

<b>Case Number:</b>	CM15-0084147		
<b>Date Assigned:</b>	05/06/2015	<b>Date of Injury:</b>	10/23/2010
<b>Decision Date:</b>	06/16/2015	<b>UR Denial Date:</b>	04/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/01/2015

### 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: California, Indiana, New York  
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:

The injured worker is a 43 year old male, who sustained an industrial injury on 10/23/10. He reported initial complaints of a fall with thoracic and lumbar spine injury. The injured worker was diagnosed as having lumbar spine herniated nucleus pulposus; lumbago. Treatment to date has included physical therapy; medications. Diagnostics included MRI lumbar spine without contrast (8/17/11); X-rays thoracic and lumbar spine (3/16/15). Currently, the PR-2 notes dated 3/16/15 indicated the injured worker complains of thoracic-lumbar spine and states he is experiencing severe pain in the lumbar spine. He states he is having significant pain with decreased motion and loss of strength to the lumbar spine. X-rays were taken of the thoracic (two views) and lumbar spine (five views) and show loss of lordosis. His treatment plan is including physical therapy 3 times a week for 4 weeks to regain core strength and body mechanics and postural stabilization. He also included an interferential unit for 30-60 day rental and purchase if effective. He has also requested medications: Gabapentin 10mg, Kera Tek gel #113 and Pyridoxine 250mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabapentin 10mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin; Anti-epilepsy Drugs (AEDs) Page(s): 16-19.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 49. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Gabapentin and Other Medical Treatment Guidelines <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682587.html>.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, Gabapentin 250mg/Pyridoxine 10mg is not medically necessary. Gabapentin is recommended for some neuropathic pain conditions in fibromyalgia. Gabapentin is associated with a modest increase in the number of patients experiencing meaningful pain reduction. Gabapentin is an anti-epilepsy drug (AED). Gabapentin is considered a first-line treatment for neuropathic pain. Pyridoxine, vitamin B6, is required for utilization of energy, production of red blood cells and proper functioning of nerves. In this case, the injured worker's working diagnoses are disorders of lumbar intervertebral disc without myelopathy; and lumbago. Documentation from a March 16, 2015 progress note subjectively states the injured worker is experiencing severe pain and lumbar spine. Objective findings include significant pain, decreased motion and loss of strength the lumbar spine. There is no quantification of muscle weakness. X-rays showed loss of lumbar lordosis. There is no clinical documentation of a vitamin B6 deficiency nor is there a clinical rationale for prescribing Pyridoxine or combination Gabapentin 250mg/Pyridoxine 10mg. There is no documentation of neuropathic pain documented in the medical record. Consequently, absent clinical documentation of neuropathic pain and a clinical indication rationale for combination gabapentin 250/Pyridoxine 10mg, Gabapentin 250mg/Pyridoxine 10mg is not medically necessary.

**Kera Tek gel #113:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical Analgesics.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, Kera Tek gel #113 is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Methyl salicylate is significantly better than placebo in acute and chronic pain, but especially acute pain. Topical salicylate was significantly better than placebo but larger more valid studies without significant effect. Methyl salicylate is not FDA approved for topical use. In this case, the injured worker's working diagnoses are disorders of lumbar intervertebral disc without myelopathy; and lumbago. Documentation from a March 16, 2015 progress note subjectively states the injured worker is experiencing severe pain and

lumbar spine. Objective findings include significant pain, decreased motion and loss of strength the lumbar spine. There is no quantification of muscle weakness. Topical methyl salicylate is not FDA approved for topical use. Any compounded product that contains at least one drug (methyl salicylate) that is not recommended is not recommended. There is no documentation of neuropathic symptoms or signs. There is no documentation of failed first-line treatment with antidepressants or anticonvulsants. Based on the clinical information the medical record and the peer-reviewed evidence-based guidelines, Kera Tek gel #113 g is not medically necessary.

**Pyridoxine 250mg:** 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 Chapter - B Vitamins & Vitamin B Complex.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682587.html>.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, Pyridoxine 10/Gabapentin 250mg is not medically necessary. Gabapentin is recommended for some neuropathic pain conditions in fibromyalgia. Gabapentin is associated with a modest increase in the number of patients experiencing meaningful pain reduction. Gabapentin is an anti-epilepsy drug (AED). Gabapentin is considered a first-line treatment for neuropathic pain. Pyridoxine, vitamin B6, is required for utilization of energy, production of red blood cells and proper functioning of nerves. In this case, the injured worker's working diagnoses are disorders of lumbar intervertebral disc without myelopathy; and lumbago. Documentation from a March 16, 2015 progress note subjectively states the injured worker is experiencing severe pain and lumbar spine. Objective findings include significant pain, decreased motion and loss of strength the lumbar spine. There is no quantification of muscle weakness. X-rays showed loss of lumbar lordosis. There is no clinical documentation of a vitamin B6 deficiency nor is there a clinical rationale for prescribing Pyridoxine or combination Gabapentin 250mg/Pyridoxine 10mg. There is no documentation of neuropathic pain documented in the medical record. Consequently, absent clinical documentation of neuropathic pain and a clinical indication rationale for combination Gabapentin 250/Pyridoxine 10mg, Pyridoxine 10mg/Gabapentin 250mg is not medically necessary.