

Case Number:	CM15-0119064		
Date Assigned:	06/29/2015	Date of Injury:	01/18/2014
Decision Date:	08/25/2015	UR Denial Date:	05/22/2015
Priority:	Standard	Application Received:	06/19/2015

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

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 34 year old male with an industrial injury dated 01/28/2013 to 01/28/2014. His diagnoses included lumbar spine herniated nucleus pulposus with annular tear at lumbar 5-sacral 1, bilateral lower extremity radiculopathy, right upper extremity radiculopathy, right shoulder sprain/strain, right wrist sprain/strain, bilateral foot sprain/strain and insomnia. Prior treatments included oral medications and pain cream. He presents on 05/01/2015 with complaints of neck pain rated as 1-2/10 which increases to 5/10 on a bad day. He also complains of intermittent moderate to moderately severe low back pain rated as 5-7 with radiation to the bilateral lower extremities with associated numbness and tingling. Physical exam revealed limited range of motion of the lumbar spine. Straight leg raise, Braggard's and Bowstring's tests were positive bilaterally. Sensory deficit was noted over the bilateral sacral 1 dermatomes. The provider documents the injured worker had worsening radicular complaints. He had failed conservative treatment and medication usage for his low back complaints. MRI of lumbar spine dated 04/24/2015 showed loss of intervertebral disc height and disc desiccation changes at cervical 3-4, cervical 5-6 and cervical 6-7. Disc protrusion was seen at cervical 3-4, cervical 5-6 and cervical 6-7. The formal report is in the submitted records. Treatment plan consisted of high volume lumbar epidural steroid injection at lumbar 5- sacral 1, pain cream and continue home exercise program. Work status was temporarily partially disabled with restriction of no lifting over 20 pounds. The treatment request is for Flurbiprofen 20% cream 120 gm, Gabapentin 10%, Cyclobenzaprine 10%, capsaicin 0.0375% cream 120 gm; Ketoprofen 20%, Ketamine 10% cream 120 gm and high volume lumbar epidural steroid injection at lumbar 5-sacral 1.

IMR ISSUES, DECISIONS AND RATIONALES

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

High volume lumbar epidural steroid injection at L5-S1: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections (ESIs) Page(s): 46.

Decision rationale: Based on the 05/01/15 progress report provided by treating physician, the patient presents with low back pain radiating to the bilateral lower extremities in the S1 dermatome distribution, with associated numbness and tingling, rated 5-7/10. The request is for High Volume Lumbar Epidural Steroid Injection at L5-S1. Patient's diagnosis per Request for Authorization form dated 05/27/15 includes lumbar spine herniated nucleus pulposus with annular tear at L5-S1, and bilateral lower extremity radiculopathy. Treatment to date has included imaging studies, home exercise program, topical creams and medications. The patient is temporarily partially disabled, with work restrictions, per 05/01/15 report. MTUS Chronic Pain Treatment Guidelines, section on Epidural steroid injections (ESIs) page 46 states these are "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy)." The MTUS Criteria for the use of Epidural steroid injections states: "Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing."; and "In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year." Physical examination to the lumbar spine on 05/01/15 revealed limited range of motion, especially on extension 5 degrees. Positive Straight leg, Braggard's, and Bowstring's tests bilaterally. Positive Valsalva. Sensory deficit noted over the bilateral S1 dermatomes. MRI of the lumbar spine dated 04/23/15 revealed "L5-S1: Annular concentric broad-based 4.5mm disc protrusion seen with a focal central annular tear...There is mild to moderate right greater than left lateral spinal and neural foraminal stenosis." Per 05/01/15 report, treater states: "The patient presents today with constant moderately severe low back pain, which radiates to the bilateral lower extremities in the S1 dermatome distribution. His radicular complaints are worsening at this time. He has failed conservative treatment and medication usage for his low back complaints." In this case, treater has documented patient's continued low back pain with radicular symptoms and supported with physical examination findings. MRI of the lumbar spine corroborates with physical exam findings for radiculopathy and requested level to be injected. Review of medical records do not indicate the patient had prior lumbar ESI. This request appears reasonable and in accordance with guidelines. Therefore, the request is medically necessary.

Flurbiprofen 20% Cream 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Topical NSAID's Page(s): 111, 29.

