

Case Number:	CM14-0148394		
Date Assigned:	10/23/2014	Date of Injury:	09/03/1991
Decision Date:	12/11/2014	UR Denial Date:	08/22/2014
Priority:	Standard	Application Received:	09/12/2014

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 Internal Medicine and Emergency Medicine and is licensed to practice in Florida. 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:

This patient is a 69 year-old with a date of injury of 09/03/91. A progress report associated with the request for services, dated 08/04/14, identified subjective complaints of left buttock and left knee pain, unchanged from previous. Objective findings included tenderness to palpation of the lumbar spine with decreased range of motion. Diagnoses (paraphrased) included sacroiliitis; lumbar disease; knee osteoarthritis and pain. Treatment had included a laminectomy and Norco. A Utilization Review determination was rendered on 08/22/14 recommending non-certification of "Vicoprofen 7.5/200 #140; Zipsor (Diclofenac); and Lidoderm Patch 5%".

IMR ISSUES, DECISIONS AND RATIONALES

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

Vicoprofen 7.5/200 #140: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines: NSAIDs (non-steroidal a.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Functional Improvement Measures; NSAIDs; Opioids Page(s): 48; 67-73; 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, NSAIDs

Decision rationale: Vicoprofen is the opioid analgesic hydrocodone in combination with the NSAID, ibuprofen. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The MTUS further states that opioids are not recommended for more than 2 weeks for low back complaints. The patient has been on opioids in excess of 16 weeks. The Medical Treatment Utilization Schedule (MTUS) states that NSAIDs are recommended for use in osteoarthritis. It is noted that they are: "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." The Official Disability Guidelines (ODG) state that studies have found that NSAIDs have more side effects than acetaminophen or placebo, but less than muscle relaxants or narcotic analgesics. Another study concluded that NSAIDs should be recommended as a treatment option after acetaminophen. Concurrent use of SSRIs is not recommended as the combination is associated with a moderate risk of serious upper GI events compared to use of NSAIDs alone (Helin-Salmivaara 2007). The record indicates that the therapy is long-term rather than for a short period. In this case, there is no documentation of the other elements of the pain assessment referenced above or necessity of therapy beyond 16 weeks or specific functional improvement. Likewise, their use is in the setting of SNRI antidepressants. Therefore, there is no documented medical necessity for Vicoprofen.

Zipsor (Diclofenac): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines: NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment in Workers' Compensation, Diclofenac

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Zipsor (diclofenac) is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and

or short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is diclofenac. In this case, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of diclofenac as an NSAID topical agent. Likewise, the request is for an indication for which there is little evidence of benefit (low back). Therefore, the medical record does not document the medical necessity for Zipsor.

Lidoderm Patch 5%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Lidoderm

Decision rationale: Lidoderm (lidocaine patch) is a topical anesthetic. The California Medical Treatment Utilization Schedule (MTUS) states: "Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI antidepressants or an anti-epilepsy drug such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia." The Official Disability Guidelines (ODG) also state that Lidoderm is not recommended until after a trial of first-line therapy. The following criteria are listed for use:- Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology;- There should be evidence of a trial of first-line neuropathic medications (tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica);- This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger joints;- An attempt to determine a neuropathic component of pain should be made;- The area for treatment should be designated as well as number of planned patches and duration of use (number of hours per day);- A trial of patch treatment is recommended for a short-term period;- Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued. Therefore, in this case, there is no documentation of the neuropathic component of the pain, failure of conventional first-line therapy, or documented functional improvement for the medical necessity of Lidoderm.