

Case Number:	CM15-0040046		
Date Assigned:	03/10/2015	Date of Injury:	02/01/2000
Decision Date:	04/22/2015	UR Denial Date:	02/17/2015
Priority:	Standard	Application Received:	03/03/2015

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: 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 60-year-old male who sustained an industrial injury on 2/1/00 involving his knees. He currently complains of persistent, achy pain in his bilateral knees. In addition, he has achy pain in his legs and ankles. The pain in all mentioned areas is 8/10. Medications include diclofenac XR, hydrocodone/APAP, Tramadol, Cartivisc. Medications have helped to reduce symptoms and increase his activities of daily living. Diagnoses include right knee pain following revision arthroscopy 10/31/11; left knee patellofemoral pain and bilateral ankle lateral gutter synovitis. Treatment to date includes Synvisc injection. In the progress note, dated 1/21/14, the treating provider's treatment plan includes requests for Tramadol for pain; Cartivisc for joint nutrition; hydrocodone/ APAP for breakthrough pain and diclofenac XR to decrease symptoms. There were no later progress notes available for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac extended release 100mg quantity 30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non Steroidal Anti Inflammatory Drugs; Diclofenac Sodium Page(s): 67-71.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints, Chapter 14 Ankle and Foot Complaints Page(s): 338, 376.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) addresses NSAIDs. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that NSAIDs are recommended for knee and ankle conditions. The orthopedic progress report dated January 21, 2014 documented the diagnoses of right knee pain following revision arthroplasty, left knee patellofemoral pain, and bilateral ankle lateral gutter synovitis. The patient complains of knee, leg, and ankle pain. Medications have helped the patient to increase activities of daily living and reduce his symptoms. Analgesia was documented. Medical records document objective physical examination findings. ACOEM guidelines supports the use of NSAID Diclofenac for knee and ankle conditions. Therefore, the request for Diclofenac is medically necessary.

Hydrocodone/acetaminophen 10/325mg quantity 60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List; Opioids, Criteria for the Use of Opioids Page(s): 91, 93-94; 76-78.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids pages 74-96; Hydrocodone/Acetaminophen page 91.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines (page 89) present the strategy for maintenance for long-term users of opioids. "Do not attempt to lower the dose if it is working." Supplemental doses of breakthrough medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain. Hydrocodone/Acetaminophen (Norco) is indicated for moderate to moderately severe pain. The orthopedic progress report dated January 21, 2014 documented the diagnoses of right knee pain following revision arthroplasty, left knee patellofemoral pain, and bilateral ankle lateral gutter synovitis. The patient complains of knee, leg, and ankle pain. Medications have helped the patient to increase activities of daily living and reduce his symptoms. Analgesia was documented. Medical records document objective physical examination findings. Per MTUS, Hydrocodone / Acetaminophen (Norco) is indicated for moderate to moderately severe pain. The request for Norco (Hydrocodone/Acetaminophen) is supported by the MTUS guidelines. Therefore, the request for Norco 10/325 mg is medically necessary.

Tramadol extended release 150mg, quantity 60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list; Criteria for use of Opioids; Page(s): 91, 93-94; 76-78; 78-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Pages 93-94, 113, 123.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address Ultram (Tramadol). Ultram is indicated for the management of moderate to moderately severe pain. The orthopedic progress report dated January 21, 2014 documented the diagnoses of right knee pain following revision arthroplasty, left knee patellofemoral pain, and bilateral ankle lateral gutter synovitis. The patient complains of knee, leg, and ankle pain. Medications have helped the patient to increase activities of daily living and reduce his symptoms. Analgesia was documented. Medical records document objective physical examination findings. Per MTUS, Ultram (Tramadol) is indicated for the management of moderate to moderately severe pain. MTUS guidelines support the prescription of Ultram (Tramadol). Therefore, the request for Tramadol is medically necessary.

Cartivisc 500/200/150mg quantity 90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) page 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound Drugs. American Family Physician (2008) <http://www.aafp.org/afp/2008/0115/p177.pdf> Osteoarthritis and Cartilage (2008) [http://www.oarsijournal.com/article/S1063-4584\(08\)00066-6/pdf](http://www.oarsijournal.com/article/S1063-4584(08)00066-6/pdf).

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines indicates that Glucosamine and Chondroitin Sulfate is recommended as an option given its low risk, in patients with moderate arthritis pain. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Cartivisc appears to be a compound product that contains Glucosamine, Chondroitin Sulfate, and Methylsulfonylmethane. The American Family Physician article "Dietary Supplements for Osteoarthritis" (2008) indicates that there is insufficient reliable evidence regarding long-term safety or effectiveness of Methylsulfonylmethane. Osteoarthritis and Cartilage journal article "Systematic review of the nutritional supplements dimethyl sulfoxide (DMSO) and methylsulfonylmethane (MSM) in the treatment of osteoarthritis" (2008) concluded that no definitive conclusion can currently be drawn for either supplement. There was no definitive evidence that MSM is superior to placebo in the treatment of mild to moderate

osteoarthritis of the knee. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Cartivisc does not contain an FDA-approved prescription drug. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for Cartivisc is not supported by MTUS or ODG guidelines. Therefore, the request for Cartivisc is not medically necessary.