central disc bulge and mild facet arthropathy. At C3-4 (cervical 3-4), there is a circumferential disc bulge and mild facet arthropathy. At C7-T1 (cervical 7-thoracic 1) and C2-3 (cervical 2-3), there are circumferential disc bulges. Surgeries to date have included cervical 5-7 anterior cervical discectomy and fusion on July 16, 2014. Treatment has included psychotherapy, aquatic therapy with benefit, a home exercise program, and medications including pain (Tylenol ES), antidepressant (Zoloft), benzodiazepine (Klonopin), proton pump inhibitor (Omeprazole) and non-steroidal anti-inflammatory (Diclofenac). Per the treating physician (May 19, 2015 report), the injured worker remains temporarily totally disabled. On (Date of RFA), the requested treatments included Tramadol 20% ointment; Cyclobenzaprine 10%, Gabapentin cream; and Flurbiprofen 20% cream. On August 17, 2015, the original utilization review non-certified a request for Tramadol 20% ointment 180gm; Cyclobenzaprine 10%, Gabapentin cream 180gm, #1; and Flurbiprofen 20% cream 180gm, #1.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 20% Ointment 180gm (retrospective DOS 05/19/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Topical analgesics, compounds.

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

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: 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. 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. 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). 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 requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.

Cyclobenzaprine 10%, Gabapentin cream 180gm, #1 (retrospective DOS 05/19/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Topical analgesics, compounds.

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

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: 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. 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. 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). 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 requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.

Flurbiprofen 20% cream 180gm, #1 (retrospective DOS 05/19/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Topical analgesics, compounds.

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

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: 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. 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. 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). 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. Non-steroidal anti-inflammatory 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: 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 lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). 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. Absorption of the drug depends on the base it is delivered in. 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. Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options but rather the diagnosis of neck and back pain. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.