

<b>Case Number:</b>	CM14-0185604		
<b>Date Assigned:</b>	11/13/2014	<b>Date of Injury:</b>	02/02/2011
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	10/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/07/2014

### 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 Family Medicine and is licensed to practice in Colorado. 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:

28 year old female with date of injury 2/2/2011 continues care with treating physician and specialists. She has ongoing low back pain radiating to right leg which is also weak. Per the records, patient's previous treatments have included physical therapy, home exercises, injections, ice/heat, modified work, massage, medications including narcotics and muscle relaxers, laminectomy and facetectomy with L5-S1 fusion 5/20/2013. Patient continues with pain despite all interventions and has diagnosis of Post Laminectomy Syndrome / Failed Back Syndrome. Patient is maintained on Vicodin and Flexeril and reports no relief of pain. The treating Physician requests refills on Vicodin, Flexeril, and Omeprazole.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20mg #30 with 1 refill prescribed on 9/19/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs GI Symptoms and Cardiovascular Risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs GI Symptoms and Cardiovascular Risk Page(s): 68.

**Decision rationale:** Per the MTUS Guidelines, Prilosec and other Proton pump inhibitors can be indicated for use with non-steroidal anti-inflammatory drugs, in those at high risk for

gastrointestinal events, or in those on high dose / multiple medications that increase risk of gastrointestinal events. For the patient of concern, the records do not indicate any diagnosis or medications that would warrant Prilosec use. Patient did previously take non-steroidal anti-inflammatory drugs, and steroids, but notes in December 2013 indicate that she was no longer taking the non-steroidal anti-inflammatory drug because of upset stomach. No further mention was made of the non-steroidal anti-inflammatory agent use, and it is no longer on her active medication list as of most recent treating physician notes. However, the Omeprazole is still prescribed without any discussion of diagnosis, risk, or medication that would indicate its use is needed. The request for Omeprazole is not medically indicated based on lack of documentation for its need.

**Flexeril 10mg #60 with 1 refill prescribed on 9/16/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril), Cyclobenzaprine (Flexeril, Amrix, Fexmid, Generic available) Page(s).

**Decision rationale:** Cyclobenzaprine (Flexeril) and other antispasmodics are recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help more than placebo with back pain and fibromyalgia, but has several side effects that limit its use. Furthermore, Cyclobenzaprine works best in the first 4 days of use, so short courses recommended, no more than 2-3 weeks. No quality, consistent evidence exists to support chronic use of Cyclobenzaprine. Common side effects of Cyclobenzaprine include: anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) The records supplied indicate patient has been taking Cyclobenzaprine greater than 3 months, albeit intermittently, and there is no documentation that her pain or function have improved with the Cyclobenzaprine. As there is no support, per the guidelines, for long term use and no documented improvement, the request for Cyclobenzaprine is not medically indicated.

**Vicodin 5/300mg #60 with 1 refill prescribed on 9/16/14: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Opioids Long-Term Users of Opioids, Opioid Specific Drug List Page(s): 79-80, 85, 88-89.

**Decision rationale:** The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were

helpful. When re-assessing, pain levels and improvement in function should be documented; pain levels should be documented every visit. Function should be evaluated every 6 months using a validated tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence" Per the Guidelines, Chelminski defines "serious substance misuse" or non-adherence as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) Procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005) 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work? Has patient had improved function and decreased pain with the opioids? Per the records for the patient of concern, her pain level is unchanged over time, and physician notes in September 2014 document her pain as 10/10 on current regimen which indicates lack of response to opioid. Likewise, the records do not include objective evidence of functional improvement on current regimen. Furthermore, the only urine drug screen referenced in the records was 1/23/2014, and the treating physician notes indicated patient would be counseled regarding the inconsistent results. (Gabapentin identified when patient was not prescribed that) There is no documentation that patient was counseled on this, and no follow up urine drug screen in the record. As patient's pain and function are not documented as objectively improved, and as patient's inconsistent urine drug screen has not been addressed and followed up, the monitoring of opioid use in this patient is lacking verifiable information. When opioid use is not monitored and managed according to the guidelines, and the opioid use is not improving pain and/or

function, then opioid use is no longer medically indicated. Based on the above, the request for Vicodin refill is not medically necessary.