

Case Number:	CM15-0069881		
Date Assigned:	04/17/2015	Date of Injury:	06/22/2010
Decision Date:	06/25/2015	UR Denial Date:	03/05/2015
Priority:	Standard	Application Received:	04/13/2015

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:

The injured worker is a 67-year-old male who sustained an industrial injury on 08/22/10. Initial complaints and diagnoses are not available. Treatments to date include medications, physical therapy, acupuncture, and back surgery. Diagnostic studies include x-rays and a MRI of the lumbar spine. Current complaints include soreness in the low back. Current diagnoses include spondylolisthesis, lumbar stenosis, radiculopathy, cauda equine syndrome, bursitis of the shoulder, and rotator cuff syndrome. In a progress note dated 01/21/15 the treating provider reports the plan of care as additional physical therapy, acupuncture, and medications including tramadol, Xanax, Celebrex, as well as a cortisone injection to the left shoulder and a lumbar epidural steroid injection. The requested treatments include [REDACTED] opioid genetics profile and drug metabolism genetic profile.

IMR ISSUES, DECISIONS AND RATIONALES

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

Outpatient [REDACTED] opioid risk genetics profile and [REDACTED] drug metabolism genetics profile: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pharmacogenetic testing/pharmacogenetics (opioids & chronic non-malignant pain).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pharmacogenetic testing/pharmacogenomics (opioids & chronic non-malignant pain). <http://www.odg-twc.com/index.html>.

Decision rationale: According to ODG guidelines, Pharmacogenetic testing Not recommended. Testing is not recommended except in a research setting. In many complex trials evaluating the effect of opioids on pain, population-based genetic association studies have had mixed success and reproducibility has been poor. Evidence is not yet sufficiently robust to determine association of pain-related genotypes and variability in opioid analgesia in human studies. There are currently multiple challenges in using this technique in the context of pain: (1) the phenotypes involved are multifaceted; (2) pain perception has a subjective nature; (3) response to analgesia can also be subjective; (4) there is a wide inter-individual pharmacologic range in response to drugs. The range in which genetic factors are thought to play a role in pain perception is from 12% to 60%. Gender and age also play a role. There are no published guidelines for generalized testing of the cytochrome system outside of certain populations (specific cancers, patients requiring anticoagulation, and human immunodeficiency virus patients). U.S. FDA: In clinical practice, no tests have been recommended by the U.S. FDA. This organization has published the Table of Pharmacogenomic Biomarkers in Drug Labeling. (FDA, 2015) Drug labeling may contain information about drug exposure and clinical response variability, risk for adverse events, genotype-specific dosing, mechanisms of drug action, and polymorphic drug target and disposition genes. Opioid and opioid-like drugs listed in this table include codeine and tramadol. These drugs are listed under the therapeutic area of anesthesiology so there is no note as to whether information provided is related to chronic non-malignant pain treatment. Suggested reasons for testing: There has been some suggestion that testing should be undertaken in patients who are on high dose opioids (morphine equivalent dose 150 mg/day). Recent opioid guidelines, including the ODG do not recommend opioids greater than this dose, and there are no randomized controlled trials to support this. In addition, most opioids can be adequately titrated in clinical practice. Opioid metabolism: Cytochrome P450 enzymes are responsible for about 80% of phase I metabolism of codeine, hydrocodone, oxycodone, tramadol, fentanyl and methadone. The three major groups responsible are CYP2D6, CYP3A, and CYP2C. Opioids that are unaffected or only mildly affected by CYP 450 include morphine, hydromorphone, oxymorphone, and tapentadol. The latter primarily use glucuronidation for metabolism. Most opioids act without biotransformation at the opioid receptor and provide pain relief without being metabolized in first-pass effect. (Vuilleumier, 2012) (Stamer, 2010) (Xu, 2013) (Nielsen, 2014) (Hajj, 2013) (Branford, 2012) See also Genetic testing for potential opioid abuse; Cytochrome P450 testing. There is no strong evidence supporting that Pharmacogenetic testing will benefit the patient pain management and will influence therapeutic decision and medication titration. Therefore, the request for Outpatient [REDACTED] opioid risk genetics profile and [REDACTED] drug metabolism genetics profile is not medically necessary.