

Case Number:	CM15-0007738		
Date Assigned:	01/23/2015	Date of Injury:	10/15/2007
Decision Date:	03/17/2015	UR Denial Date:	12/26/2014
Priority:	Standard	Application Received:	01/14/2015

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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 47 year old male, who sustained an industrial injury on 10/15/2007. He has reported spinal cord injury and multiple fractures to face and bilateral wrists. The diagnoses have included spinal cord compression, status post T10 to T12 laminectomy and decompression, status post tracheostomy, internal fixation, bilateral ulnar and radial fracture, status post ORIF, open reduction of dental alveolar fracture, cranial bone grafts and closed reduction of nasal fracture, bilateral carpal tunnel release, neurogenic bladder and bowel, spasticity status post intrathecal baclofen pump and musculoskeletal and neuropathic. Treatment to date has included spinal cord decompression, laminectomy, reduction of nasal fracture, acute rehabilitation program and medications, including muscle relaxant via intrathecal pump and Lidoderm patch. Currently, the IW complains of muscle spasms, burning, paresthesia and numbness of bilateral legs and fingers slightly numb bilaterally. Physical examination on 12/17/14 revealed well healed surgical scars, normal motor strength of upper extremities, hand grips normal and gait was not tested. On 12/26/14 Utilization Review non-certified prescriptions for Gabapentin, Genteal eye drops and Clonazepam, noting they are not medically recommended due to lack of documentation with current subjective and objective findings; and dosage, number prescribed and number of refills was not documented. The MTUS, ACOEM Guidelines, was cited. On 1/14/15, the injured worker submitted an application for IMR for review of Gabapentin, Genteal eye drops and Clonazepam.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs Page(s): 18-19.

Decision rationale: Gabapentin is an anti-epilepsy drug. The MTUS recommends use of antiepileptic drugs for neuropathic pain. Most randomized controlled trials for the use of this class of medications for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy. There are few randomized control trials directed at central pain and none for painful radiculopathy. The choice of specific agents depends on the balance between effectiveness and adverse reactions. A good response to the use of antiepileptic drugs is defined as a 50% reduction in pain and a moderate response as a 30% reduction. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects and concurred with use. The continued use of antiepileptic drugs depends on improved outcomes versus tolerability of adverse effects. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The medical records provided do note that another anti-epilepsy drug, Lyrica, has been used on a long term basis since at least June 2014. The medical records do demonstrate neuropathic pain however, the records do not indicate whether Lyrica is being replaced with gabapentin or both medications will be used. The request does not indicate the dosage, quantity and duration/refills as requested in the Utilization Review of 12/26/14, The request for gabapentin is not medically necessary.

Genteal eye drops: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Product information.

Decision rationale: The MTUS does not address the use of GenTeal eye drops. GenTeal PF is a hypotonic and preservative-free solution, specially formulated to be a soothing lubricant. GenTeal PF is available in a pack of 36 single-use containers 0.105 fl. oz. in each container, Made in [REDACTED] for [REDACTED]. Uses for GenTeal products: Relieves dryness of the eye. Temporarily relieves discomfort due to minor irritations of the eye from exposure to wind, sun, or other irritants. As a protectant against further irritation. In this case the request for GenTeal eye drops is noted to be for eye dryness secondary to medications but does not specify directions for use, quantity of medication and whether refills are authorized. The request for Genteal eye drops is not medically necessary.

Clonazepam: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Benzodiazepines

Decision rationale: Clonazepam (Klonopin) is a benzodiazepine type of medication. The MTUS notes that benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limiting use to 4 weeks. The range of action includes sedative/hypnotic, anxiolytic, anticonvulsants, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. The ODG guidelines note that benzodiazepines are not recommended for long-term use (longer than two weeks), because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) Adults who use hypnotics, including benzodiazepines such as temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. In 2010, hypnotics may have been associated with 320,000 to 507,000 excess deaths in the U.S. alone. A dose-response effect was evident, with a hazard ratio of 3.60 for up to 18 pills per year, 4.43 for 18-132 pills per year, and 5.32 for over 132 pills per year. (Kripke, 2012) The AGS updated Beers criteria for inappropriate medication use includes benzodiazepines. (AGS, 2012) Use of benzodiazepines to treat insomnia or anxiety may increase the risk for Alzheimer's disease (AD). (Billioti, 2014) See also Anxiety medications in chronic pain; & Insomnia treatment. Benzodiazepines that are commonly prescribed include the following: alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, & triazolam. (Clinical Pharmacology, 2010) The potential for adverse outcomes increases with concurrent prescribing of medications with sedative properties; thus, concomitant prescribing of opioids, tramadol, benzodiazepines, and other sedating medications (such as H1 blocker antihistamines) is not recommended. The prescribing of psychostimulants to combat the sedating side effects of other medications is discouraged. If a pharmacologic intervention produces side effects significant enough to warrant their own treatment, the pharmacologic intervention itself should be considered ineffective secondary to intolerable side effects. (Atluri, 2012) Benzodiazepines are Not Recommended as first-line medications by ODG. Criteria for use if provider & payer agree to prescribe anyway: 1) Indications for use should be provided at the time of initial prescription. 2) Authorization after a one-month period should include the specific necessity for ongoing use as well as documentation

of efficacy. Benzodiazepine maintenance is recommended for selected patients, due to risks of weaning. Early research indicates that switching from rapid-onset, short-acting benzodiazepines to slow-onset, long-acting formulations is an option. In some cases this will actually allow for ultimate discontinuation of this class of drugs. Clonazepam is the suggested drug to switch to. It has a slow onset of action, half-life of 18-50 hours, high potency and lack of active metabolites. (Liebrenz, 2010) (Maremmani, 2013) See also Weaning, benzodiazepines (specific guidelines). The medical records indicate that the injured worker has been prescribed Klonopin to manage anxiety and spasticity. It is not clear how long he has been on Klonopin but it has been used since at least June 2014.. As noted above, if using a benzodiazepine, a long-acting formulation such as Klonopin is preferred. Although not recommended for long-term use, it does appear that the current use of Klonopin is required to manage the spasticity and mental health aspects of this case. The Utilization Review on 12/26/14 requested that information regarding dosage, quantity and duration/refills be provided. Without that information the request for clonazepam remains not necessary.