

Case Number:	CM14-0003704		
Date Assigned:	01/31/2014	Date of Injury:	03/23/2006
Decision Date:	06/27/2014	UR Denial Date:	12/30/2013
Priority:	Standard	Application Received:	01/09/2014

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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 53-year-old male who reported an injury on 03/23/2006; the mechanism of the injury was not provided within the medical records. The clinical note dated 12/05/2013 indicated diagnoses including thoracic spine sprain/strain, lumbar spine degenerative disc disease with radiculitis, bilateral hip osteoarthritis left more severe, right knee osteoarthritis, status post left knee arthroscopy and severe osteoarthritis, morbid obesity, depression, and insomnia. Upon physical exam of the thoracic spine, there was tenderness to palpation and spasms over the paraspinal muscles with restricted range of motion. The lumbar spine had tenderness to palpation and palpable spasms over the paraspinal muscles with restricted range of motion. There was tenderness to palpation with palpable spasms over the bilateral hips with full range of motion. There was tenderness to palpation to the bilateral knees with full range of motion, McMurray's test was positive to the left knee, and there was tenderness to the medial and lateral joint line. The injured worker's prior treatments were not provided for review. The injured worker's prior treatments were not provided for review. The injured worker's treatment plan included physical therapy on hold at this time, Fluriflex, TGHOT, Tramadol, a custom knee brace, and a referral for extracorporeal shockwave therapy to the left knee. The provider indicated topical medications were prescribed in order to minimize possible neurovascular complications, and to avoid complications associated with the use of narcotic medications, as well as upper gastrointestinal bleeding from the use of NSAID medications. The provider submitted a request for a left knee custom unloader brace replacement, bilateral knee elastic support, fluriflex 180gm #1 cream and TGHOT 180gm #1 cream. The Request for Authorization for left knee custom unloader brace replacement, bilateral knee elastic support, fluriflex 180gm #1 cream, TGHOT 180gm #1 cream, and Tramadol 50mg #60 was submitted on 12/05/2013; however, a rationale for the requests was not provided within the documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

LEFT KNEE CUSTOM UNLOADER BRACE REPLACEMENT: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 339-340. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg, Unloader braces for the knee.

Decision rationale: The request for left knee custom unloader brace replacement is non-certified. The American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) states a brace can be used for patellar instability, anterior cruciate ligament (ACL) tear, or medical collateral ligament (MCL) instability although its benefits may be more emotional (i.e., increasing the patient's confidence) than medical. Usually a brace is necessary only if the patient is going to be stressing the knee under load, such as climbing ladders or carrying boxes. For the average patient, using a brace is usually unnecessary. In all cases, braces need to be properly fitted and combined with a rehabilitation program. The Official Disability Guidelines (ODG) indicate the unloader braces are designed specifically to reduce the pain and disability associated with osteoarthritis of the medial compartment of the knee by bracing the knee in the valgus position in order to unload the compressive forces on the medial compartment. Several case series suggest that unloader knee braces appear to be associated with a reduction in pain in patients with painful osteoarthritis of the medial compartment. Custom-fabricated knee braces may be appropriate for patients with the following conditions which may preclude the use of a prefabricated model include Abnormal limb contour (valgus, vargus, tibial varum, disproportionate thigh and calf or minimal muscle mass on which to suspend a brace), skin changes (excessive redundant soft skin or thin skin with risk of skin breakdown), severe osteoarthritis (grade III or IV), maximal off-loading of painful or repaired knee compartment (heavy patient, significant pain) or severe instability as noted on physical examination of the knee. Although the injured worker is morbidly obese, status post knee arthroscopy and severe osteoarthritis, there was lack of evidence as to what grade the osteoarthritis was. In addition, there was lack documentation of a pain assessment. Therefore the request for left knee custom unloader brace replacement is not medically necessary and appropriate.

BILATERAL KNEE ELASTIC SUPPORT: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE PRACTICE GUIDELINES, 2ND EDITION, 2004, CHAPTER 13-KNEE COMPLAINTS, 339-340

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 339-340. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg, Knee braces.

Decision rationale: The request for Bilateral Knee elastic support is non-certified. The American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) states a brace can be used for patellar instability, anterior cruciate ligament (ACL) tear, or medical collateral ligament (MCL) instability although its benefits may be more emotional (i.e., increasing the patient's confidence) than medical. Usually a brace is necessary only if the patient is going to be stressing the knee under load, such as climbing ladders or carrying boxes. For the average patient, using a brace is usually unnecessary. In all cases, braces need to be properly fitted and combined with a rehabilitation program. The Official Disability Guidelines (ODG) indicate there are no high quality studies that support or refute the benefits of knee braces for patellar instability, ACL tear, or MCL instability, but in some patients a knee brace can increase confidence, which may indirectly help with the healing process. Although the injured worker had bilateral knee complaints with osteoarthritis, there was lack of evidence of knee instability in the clinical. As with the previous request for the left custom unloader brace replacement, it is not indicated why the injured worker would need an elastic knee support. Therefore, per the ACOEM guidelines the request for Bilateral Knee elastic support is not medically necessary and appropriate.

FLURIFLEX 180GM #1 CREAM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN GUIDELINES, TOPICAL ANALGESICS, 111-113

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The request for Fluriflex 180gm #1 cream is non-certified. Fluriflex (flubiprofen/cyclobenzaprine 15/10%). The California Chronic Pain Medical Treatment Guidelines state that transdermal compounds are largely experimental in use with few randomized controlled trials to determine efficiency or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ 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 use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Flubiprofen, an NSAID is indicated for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment it is recommended for short-term use (4-12 weeks). Cyclobenzaprine is a muscle relaxant, the guidelines indicate there is no

evidence for use of any other muscle relaxant as a topical product. Although the injured worker had bilateral hip osteoarthritis and right knee osteoarthritis, Cyclobenzaprine is not recommended, the guidelines indicate any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In addition, there was lack of documentation to indicate neurovascular complications, or upper gastrointestinal complications in the documentation. Furthermore, the request did not provide a frequency for the medication. Therefore, per the CA MTUS guidelines, the request for Fluriflex 180gm #1 cream is not medically necessary and appropriate.

TGHOT 180GM #1 CREAM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN GUIDELINES, TOPICAL ANALGESICS, 111-113

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

Decision rationale: The request for TGHOT 180 #1 cream is non-certified. TGHOT (Tramadol/Gabapentin/Menthol/Camphor/Capsaicin 8/10/2/.05.) The California Chronic Pain Medical Treatment Guidelines state that transdermal compounds are largely experimental in use with few randomized controlled trials to determine efficiency or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines note any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There was lack of evidence in the clinical of neuropathic deficit. Furthermore, the Guidelines do not support the use of Gabapentin as a cream. In addition, the guidelines recommend Capsaicin in 0.025%, the 0.05% formulation in the TGHOT exceeds the guidelines recommendation. Therefore, per the CA MTUS guidelines, the request for Fluriflex is not medically necessary and appropriate.

TRAMADOL 50MG #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN GUIDELINES, , 79-81

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Opioids Page(s): 74-95.

Decision rationale: The request for Tramadol 50mg #60 is non-certified. The California Chronic Pain Medical Treatment Guidelines recommend the use of opioids for the on-going management of chronic low back pain. The ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects should be evident. There is a lack of significant evidence of an objective assessment of the injured workers pain level. The request as submitted failed to provide the frequency of the medication. Therefore, the request for TRAMADOL 50MG #60 is not medically necessary and appropriate.