Decision rationale: Based on the 05/01/15 progress report provided by treating physician, the patient presents with low back pain radiating to the bilateral lower extremities, neck pain radiating to the upper extremities, and right shoulder pain. The request is for Flurbiprofen 20% Cream 120gm. Patient's diagnosis per Request for Authorization form dated 05/27/15 includes lumbar spine herniated nucleus pulposus with annular tear at L5-S1, and bilateral lower extremity radiculopathy. Physical examination to the lumbar spine on 05/01/15 revealed limited range of motion, especially on extension 5 degrees. Positive Straight leg, Braggard's, and Bowstring's tests bilaterally. Positive Valsalva. Sensory deficit noted over the bilateral S1 dermatomes. MRI of the lumbar spine dated 04/23/15 revealed "L5-S1: Annular concentric broad-based 4.5mm disc protrusion seen with a focal central annular tear. There is mild to moderate right greater than left lateral spinal and neural foraminal stenosis." Treatment to date has included imaging studies, home exercise program, topical creams and medications. The patient is temporarily partially disabled, with work restrictions, per 05/01/15 report. Topical NSAIDs are indicated for peripheral joint arthritis/tendinitis, MTUS page 29 guidelines state that Flurbiprofen topical is recommended only as an option in patients who have not responded or are intolerant to other treatments. Indications are osteoarthritis, fibromyalgia, chronic non-specific back pain and it is also helpful for chronic neuropathic and musculoskeletal pain. The MTUS has the following regarding topical creams (p111, chronic pain section): "Topical Analgesics: Recommended as an option as indicated below. 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." Per 03/27/15 report, treater states "The patient presents today with continued neck and back pain which radiates to the right upper extremity and bilateral lower extremities. He will be provided a prescription of topical cream medications for pain, muscle spasm and inflammation. The goal is to provide an adjunctive treatment to allow a reduction in the total amount of oral medications required, minimizing the potential side effects of oral medications." However, treater does not discuss how the topical has been used for which body part; and with what effectiveness in terms of pain reduction and function. MTUS requires recording of pain and function when medications are used for chronic pain. This request does not meet guideline recommendations. Therefore, the request is not medically necessary.

Ketoprofen 20%, Ketamine 10% Cream 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 112.

Decision rationale: The request is for Ketoprofen 20%, Ketamine 10% Cream 120gm. Patient's diagnosis per Request for Authorization form dated 05/27/15 includes lumbar spine herniated nucleus pulposus with annular tear at L5-S1, and bilateral lower extremity radiculopathy. Physical examination to the lumbar spine on 05/01/15 revealed limited range of motion, especially on extension 5 degrees. Positive Straight leg, Braggard's, and Bowstring's tests bilaterally. Positive Valsalva. Sensory deficit noted over the bilateral S1 dermatomes. MRI of the lumbar spine dated 04/23/15 revealed "L5-S1: Annular concentric broad-based 4.5mm disc protrusion seen with a focal central annular tear. There is mild to moderate right greater than left lateral spinal and neural foraminal stenosis." Treatment to date has included imaging studies, home exercise program, topical creams and medications. The patient is temporarily partially disabled, with work restrictions, per 05/01/15 report. MTUS Topical Analgesics guidelines pages 111 and 112 has the following regarding topical creams, "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." MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo-contact dermatitis." Per 03/27/15 report, treater states "The patient presents today with continued neck and back pain which radiates to the right upper extremity and bilateral lower extremities. He will be provided a prescription of topical cream medications for pain, muscle spasm and inflammation. The goal is to provide an adjunctive treatment to allow a reduction in the total amount of oral medications required, minimizing the potential side effects of oral medications." However, the requested topical compound contains Ketoprofen, which is not currently FDA approved for topical application, per MTUS. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. This request is not in accordance with guidelines. Therefore, the request is not medically necessary.

Gabapentin 10%, Cyclobenzaprine 10%, Capsaicin 0.0375% cream 120gm: 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 request is for Gabapentin 10%, Cyclobenzaprine 10%, Capsaicin 0.0375% Cream 120gm. Patient's diagnosis per Request for Authorization form dated 05/27/15 includes lumbar spine herniated nucleus pulposus with annular tear at L5-S1, and bilateral lower extremity radiculopathy. Physical examination to the lumbar spine on 05/01/15 revealed limited range of motion, especially on extension 5 degrees. Positive Straight leg, Braggard's, and Bowstring's tests bilaterally. Positive Valsalva. Sensory deficit noted over the bilateral S1 dermatomes. MRI of the lumbar spine dated 04/23/15 revealed "L5-S1: Annular concentric broad-based 4.5mm disc protrusion seen with a focal central annular tear. There is mild to moderate right greater than left lateral spinal and neural foraminal stenosis." Treatment to date has included imaging studies, home exercise program, topical creams and medications. The patient is temporarily partially disabled, with work restrictions, per 05/01/15 report. MTUS has the following regarding topical creams (p111, chronic pain section): "Topical Analgesics: 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. 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. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." MTUS, pg 111-113, Topical Analgesics state they are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and recommends for neuropathic pain when trials of antidepressants and anticonvulsants have failed. MTUS, pg 29, Capsaicin, topical, " Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis osteoarthritis, fibromyalgia, and chronic non-specific back pain. 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. Per 03/27/15 report, treater states: "The patient presents today with continued neck and back pain which radiates to the right upper extremity and bilateral lower extremities. He will be provided a prescription of topical cream medications for pain, muscle spasm and inflammation. The goal is to provide an adjunctive treatment to allow a reduction in the total amount of oral medications required, minimizing the potential side effects of oral medications." However, the requested topical compound contains Gabapentin, Cyclobenzaprine, and Capsaicin 0.0375%, which are not currently FDA approved for topical application, per MTUS. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. This request is not in accordance with guidelines. Therefore, the request is not medically necessary.