

Case Number:	CM15-0208239		
Date Assigned:	10/27/2015	Date of Injury:	12/13/2004
Decision Date:	12/28/2015	UR Denial Date:	09/26/2015
Priority:	Standard	Application Received:	10/22/2015

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 40 year old male, who sustained an industrial injury on 12-13-2004. A review of the medical records indicates that the worker is undergoing treatment for status post spinal fusion L4-S1, failed back syndrome with possible painful hardware, possible sacroilitis, status post hardware removal L4-S1 and questionable L3-L4 left-sided disc protrusion. Subjective complaints (05-17-2015, 06-15-2015 and 07-27-2015) included intractable low back pain with episodic giving way of the left lower extremity. On 07-27-2015 the injured worker noted temporary relief with transdermal creams that were previously prescribed but there was no indication as to which creams had been prescribed. Objective findings (05-17-2015) showed pain to palpation of the lumbar facet bilaterally at L3-S1, pain over the lumbar intervertebral spaces, palpable twitch positive trigger points in the lumbar paraspinous muscles, pain with anterior lumbar flexion, extension and left lateral flexion. Objective findings (06-15-2015 and 07-27- 2015) included focal tenderness at the lumbosacral junction as well as superior iliac crest and giving way of the left quads. Treatment has included Norco, Tramadol and caudal epidural steroid injection with minimal benefit. The physician indicated that the injured worker had not been tolerating oral medication and that to avoid or minimize the amount of oral medication, transdermal creams were being requested including Flurbiprofen-Lidocaine was being requested for maintenance and relief of mild to moderate pain, Gabapentin-Amitriptyline-Capsaicin was being requested for relief of muscle spasm and neuropathic pain and Cyclobenzaprine-Lidocaine was being requested for relief of muscle spasm. A utilization review dated 09-26-2015 non-certified requests for Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 3-day supply,

Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 150 gm, Cyclobenzaprine 10%, Lidocaine 2%, 3-day supply and Cyclobenzaprine 10%, Lidocaine 2%, 150 gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 3 day supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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 According to the California MTUS Guidelines (2009), topical analgesics are 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, the topical analgesic compound contains: Gabapentin 10%, Amitriptyline 5%, and Capsaicin 0.025%. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines, and there is no peer-reviewed literature to support its use. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Since the guidelines do not recommend some of the ingredients, there is no medical necessity for this compound. Additionally, the documentation submitted for review does not provide evidence of the necessity for 2 different topical compounded analgesics. Medical necessity for the requested 3-day supply of this compounded topical analgesic has not been established. The requested treatment is not medically necessary.

Gabapentin 10%, Amitriptyline 5%, Capsaicin 0.025%, 150 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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 According to the California MTUS Guidelines (2009), topical analgesics are 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, the topical analgesic compound contains: Gabapentin 10%, Amitriptyline 5%, and Capsaicin 0.025%. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines, and there is no peer-reviewed literature to support its use. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Since the guidelines do not recommend some of the ingredients, there is no medical necessity for this compound. Additionally, the documentation submitted for review does not provide evidence of the necessity for 2 different topical compounded analgesics. Medical necessity for the requested compounded topical analgesic has not been established. The requested treatment is not medically necessary.

Cyclobenzaprine 10%, Lidocaine 2%, 3 day supply: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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, the topical analgesic contains Cyclobenzaprine 10%, and Lidocaine 2%. 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. In addition, Cyclobenzaprine is not FDA approved for use as a topical application. Medical necessity of the requested topical analgesic compounded medication, for a 3-day supply, has not been established. The requested topical compound is not medically necessary.

Cyclobenzaprine 10%, Lidocaine 2%, 150 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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, the topical analgesic contains Cyclobenzaprine 10%, and Lidocaine 2%. 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. In addition, Cyclobenzaprine is not FDA approved for use as a topical application. Medical necessity of the requested topical analgesic compounded medication has not been established. The requested topical compound is not medically necessary.