

Case Number:	CM15-0100510		
Date Assigned:	06/02/2015	Date of Injury:	06/21/2011
Decision Date:	07/07/2015	UR Denial Date:	05/05/2015
Priority:	Standard	Application Received:	05/26/2015

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: Pennsylvania

Certification(s)/Specialty: Internal 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:

This 41 year old woman sustained an industrial injury on 6/21/2011 due to lifting a chair. Diagnoses include failed back fusion with left radiculopathy, bilateral carpal tunnel syndrome, status post right elbow lateral release, left leg numbness, chest pain, hypertension, sleep disorder, depressive disorder, and incontinence. Treatment has included oral and topical medications, injections, lumbar laminectomy and fusion, right carpal tunnel release, elbow surgery. A progress note from February 2014 notes that the injured worker complained of persistent leg pain and increased bladder dysfunction, that urecholine was not working as before, and a urology consultation was requested. Norco, omeprazole, gabapentin, cyclobenzaprine, ambien, atenolol, lexapro, and urecholine were prescribed in September 2014. Per a neurosurgical evaluation in November 2014, urecholine was noted to be prescribed for "sleepy bladder," norco for pain, flexeril for muscle relaxation, gabapentin for pain, ambien for insomnia, and atenolol for high blood pressure. Work status at that time was noted as temporary total disability. Protonix, cyclobenzaprine, Neurontin, urecholine, atenolol, and ambien were among prescribed medications in December 2014 and January 2015. Work status in January 2015 was noted as temporarily totally disabled. Pain and numbness were reported to be worse in May 2015, and a spinal cord stimulator trial was discussed. On 5/5/15, Utilization Review (UR) non-certified or modified requests for the items currently under Independent Medical Review, citing the MTUS, ODG, and drugs.com

IMR ISSUES, DECISIONS AND RATIONALES

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

Urecholine 25mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medline Plus.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Bethanechol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Bethanechol (urecholine) is a cholinergic agonist used for treatment of neurogenic bladder and urinary retention. The MTUS and ODG are silent regarding urecholine. This injured worker was noted to have a diagnosis of incontinence. Urecholine was prescribed since at least February 2014, at which time it was noted to be not working as previously, with increased bladder dysfunction. A neurosurgical report notes that urecholine was prescribed for "sleepy bladder" without further discussion. The treating physician has documented a plan for urology consultation, without further discussion of any urinary signs and symptoms. No diagnostic evaluation for bladder issues was documented. There was no specific documentation of diagnoses of neurogenic bladder or urinary retention, the approved indications for this medication. Due to insufficient documentation of specific indication, and lack of sufficient evaluation for bladder dysfunction, the request for urecholine is not medically necessary.

Gabapentin 300mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): 16-22.

Decision rationale: This injured worker has chronic back pain. Gabapentin (Neurontin) has been prescribed since at least September 2014. Per the MTUS, anti-epilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. The MTUS notes the lack of evidence for treatment of radiculopathy. In this case, there was no documentation of the reason for prescription of gabapentin, and no documentation of presence of neuropathic pain. A 'good' response to the use of AEDs is defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. Lack of at least a 30% response per the MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. In this case, there was no documentation of reduction in pain or improvement in function as a result of use of gabapentin. The most recent work status documented was temporarily totally disabled, and there was no discussion of return to work or improvement in activities of daily living. Due to lack of specific indication and lack of functional improvement, the request for gabapentin is not medically necessary.

Lexapro 20mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Stress related conditions, Antidepressants.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 401-402, Chronic Pain Treatment Guidelines antidepressants p. 13-16, SSRIs

p. 107 Page(s): 13-16, 107. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) mental illness and stress chapter: antidepressants for treatment of major depressive disorder.

Decision rationale: This injured worker has chronic back pain and history of depression. The reason for prescription of lexapro was not discussed by the treating physician. Lexapro has been prescribed since at least September 2014. The MTUS states that antidepressants are recommended as a first line option for neuropathic pain and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Selective serotonin reuptake inhibitors (SSRIs) are controversial based on clinical trials. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. The ACOEM notes that brief courses of antidepressants may be helpful to alleviate symptoms of depression, but that given the complexity of available agents, referral for medication evaluation is advised. The ODG states that antidepressants offer significant benefit in the treatment of the severest depressive symptoms, but may have little or no therapeutic benefit over and above placebo in patients with mild to moderate depression. There was no documentation of psychological or psychiatric assessment, and no signs and symptoms or severity of depression were discussed. No mental status examination was submitted. There was no documentation of functional improvement as a result of treatment with lexapro. Due to insufficient documentation of the indication for this medication, the lack of functional improvement, and lack of a psychological assessment, the request for lexapro is not medically necessary.

