MAXIMUS Federal Services

Case Number:	CM15-0091565		
Date Assigned:	05/15/2015	Date of Injury:	05/19/2003
Decision Date:	06/17/2015	UR Denial Date:	04/15/2015
Priority:	Standard	Application Received:	05/12/2015

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 Jersey, Alabama, California
Certification(s)/Specialty: Neurology, Neuromuscular 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:

This 67-year-old woman sustained an industrial injury on 5/19/2003. The mechanism of injury is not detailed. Evaluations include hip and pelvis x-rays that are undated, left hip MRI, Lidoderm patch, Zarvlex, Diagnoses include lumbar facet arthralgia, left greater trochanteric bursitis with hip pain, lumbar disc injury, and left sacroiliac arthralgia. Treatment has included oral and topical medications. Physician notes dated 4/7/2015 show complaints of left low back and left hip pain. The pain is rated 5/10 with medications and 10/10 without medications. Recommendations include left hip MRI, Lidoderm patch, Zarvolex, and follow up in one month.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zorvolex 28mg one (1) BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zorvolex (diclofenac). http://www.odg-twc.com/index.html.

Decision rationale: According to ODG guidelines, Zorvolex (diclofenac) "not recommended except as a second-line option, because diclofenac products are are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac. In late 2013 FDA approved diclofenac capsules (Zorvolex, Iroko Pharmaceuticals LLC) at 18-mg and 35-mg doses for the treatment of mild to moderate acute pain in adults. These dosages are 30% lower in strength than the 25-mg and 50-mg diclofenac products already on the market. The FDA also approved another lower-dose NSAID from Iroko Pharmaceuticals, indomethacin capsules (Tivorbex). While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes-serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries." (FDA, 2013) There is no documentation that the patient failed first line NSAID. There is no documentation of the advantage of using Zorvolex rather than other NSAID. There is no documentation that the drug has a less side effect profile than other NSAID. Therefore, the request for Zorvolex 28mg one (1) BID #60 is not medically necessary.

Lidoderm 5% patch 12 hour on/ 12 hour off #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56.

Decision rationale: According to MTUS guidelines, "Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin." In this case, there is no documentation that the patient developed neuropathic pain that did not respond to first line therapy and the need for Lidoderm patch is unclear. There is no documentation of efficacy of previous use of Lidoderm patch. Therefore, the prescription of Lidoderm patches #90 is not medically necessary.