

<b>Case Number:</b>	CM13-0064593		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	04/30/2000
<b>Decision Date:</b>	05/22/2014	<b>UR Denial Date:</b>	11/18/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/12/2013

### 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 Medicine and is licensed to practice in California. 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 patient is a 63-year-old female who was injured on 4/30/2000. According to the records provided, she carries a diagnosis of hypertension, gastritis, metabolic syndrome, depression, discogenic disease of the cervical spine with radiculopathy of the upper extremities, discogenic disease of the lower back with bilateral sciatica, and chronic pain syndrome. The medications include prilosec, ultracet, certavisc and gabeketolido ointment. The patient also uses a lumbosacral corset and performs back exercises. The following key studies obtained from the records are as follows: the cervical MRI in November 2001, found neural foraminal stenosis at C3-4 and C5-6; no cord compression. The thoracic MRI showed no evidence of disk protrusion. The lumbar MRI demonstrated L4-5 disk bulge with minimal foraminal encroachment. The nerve conduction study (NCS) from November 2000 demonstrated L5-L1 nerve root injury. A PR-2 (progress report) dated 1/29/2013, indicated that the patient was complaining of continued neck and back pain. On exam she had a positive foraminal test on the left radiating to left had, and pressure of the iliolumbar angles positive radiating to feet more on the right. She was diagnosed with discogenic disease of the cervical spine with radiculopathy of the upper extremities, as well as discogenic disease of the lower back with bilateral sciatica. The plan was to continue prilosec, ultracet, certavisc and gabeketolido ointment. She was also told to continue the use of the lumbosacral corset and back exercises, and return in three (3) months for reevaluation. The patient was subsequently seen on 4/30/13 and 7/20/13, with the same objective and subjective findings. A PR-2 note dated 10/29/13, stated that the patient complained of stress and anxiety. Otherwise, the subjective and objective findings were identical to the previous visits. In a note written by [REDACTED] on 2/8/13, the patient is diagnosed with chronic cervical and shoulder strain. She is deemed not to be a surgical candidate and it is noted that she would not benefit from epidural steroid injections.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**CONDROLITE 500/200/150MG # 90, + 3 REFILLS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines GLUCOSAMINE (AND CHONDROITIN SULFATE) Page(s): 50.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, KNEE; GLUCOSAMINE (AND CHONDROITIN SULFATE), and [HTTP://ENOVACHEM.US.COM/PORTFOLIO/CONROLITE/](http://enovachem.us.com/portfolio/condrolite/).

**Decision rationale:** The Chronic Pain Guidelines and the Official Disability Guidelines indicate that Glucosamine (and Chondroitin Sulfate) is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. According to the medical records the patient complains of constant neck pain radiating down to the fingers and constant back pain radiating down to the bilateral legs. She carries a diagnosis of discogenic disease of the cervical and lumbar spine with radiculitis. There are no records that demonstrate that the patient has osteoarthritis. There does not appear to be any subjective complaint, clinical findings or corroborative diagnostic evidence of osteoarthritis. The medical records do not indicate that this patient has moderately severe osteoarthritis. Consequently, the medical necessity of Condrolite, a non-FDA regulated product containing Glucosamine sulfate, Chondroitin sulfate and MSM, is not medically necessary

**PRILOSEC 20MG, #60 + 3 REFILLS:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI SYMPTOMS, AND CARDIOVASCULAR RISK Page(s): 68-69.

**Decision rationale:** The Chronic Pain Guidelines indicate that medications such as omeprazole (Prilosec) may be recommended for patients at risk for gastrointestinal (GI) events, which should be determined by the clinician, such as: 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of aspirin (ASA), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple non-steroidal anti-inflammatory drug (NSAID). Patients with peptic ulcer disease, gastroesophageal reflux disease (GERD) and dyspepsia might also benefit from proton pump inhibitors such as Prilosec. While the patient is noted in one report of previously being diagnosed with gastritis, there is no further mention of its work up, diagnosis or management. There is no documentation that the patient is benefiting from taking omeprazole. The medical records reviewed do not document any gastrointestinal complaints. In accordance with the guidelines, Prilosec is not medically necessary.

**ULTRACET 37.5/325MG, #120 +3 REFILLS:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS FOR CHRONIC PAIN, WEANING OF MEDICATIONS Page(s): 74-75, 80.

**Decision rationale:** The Chronic Pain Guidelines indicate that Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. It is indicated for moderate to severe pain. The Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." According to the medical records, the patient was seen for follow-up evaluation on 10/29/2013, with stated complaints of constant neck pain radiating down to the fingers and constant back pain radiating down to the bilateral legs, greater on the right. The examination findings were unchanged from prior reports stating positive foraminal compression test and pressure over the iliolumbar angles, producing radicular pain down to the bilateral feet. The diagnosis was discogenic disease of the cervical spine with upper extremity radiculitis on the left, discogenic disease of the low back with bilateral radiation greater on the right. There is no report of current pain levels with and without medication use. There is no evidence that notable pain relief and functional improvement have been obtained as result of ongoing use of Ultracet. There is no indication that the regular assessment of non-opioid and non-pharmacologic means of pain management have been done. The guidelines state opioids may be continued: (a) if the patient has returned to work; and (b) if the patient has improved functioning and pain. The medical records have not demonstrated the requirements according to the guidelines, for continued opioid therapy have been met. The medical necessity for Ultracet has not been established.

**GABAPENTIN/KETOPROFEN/LIDOCAINE 15%, 20%. 6%, 100MG + 3 REFILLS:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** Topical analgesics are an option for specific types of pain, and many agents are compounded as monotherapy or in combination for pain control, including non-steroidal anti-inflammatory drugs (NSAIDs), opioids, capsaicin, local anesthetics, antidepressants, and glutamate receptor antagonists, to name a few. There is little to no research to support the use of many of these agents. The Chronic Pain Guidelines indicate that Gabapentin is not recommended for topical formulations as there is no strong evidence to support its use topically. Ketoprofen is not FDA-approved for a topical application. Furthermore, it has an extremely high incidence of

photo contact dermatitis. The Guidelines state that only Lidocaine in the formulation of a Lidoderm patch may be considered for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). The Guidelines also indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the requested topical compounded product is not supported as medically necessary.