

Case Number:	CM15-0018906		
Date Assigned:	02/06/2015	Date of Injury:	01/24/2007
Decision Date:	04/03/2015	UR Denial Date:	01/02/2015
Priority:	Standard	Application Received:	02/02/2015

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: New York
 Certification(s)/Specialty: Anesthesiology

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 70 year old male, who sustained an industrial injury on January 24, 2007. The diagnoses have included lumbar post laminectomy syndrome, lumbosacral neuritis/radiculitis, myofascial pain syndrome, SI joint dysfunction, depression, anxiety, and carpal tunnel syndrome. Treatment to date has included lumbar laminectomy/fusion x2, knee surgery x2, lumbar support vest, and medications. Currently, the injured worker complains of pain in the legs, with lower and mid back, hands, and knee pain. The Treating Physician's report dated December 18, 2014, noted the injured worker with an antalgic gait, with reduced lumbar range of motion (ROM) and reduced right L3-L5 dermatome sensory examination. A lumbar spine MRI from March 2014 was noted to show L3-S1 fusion with multiple level foraminal stenosis and arachnoiditis noted. On January 2, 2015, Utilization Review non-certified retrospective requests for Lidocaine powder (DOS 11/17/2014), Flurbiprofen powder (DOS 11/17/2014), Cyclobenzaprine HCL powder (DOS 11/17/2014), and [REDACTED] custom Lipo-max cream (DOS 11/17/2014). The UR Physician noted that the injured worker was provided a compound cream containing lidocaine, flurbiprofen, and cyclobenzaprine in a [REDACTED] base, and that the guidelines did not specifically recommend the use of flurbiprofen cream, that topical flurbiprofen was not FDA approved, and that topical cyclobenzaprine was not recommended, therefore the use of the compounded topical medication was not indicated, citing the MTUS Chronic Pain Medical Treatment Guidelines, the American College of Occupational and Environmental Medicine Guidelines, and the Official Disability Guidelines (ODG). On February 2, 2015, the injured worker submitted an application for IMR for review of retrospective requests for Lidocaine

powder (DOS 11/17/2014), Flurbiprofen powder (DOS 11/17/2014), Cyclobenzaprine HCL powder (DOS 11/17/2014), and [REDACTED] custom Lipo-max cream (DOS 11/17/2014).

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective - Lidocaine powder (DOS 11/17/2014): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Compounded. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical Analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of intolerance to other previous oral medications. MTUS guidelines state that Fluriprofen, lidocaine, capsaicin and/or muscle relaxants are not recommended for topical applications. Custom Lipo-max cream base is only available from the [REDACTED]. The [REDACTED] cream base has the ability to deliver four (4) drugs at once. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) is FDA approved for neuropathic pain, and used off-label for diabetic neuropathy. NO OTHER Lidocaine topical creams or lotions are indicated for neuropathic or non-neuropathic pain. Medical necessity for the topical analgesic containing, Lidocaine, Flurbiprofen, and Cyclobenzaprine powders in a [REDACTED] lipo-max cream, has not been established. The request for retrospective treatment with this topical analgesic, containing Lidocaine, is not medically necessary.

Retrospective - Flurbiprofen powder (DOS 11/17/2014): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack

of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of intolerance to other previous oral medications. MTUS guidelines state that Fluriprofen, lidocaine, capsaicin and/or muscle relaxants are not recommended for topical applications. Lipo-max (or Lipo-derm) cream is only available from the [REDACTED]. The [REDACTED] base has the ability to deliver four (4) drugs at once. There are no clinical studies to support the safety and effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Medical necessity for this topical analgesic containing, Lidocaine, Flurbiprofen, and Cyclobenzaprine powders in a [REDACTED] lipo-max cream, has not been established. The request for retrospective treatment with this topical analgesic, containing Flurbiprofen, is not medically necessary.

Retrospective - Cyclobenzaprine HCL powder (DOS 11-17-14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, compounded. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of intolerance to other previous oral medications. MTUS guidelines state that Fluriprofen, lidocaine, capsaicin and/or muscle relaxants (Cyclobenzaprine in this case) are not recommended for topical applications. Lipo-derm (or Lipo-max) cream is only available from the [REDACTED]. The [REDACTED] base has the ability to deliver four (4) drugs at once. Cyclobenzaprine is not recommended as there is no evidence for the use of any muscle relaxant as a topical agent. Medical necessity for this topical analgesic containing, Lidocaine, Flurbiprofen, and Cyclobenzaprine powders in a [REDACTED] lipo-max cream, has not been established. The request for retrospective treatment with this topical analgesic, containing Cyclobenzaprine, is not medically necessary.

Retrospective - [REDACTED] custom Lipo-max cream (DOS 11-17-14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, compounded. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

Decision rationale: Pharmacy compounding can provide alternate methods of delivery to make the process easier. Instead of a capsule or tablet, pain medications often can be compounded as dosage forms such as, a topical gel or cream that can be applied directly to the site of pain and absorbed through the skin. Custom Lipomax cream is only available from the [REDACTED]. The [REDACTED] base has the ability to deliver four (4) drugs at once. However, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Medical necessity of the compound cream containing lidocaine, flurbiprofen, and cyclobenzaprine in a [REDACTED] base, has not been established. The request for retrospective [REDACTED] Lipo-max cream base is not medically necessary.