

Case Number:	CM15-0099413		
Date Assigned:	06/01/2015	Date of Injury:	06/22/2011
Decision Date:	07/07/2015	UR Denial Date:	05/14/2015
Priority:	Standard	Application Received:	05/22/2015

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: Physical Medicine & Rehabilitation

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 (IW) is a 66-year-old male who sustained an industrial injury on 06/22/2011. The original report of injury is not in the medical records submitted. The injured worker was diagnosed as having lumbar sprain and strain, displacement intervertebral disc site without myelopathy. Treatment to date has included a lumbar epidural steroid injection to which he had no response, and medications for pain, and sleep. Currently, the injured worker complains of ongoing back pain with numbness and tingling in the right lower extremity. He complains of sexual dysfunction due to pain and to lumbar disc herniation. He denies any bowel or bladder incontinence. On examination, his lumbar spine is tender with spasm and decreased range of motion. Electromyograms showed a L5 radiculopathy. X-rays showed loss of disc height at L4- 5 and L5-S1 with osteophyte formation and facet arthropathy. MRI show multilevel degenerative disc disease. He awaits authorization for a L5-S1 fusion. Requests for authorization are submitted for: Vicoprofen 7. 5mg #40, prescribed 5/5/15 and Cialis 5mg #30, prescribed 5/5/15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Vicoprofen 7. 5mg #40, prescribed 5/5/15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-78, 88-89. Decision based on Non-MTUS Citation Official disability guidelines Drug Formulary, specifically discusses Hydrocodone/Ibuprofen (Vicoprofen®).

Decision rationale: The patient presents with pain and weakness in his lower back and lower extremity. The request is for VICOPROFEN 7.5MG #40. RFA is dated on 05/07/15. Regarding work status, the treater states that the patient "may work with restrictions beginning immediately." Review of the reports does not provide any discussion specific to this medication. Vicoprofen and Cialis are prescribed on the 05/05/15 progress report. Multiple MRIs of the lumbar spine from 07/26/11, 07/29/12, and 07/29/13 demonstrate degenerative disc disease at L4-5 and L5-S1 with L4-5 anterolisthesis and central/foraminal stenosis. EMG/NCV from 10/02/12 reveals right L5 radiculopathy. Regarding chronic opiate use, MTUS guidelines page 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. ODG guidelines, under Drug Formulary, specifically discusses Hydrocodone/Ibuprofen (Vicoprofen) and "Recommended for short term use only. This combination opioid/NSAID has a low dose of ibuprofen (200mg) that is below the normal adult dose of 400 to 800 mg per dose and total max daily dose of 2400mg. Vicoprofen was approved only based on single dose, post-op pain and is approved to treat acute pain for generally less than 10 days. It may be considered an option for use at the time of injury, but the fixed dose of hydrocodone 7.5mg/ibuprofen 200mg and the maximum approved dose of 5 tablets daily may limit acute pain relief. Prescribing information also stresses that this product is not indicated for treating conditions such as rheumatoid arthritis or osteoarthritis. (Vicoprofen prescribing information) In addition, there is also a cost difference between the generic Vicodin (approx [REDACTED]/tab) and generic Vicoprofen([REDACTED]/tab)." In this case, the four A's including analgesia, ADL's, side effects, and aberrant drug seeking behavior are not addressed as required by MTUS for chronic opiate use. There are no before and after pain scales to show analgesia; no specific ADL's are mentioned to show functional improvement; no urine toxicology, CURES reports showing opiate monitoring. Given the lack of sufficient documentation demonstrating efficacy for chronic opiate use, the patient should slowly be weaned as outlined in MTUS guidelines. The request IS NOT medically necessary.

Cialis 5mg #30, prescribed 5/5/15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines <http://www.drugs.com/pro/cialis.html#indications>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation AETNA Guidelines Clinical Polity Bulletin No. 0007 regarding erectile dysfunction.

Decision rationale: The patient presents with pain and weakness in his lower back and lower extremity. The request is for CIALIS 5MG #30. RFA is dated on 05/07/15. Regarding work status, the treater states that the patient "may work with restrictions beginning immediately. " There are conflicting documentations regarding the patient's sexual dysfunction. The 04/16/15 progress report states that "the patient denies sexual dysfunction. " The 05/05/15 progress report states that the patient has "sexual dysfunction due to pain, lumbar disc herniation. " MTUS, ODG and ACOEM are silent on Cialis. FDA indications/boxed label state that CIALIS is approved to treat erectile dysfunction. AETNA Guidelines Clinical Polity Bulletin No. 0007 regarding erectile dysfunction states that a comprehensive physical/examination and lab workup for the diagnosis of erectile dysfunction (ED) including medical, sexual, and psychosocial evaluation is required. AETNA also does not support performance-enhancing drugs such as Viagra or Cialis. In this case, there is no documentation of hypo-gonadism, no indication that the patient is on chronic opioids with low-testosterone level. There is no discussion regarding erectile dysfunction and performance-enhancing drugs such as Cialis are not typically supported by the guidelines. This request IS NOT medically necessary.