

Case Number:	CM15-0202174		
Date Assigned:	10/19/2015	Date of Injury:	12/19/1997
Decision Date:	12/24/2015	UR Denial Date:	10/13/2015
Priority:	Standard	Application Received:	10/14/2015

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: 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 68 year old female, who sustained an industrial injury on 12-19-1997. A review of the medical records indicates that the worker is undergoing treatment for knee pain and pain in joint of lower leg. Subjective complaints (05-27-2015, 08-05-2015, 09-30-2015) included bilateral knee pain that was rated as 9 out of 10 without medication and 7 out of 10 with medication. The injured worker reported that medications were working well. The duration of pain relief was not documented and the specific efficacy of each pain medication was not documented. Objective findings (05-27-2015, 08-05-2015, 09-30-2015) included restricted range of motion of the lumbar spine and right knee, decreased range of motion of the lumbar spine and right knee, tenderness to palpation of the lumbar spine and right knee and mild effusion in the right knee joint. There was no documentation of improved quality of life or increased ability to perform activities of daily living. Treatment has included LidoPro ointment, Diclofenac ER, and Terocin patch (all prescribed since at least 05-27-2015), physical therapy and Monovisc injection. The physician noted that a request for Monovisc injection of the right knee was being submitted and that prior Monovisc injection was effective at reduced pain for greater than 3 months, although there is no documented evidence of efficacy with prior injections. Documentation shows that Synvisc injection of the right knee was approved on 06-17-2015 but that the worker previously requested to hold as "she is unable to do Synvisc series as downtime is increased with series of injections." A utilization review dated 10-13-2015 non-certified requests for Terocin 4-4% patches #10 (RX 09-30-2015), LidoPro ointment (4.5-27.5%-0.0325%-10%) #1 (Rx 9-30-15), Diclofenac ER 100mg #60 (Rx 9-30-15), Monovisc one

injection to the right knee, hepatic function panel including AST and ALT, BUN and urine creatinine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 4-4% patches #10 (Rx 9/30/15): Upheld

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

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically 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, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. The treating provider's notes are not clear about using Terocin patches. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin 4-4% patches #10 is not medically necessary.

LidoPro ointment (4.5%/27.5%/0.0325%/10%) #1 (Rx 9/30/15): Upheld

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

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

Decision rationale: 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. Lidopro contains lidocaine, capsaicin, menthol, and methyl salicylate. 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. Capsaicin has some indications, in the standard formulations readily available without custom compounding. The MTUS also states that capsaicin is only recommended when other treatments

have failed. 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 is silent with regards to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. Topical salicylates are recommended for use for chronic pain and have been found to be significantly better than placebo in chronic pain. In this case, there was no discussion of trial and failure of antidepressant and anticonvulsant agents. The requested treatment contains at least one drug or drug class that is not recommended. The requested treatment is not medically necessary.

Diclofenac ER 100mg #60 (Rx 9/30/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Anti-inflammatory medications.

Decision rationale: Diclofenac Sodium is classified as a non-steroidal anti-inflammatory drug (NSAID). According to California MTUS Chronic Pain Medical Treatment Guidelines, NSAIDs are "recommended for osteoarthritis at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular, or renovascular risk factors". Under back pain - chronic low back pain, it is "recommended as an option for short term symptomatic relief" and "that non-steroidal anti-inflammatory drugs (NSAIDs) were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants." Review of the received medical records do not indicate that Diclofenac Sodium is providing any specific analgesic benefits, such as percent pain reduction or reduction in pain level, or any objective functional improvement. Based on the Guidelines and submitted medical records, the request for Diclofenac ER 100mg #60 is not medically necessary.

Monovisc one injection to the right knee: 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) Knee & Leg (Acute & Chronic)-Hyaluronic acid injections.

Decision rationale: As per Official Disability Guidelines (ODG), it is recommended as a possible option for severe osteoarthritis for patients who have not responded adequately to recommended conservative treatments (exercise, NSAIDs or acetaminophen), to potentially delay total knee replacement, but in recent quality studies the magnitude of improvement appears modest at best. See recent research below. While osteoarthritis of the knee is a recommended indication, there is insufficient evidence for other conditions, including

patellofemoral arthritis, chondromalacia patellae, osteochondritis dissecans, or patellofemoral syndrome (patellar knee pain). Hyaluronic acids are naturally occurring substances in the body's connective tissues that cushion and lubricate the joints. Intra-articular injection of hyaluronic acid can decrease symptoms of osteoarthritis of the knee; there are significant improvements in pain and functional outcomes with few adverse events. Review of submitted medical records of injured worker do not indicate severe osteoarthritis. Given the lack of documentation about failed therapies and other modalities, and also lack of clinical data to support the diagnosis of osteoarthritis, medical necessity of the requested item has not been established. Therefore the request is not medically necessary.

Hepatic function panel including AST and ALT: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: MTUS state use NSAIDS with caution in patients with moderate hepatic impairment, and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15 percent of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Medical records are not clear if this injured worker had previous lab tests. No previous lab test reports can be located in the submitted medical records. Without such information, medical necessity of the requested treatment has not been established. Therefore the request is not medically necessary.

BUN (Blood urea nitrogen): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: MTUS state use NSAIDS with caution in patients with moderate hepatic impairment, and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15 percent of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). Medical records are not clear if

this injured worker had previous lab tests. No previous lab test reports can be located in the submitted medical records. Without such information, medical necessity of the requested treatment: BUN cannot be established. Therefore the request is not medically necessary.

Urine creatinine: 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 www.nlm.nih.gov (National Library of Medicine) Labtestsonline.org.

Decision rationale: CA MTUS does not address this, therefore, alternate guidelines were reviewed. Creatinine is a waste product creatine. It is a chemical made by body and test is done to see how well kidneys work. The notes do not indicate comorbid conditions. Based on the currently available medical information for review, there is no clear rationale provided by the treating provider that indicates why this test is requested. The Requested Treatment: Labs: Urine creatine is not medically necessary and appropriate.