Atenolol 50mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) diabetes chapter: hypertension treatment and Other Medical Treatment Guidelines Overview of hypertension in adults. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: This injured worker has a diagnosis of hypertension. The reason for prescription of atenolol was not discussed by the treating physician, but is presumably related to this diagnosis per the neurosurgical consultation. The MTUS is silent on treatment of hypertension. The ODG addresses hypertension treatment in the context of patients with additional diagnosis of diabetes (which is not present for this injured worker). The additional UpToDate citation notes that all hypertensive patients should undergo appropriate lifestyle

modification. Antihypertensive medications should generally be begun if the systolic blood pressure is persistently more than or equal to 140 mmHg in patients younger than 60 years, or more than or equal to 150 mmHg in patients 60 years and older, and/or the diastolic pressure is persistently more than 90 despite attempted non-pharmacologic therapy. Starting with two drugs should be considered in patients with a baseline blood pressure above 160/100. There are four main classes of drugs that are recommended for use as initial monotherapy: thiazide diuretics, long acting calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin II receptor blockers (ARBs). Most guidelines support the use of any of these classes as initial therapy in many patients. Atenolol is a beta blocker. The guideline cited does not support the use of a beta blocker for initial therapy of hypertension. In this case, there was no documentation of blood pressure measurements in spite of treatment with atenolol for at least eight months. There was some minimal notation in the records submitted regarding weight issues, but no discussion about the use of lifestyle modifications for the management of hypertension. As atenolol is not considered a first line agent for hypertension, and as the records submitted contain no evidence of blood pressure monitoring or sufficient discussion of the use of lifestyle modifications, the request for atenolol is not medically necessary.

Ambien 10mg #30: 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, 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) chronic pain chapter: insomnia treatment, Ambien.

Decision rationale: This injured worker has ongoing back pain and a diagnosis of sleep disorder. Ambien has been prescribed for insomnia for at least eight months. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia were not addressed. Ambien (Zolpidem) is a prescription short-acting non-benzodiazepine hypnotic which is recommended for short-term (7-10 days) treatment of insomnia; it is not recommended for long-term use. It may be habit-forming and may impair function and memory, and there is a concern that it may increase pain and depression over the long term. It is recommended for short term use only. The Official Disability Guidelines citation recommends short term use of zolpidem, a careful analysis of the sleep disorder, and caution against using zolpidem in the elderly. Due to length of use in excess of the guideline recommendations and insufficient documentation of evaluation for sleep disturbance, the request for ambien is not medically necessary.

Lisinopril 10mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) diabetes chapter: hypertension treatment and Other Medical Treatment Guidelines Overview of hypertension in adults. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: This injured worker has a diagnosis of hypertension. The reason for prescription of lisinopril was not discussed by the treating physician, but is presumably related to this diagnosis. The MTUS is silent on treatment of hypertension. The ODG addresses hypertension treatment in the context of patients with additional diagnosis of diabetes (which is not present for this injured worker). The additional UpToDate citation notes that all hypertensive patients should undergo appropriate lifestyle modification. Antihypertensive medications should generally be begun if the systolic blood pressure is persistently more than or equal to 140 mmHg in patients younger than 60 years, or more than or equal to 150 mmHg in patients 60 years and older, and/or the diastolic pressure is persistently more than 90 despite attempted non-pharmacologic therapy. Starting with two drugs should be considered in patients with a baseline blood pressure above 160/100. There are four main classes of drugs that are recommended for use as initial monotherapy: thiazide diuretics, long acting calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors (such as lisinopril), and angiotensin II receptor blockers (ARBs). Most guidelines support the use of any of these classes as initial therapy in many patients. The use of lisinopril was not previously documented in the records submitted, and the request is consistent with a new request. The records indicate prior treatment (presumably for hypertension) with atenolol. In this case, there was no documentation of blood pressure measurements in spite of treatment with atenolol for at least eight months. There was some minimal notation in the records submitted regarding weight issues, but no discussion about the use of lifestyle modifications for the management of hypertension. As there were no blood pressure measurements submitted to support the need for two antihypertensive agents, and insufficient documentation of the use of lifestyle modifications, the request for lisinopril is not medically necessary.

Pantoprazole DR 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: This injured worker has chronic back pain. Proton pump inhibitors have been prescribed for at least eight months. Per the MTUS, co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). None of these risk factors were present for this injured worker, and there was no documentation of the use of NSAIDS. There are no medical reports which adequately describe any signs and symptoms of possible GI (gastrointestinal) disease. There is no examination of the abdomen on record. Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures, pneumonia, Clostridium-difficile-

associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. Due to lack of specific indication, and potential for toxicity, the request for pantoprazole is not medically necessary.

Cyclobenzaprine 7.5mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42, muscle relaxants p. 63-66.

Decision rationale: This injured worker has chronic back pain. Cyclobenzaprine has been prescribed for at least eight months. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix, Trabadol) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple additional medications. Limited, mixed evidence does not allow for a recommendation for chronic use. Cyclobenzaprine, per the MTUS, is not recommended in combination with other agents. This injured worker has been prescribed multiple medications along with cyclobenzaprine. Due to length of use in excess of the guideline recommendations, the request for cyclobenzaprine is not medically necessary.

Hydrocodone/APAP 10/325 #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96.

Decision rationale: This injured worker has chronic back pain. Hydrocodone/acetaminophen (Norco) has been prescribed for at least eight months. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects,

and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. As currently prescribed, Hydrocodone/APAP does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.