

Case Number:	CM13-0050756		
Date Assigned:	12/27/2013	Date of Injury:	08/31/2004
Decision Date:	02/27/2014	UR Denial Date:	11/06/2013
Priority:	Standard	Application Received:	11/14/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, 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 physician 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 43 year-old male patient sustained an injury on 8/31/04. Requests under consideration include Norco #120, Norflex #100, Lyrica, and Intrathecal Ziconotide. Report of 10/3/13 from [REDACTED] noted patient with complaints of ongoing throbbing and aching right leg with tingling radiating to right foot with numbness. The patient underwent a trial of intrathecal Dilaudid on 7/22/13. Pain is greatly improved, but had some side effects of pruritis. Exam showed tenderness of the lumbar spine at L4 and iliolumbar region; 4/5 strength in left ankle dorsiflexion, TA, great extensor and gastrocnemius; decreased sensation in right lateral leg and dorsum of foot, sole and posterior leg. Diagnoses included facet syndrome, disc disease, thoracic/ lumbosacral neuritis, degeneration of lumbar or lumbosacral intervertebral disc, and lumbar sprain. Reports state the patient is not adequately managed on Norco 10/325 mg QID, Norflex, and Lidocaine cream. He has not received Lyrica, but has developed side effects in the past from gabapentin. Report of 8/22/13 noted the patient had side effects with intrathecal Dilaudid, recommending Ziconotide, a derivative of sea snail poison that helps with neuropathic pain. Medication requests were non-certified on 11/6/13 citing guidelines criteria and lack of medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines When to Discontinue Opioids Page(s): 79.

Decision rationale: Per the MTUS Guidelines cited, opioid use in the setting of chronic, non-malignant, or neuropathic pain is controversial. Patients on opioids should be routinely monitored for signs of impairment and use of opioids in patients with chronic pain should be reserved for those with improved functional outcomes attributable to their use, in the context of an overall approach to pain management that also includes non-opioid analgesics, adjuvant therapies, psychological support, and active treatments (e.g., exercise). Submitted documents show no evidence that the treating physician is prescribing opioids in accordance to change in pain relief, functional goals with demonstrated improvement in daily activities, decreased in medical utilization or returned to work status. There is no evidence presented of random drug testing or utilization of pain contract to adequately monitor for narcotic safety, efficacy, and compliance. The MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain. Norco #120 is not medically necessary and appropriate.

Norflex #100: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 128.

Decision rationale: Guidelines do not recommend long-term use of this muscle relaxant for this chronic injury of 2004. Additionally, the efficacy in clinical trials has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Submitted reports have not adequately demonstrated the indication or medical need for this treatment and there is no report of significant clinical findings, acute flare-up or new injury to support for its long-term use. There is no report of functional improvement resulting from its previous treatment to support further use. The Norflex #100 is not medically necessary and appropriate.

Lyrica: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
Pregabalin (Lyrica) Page(s): 100.

Decision rationale: Pregabalin (Lyrica®) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This anti-epileptic medication may be helpful in the treatment of radiculopathy and would be indicated if there is documented significant benefit. A trial of Lyrica may be appropriate with further consideration of functional efficacy from its use. Submitted medical report has adequately demonstrated indication. Lyrica is medically necessary and appropriate.

Intrathecal Ziconotide: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), pages 875-877

Decision rationale: Ziconotide, a synthetic equivalent of a naturally occurring conopeptide found in the piscivorous marine snail, *Conus magus*. Ziconotide is a 25 amino acid, polybasic peptide containing three disulfide bridges. Ziconotide solution, an intrathecal infusion indicated for the management of severe chronic pain in adult patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine. ODG recommends Ziconotide for use after there is evidence of failure of a trial of intrathecal morphine or Hydromorphone (Dilaudid). The medication is indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine, and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. Submitted reports have not demonstrated specific indication or necessity for this intrathecal medication. Although the patient developed side effects from IT Dilaudid, oral Norco daily dosing has low morphine equivalent and there is no clear indication for needing this intrathecal option reserved for patient refractory to systemic analgesics, therapy, and IT morphine. The Intrathecal Ziconotide is not medically necessary and appropriate.