

Case Number:	CM14-0103053		
Date Assigned:	09/24/2014	Date of Injury:	02/16/2005
Decision Date:	01/07/2015	UR Denial Date:	06/04/2014
Priority:	Standard	Application Received:	07/03/2014

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:

The injured worker is a 50 year old male with date of injury of 2/15/2005 who continues care with the treating physician. His complaints include pelvis and thigh pain with left hip pain radiating to left foot. He is status post left total hip replacement in 2005 for avascular necrosis. The patient is maintained on a medication regimen and the treating physician requests continuation of medications: Ambien, Baclofen, Ibuprofen, Protonix, and Norco.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien 10 mg tablet, QTY: 30.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Zolpidem (Ambien)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index 11th Edition, Pain Chapter, Ambien Other Medical Treatment Guideline or Medical Evidence: <http://www.fda.gov/Drugs/default.htm>

Decision rationale: The MTUS Guidelines and ACEOM do not address Ambien, so alternate references were consulted. Per the FDA, Ambien is indicated for short term treatment of

insomnia. Ambien has been shown in quality controlled studies to decrease time to sleep for up to 35 days. Per the FDA dosage guidelines, lowest effective dose is recommended, 5mg for women and geriatric patients or patients with liver impairment, and 5mg-10mg for men. Patient should be re-evaluated and Ambien reconsidered if sleep is not improved after 7-10 days. Likewise, the ODG recommends Ambien only for short term use, 2-6 weeks. Long term use of Ambien is not supported because of risks of tolerance and dependence as well as risks of worsening depressive symptoms. Per the ODG, good sleep hygiene is also considered an important recommendation to be used in conjunction with Ambien. Per the records supplied for review, the patient of concern has been taking Ambien long term, greater than 6 weeks, at the time of the request for refill. (While the treating physician's appeal letter indicates patient takes Ambien as needed, not routine, regardless, the cumulative time he has been using this medication exceeds recommendations) As above, long term use is not an FDA-approved indication or ODG recommended use for Ambien, so the Ambien request is not medically indicated.

Baclofen 10 mg tablet QTY: 30.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 63-64.

Decision rationale: Per the Guidelines, muscle relaxers are recommended, as second line therapy for low back pain, primarily acute exacerbations of chronic issue. (Muscle relaxers are prescribed, however, for many musculoskeletal conditions) Some evidence suggests that muscle relaxers may help decrease pain and muscle spasm, and may increase mobility, but those effects are short lived. No benefit has been shown when muscle relaxers are added to non-steroidal anti-inflammatory drugs for pain. Appropriate effects of muscle relaxers diminish over time, and long term use with some can lead to dependence. Therefore, though these medications are commonly prescribed for a variety of conditions, they are not recommended as primary treatment for chronic painful musculoskeletal conditions. Of the muscle relaxers available, those with the least evidence to support their use include Chlorzoxazone, Methocarbamol, Dantrolene and Baclofen. (Chou, 2004) Baclofen is classified as an anti-spasticity drug, per the Guidelines, and works at the pre-synaptic and post-synaptic levels for GABA receptors. It is indicated to treat spasms and spasticity related to multiple sclerosis and spinal cord injuries, and has been used off label for paroxysmal neuropathy such as trigeminal neuralgia. Recommended dosing for Baclofen is 5mg 3 times per day, to titrate up as needed. Baclofen should not be abruptly discontinued due to possible hallucinations / seizures that may develop. For the patient of concern, the Baclofen is intended to be used for hip pain with related spasms. Per the records, the patient previously took Tizanidine as needed with insufficient improvement, so Baclofen was prescribed as alternative. There is no evidence to support the change from one muscle relaxer to another because of lack of efficacy. Furthermore, patient does not have spasticity or spinal cord injury / multiple sclerosis, so Baclofen has little support for its use in this patient's condition. It is unclear in the record exactly how the Baclofen here is to be dosed, but the requested strength of 10mg tablet exceeds the starting dose recommended for Baclofen. As patient has not had relief

from previous extended use of muscle relaxer, and current dose requested exceeds recommended starting dose for Baclofen, the request for Baclofen is not medically indicated.

Ibuprofen 800 mg tablet QTY: 90.00 with 6 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list and adverse effects Page(s): 70.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 22 and 68.

Decision rationale: Per the MTUS Guidelines, non-steroidal anti-inflammatory drugs are recommended as second line agents for pain, after trial of Acetaminophen, (particularly for those patients at risk for gastrointestinal events, cardiac events, and renal disease), to be taken at the lowest effective dose for shortest period of time. Non-steroidal anti-inflammatory drugs may be first line for moderate to severe pain, based on available evidence, though studies cannot consistently confirm that non-steroidal anti-inflammatory drugs are superior to Acetaminophen. There is no evidence that any of the non-steroidal anti-inflammatory drugs are effective long term for pain relief or functional improvement. There is no consistent evidence that non-steroidal anti-inflammatory drugs are useful for long term management of neuropathic pain. For the patient of concern, the records supplied do indicate 50% improvement in pain with Ibuprofen as part of his regimen, though no pain ratings are included in the documentation to clarify that. The treating physician's notes indicate patient's function is improved on his current regimen (including Ibuprofen), but the notes do not provide specifics on improved activities of daily living or work activities to objectively quantify the improvement. The treating physician's appeal letter indicates patient only takes the Ibuprofen as needed, yet he has still cumulatively exceeded the short term use recommended for non-steroidal anti-inflammatory drugs. Given the lack of evidence, per the Guidelines, to support long term use of non-steroidal anti-inflammatory drugs in pain treatment, and the lack of verifiable improvement in function for this patient with non-steroidal anti-inflammatory drug, the request for Ibuprofen is not medically necessary.

Pantoprazole-protonix 20 mg, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Pain (Chronic) Proton pump inhibitors (PPIs)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 68.

Decision rationale: Per the Guidelines, a patient at intermediate risk for gastrointestinal event, but at no risk from cardiovascular event, would need a non-selective non-steroidal anti-inflammatory drug, and Proton Pump Inhibitor to protect stomach. Non-steroidal anti-inflammatory drugs do carry risks of gastrointestinal symptoms and cardiovascular and renal effects. The following questions should be taken into consideration when providing non-steroidal anti-inflammatory drugs for pain patients:(1) age > 65 years; (2) history of peptic ulcer,

GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the records for the patient of concern, the issue of gastrointestinal events was not addressed except in the appeal letter, where it is indicated that patient had gastrointestinal upset and abdominal pain when taking Celebrex. (No known peptic ulcer disease of bleed) He would still not meet the above criteria for proton pump inhibitor addition to non-steroidal anti-inflammatory drug use. Furthermore, as it is not recommended for patient to continue non-steroidal anti-inflammatory drug use, then the protective proton pump inhibitor, Protonix, would not be medically necessary.

Norco 10-325mg #90, with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89, and 91.

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) For the patient of concern, the records supplied do indicate 50% improvement in pain with Norco as part of his regimen, though no pain ratings (pain level out of 10) are included in the documentation to clarify that. The treating physician's notes indicate patient's function is improved on his current regimen (including Norco), but the notes do specify any objective evaluation to quantify the improvement. While the treating physician indicates in a peer to peer report that patient continues to meet the "4 A's" for monitoring of opioid use, the records supplied do not otherwise indicate that patient is being monitored for objective functional improvement or aberrant drug-taking behavior. Given the lack of verifiable improvement in function and the lack of documentation of appropriate monitoring of opioid use for this patient, the request for Norco is not medically necessary.