

Case Number:	CM14-0138614		
Date Assigned:	09/05/2014	Date of Injury:	02/17/2010
Decision Date:	10/14/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	08/27/2014

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 Texas. 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 54 year old male injured on 02/17/10 when he was kneeling on the floor and attempted to stand resulting in bilateral knee pain. Prior treatment included physical therapy, bracing, orthotics, and medication management. The injured worker underwent surgical procedures to the right knee in 2012 and 2013 with ongoing knee pain, right greater than left. Diagnoses included right greater than left medial and lateral meniscal injury with degenerative joint disease and right chondromalacia. Clinical note dated 08/27/14 indicated the injured worker represented complaining of ongoing right knee pain rated 8/10 visual analogue scale characterized as constant and aching with occasional stabbing pain. The injured worker utilized approximately four tablets of Norco 10/325mg for pain management. Physical examination of bilateral lower extremities revealed significant effusion in right knee, significant tenderness to palpation in the medial and lateral joint spaces of the right knee, limited range of motion in flexion to approximately 130 degrees with extension to approximately 30 degrees, manual muscle testing 5/5 throughout bilateral lower extremities, sensation to light touch grossly intact, and reflexes deferred. The use of freeze on was helpful with pain relief. Initial request was non-certified on 08/20/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10mg/325mg #120 with 4 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-80, 91, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Page(s): 77.

Decision rationale: As noted on page 77 of the Chronic Pain Medical Treatment Guidelines, patients must demonstrate functional improvement in addition to appropriate documentation of ongoing pain relief to warrant the continued use of narcotic medications. There is no clear documentation regarding the functional benefits or any substantial functional improvement obtained with the continued use of narcotic medications. Specific examples of improved functionality should be provided to include individual activities of daily living, community activities, and exercise able to perform as a result of medication use. As such, Norco 10mg/325mg #120 with 4 refills is not medically necessary at this time.

Zorvolex 3.5 mg #90 with 4 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac Page(s): 43.

Decision rationale: As noted on page 43 of the Chronic Pain Medical Treatment Guidelines, Diclofenac is not recommended as first line treatment due to increased risk profile. Zorvolex (Diclofenac) is indicated for management of osteoarthritis pain. Post marketing surveillance has revealed that treatment with all oral and topical Diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. The United States Federal Drug Administration advised physicians to measure transaminases periodically in patients receiving long-term therapy with Diclofenac and issued warnings about the potential for elevation in liver function tests during treatment with all products containing Diclofenac sodium. With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. As such, the request for Zorvolex 3.5 mg #90 with 4 refills is not medically necessary at this time.

Solaraze 3% gel topically #1 with 4 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines- compound drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Voltaren Gel (diclofenac) Page(s): 112.

Decision rationale: As noted on page 112 of the Chronic Pain Medical Treatment Guidelines, Diclofenac is not recommended as a first-line treatment. Solaraze (Diclofenac sodium) Gel, 3%, contains the active ingredient, Diclofenac sodium. Diclofenac is recommended for osteoarthritis after failure of an oral NSAID, contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with Diclofenac, including topical formulations. According to FDA MedWatch, post-marketing surveillance of Diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. As such the request for Solaraze 3% gel topically #1 with 4 refills is not medically necessary at this time.

Freeze on topically #1 with 4 refills: Upheld

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

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

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. The components of Freeze On topical cream could not be located following an exhaustive search of the internet. Therefore Freeze on topically #1 with 4 refills is not medically necessary.