

<b>Case Number:</b>	CM14-0109202		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	09/27/2007
<b>Decision Date:</b>	09/24/2014	<b>UR Denial Date:</b>	06/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/14/2014

### 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 Internal & Emergency Medicine, and is licensed to practice in Florida. 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:

This patient is a 34 year-old with a date of injury of 09/27/07. A progress report associated with the request for services, dated 06/02/14, identified subjective complaints of low back pain into the lower extremities. No objective findings were listed. Diagnoses included (paraphrased) cervical, thoracic, and lumbar disc disease. Treatment had included medications, PT, an epidural injection, and participation in a HEP. She had reported some pain relief from previous therapy with gabapentin. A Utilization Review determination was rendered on 06/24/14 recommending non-certification of "Gralise 600mg ER #90; Gralise 30-Day Starter pack 300mg (9 600mg tablets); and Norco 10/325mg #180".

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #180:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids for Chronic Pain.

**Decision rationale:** The MTUS Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. The guidelines note that a recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The MTUS Chronic Pain Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The MTUS Chronic Pain Guidelines further state that opioid therapy is not recommended for the low back beyond 2 weeks. The patient has been on Norco in excess of 16 weeks. The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." Therapy with Norco appears to be ongoing. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Therefore, the record does not demonstrate medical necessity for Norco.

**Gralise 30-Day Starter pack 300mg (9 600mg tablets):** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Anti-epilepsy drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs Page(s): 16-21, 49.

**Decision rationale:** Gabapentin (Gralise) is an anti-seizure agent. The MTUS Chronic Pain Guidelines note that this class of agents is recommended for neuropathic pain, but there are few randomized trials directed at central pain and none for painful radiculopathy. Further, it states: "A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain." The Guidelines also state that the role for Gabapentin is for: "...treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered first-line treatment for neuropathic pain." No recommendations are made for specific musculoskeletal etiologies. In this case, there is no documentation for a neuropathic component to the pain, and little evidence to support its use specifically in low back pain and radiculopathy. Also, there is no evidence of functional improvement from the Gabapentin. Therefore, the record does not document the medical necessity for Gralise (Gabapentin) in this case.

**Gralise 600mg ER #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Anti-epilepsy drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs Page(s): 16-21 49.

**Decision rationale:** Gabapentin (Gralise) is an anti-seizure agent. The MTUS Chronic Pain Guidelines note that this class of agents is recommended for neuropathic pain, but there are few randomized trials directed at central pain and none for painful radiculopathy. Further, it states: "A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain." The Guidelines also state that the role for Gabapentin is for: "...treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered first-line treatment for neuropathic pain." No recommendations are made for specific musculoskeletal etiologies. In this case, there is no documentation for a neuropathic component to the pain, and little evidence to support its use specifically in low back pain and radiculopathy. Also, there is no evidence of functional improvement from the Gabapentin. Therefore, the record does not document the medical necessity for Gralise (Gabapentin) in this case.