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 48 year old male, who sustained an industrial injury on 10/16/2000. The injured worker is currently permanent and stationary. The injured worker is currently diagnosed as having lumbar sacral spondylosis without myelopathy, hip osteoarthritis, lumbar spine strain, and depressive disorder. Treatment and diagnostics to date has included medications. In a progress note dated 03/10/2015, the injured worker presented with complaints of back pain. Objective findings include limited lumbar and right hip range of motion. The treating physician reported requesting authorization for compound creams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen powder, Lidocaine, Versapro base dispensed 3/13/15: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 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, the topical compound contains Flurbiprofen and Lidocaine. Flurbiprofen, used as a topical NSAID, has been shown to be superior to placebo during the first two weeks of treatment for osteoarthritis, but either not afterward, or with diminishing effect over another two-week period. 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. There was no documentation of intolerance to other previous oral medications. The medical necessity of the requested topical medication was not established. The requested topical analgesic is not medically necessary.

**Gabapentin powder, Amitriptyline, Capsaicin, Versapro base dispensed 3/13/15:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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, the topical compound contains Gabapentin, Amitriptyline and Capsaicin. Amitriptyline and Gabapentin are not FDA approved for topical application. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. There was no documentation of intolerance to other previous oral medications. The medical necessity of the requested topical medication was not established. The requested topical analgesic is not medically necessary.

**Cyclobenzaprine powder, Lidocaine, Versapro base dispensed 3/13/15:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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, the topical compound contains Cyclobenzaprine and Lidocaine. Cyclobenzaprine is not FDA approved for topical application. 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. There was no documentation of intolerance to other previous oral medications. The medical necessity of the requested topical medication was not established. The requested topical analgesic is not medically necessary.

**Flurbiprofen powder, Lidocaine, Versapro base dispensed 3/10/13:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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, the topical compound contains Flurbiprofen and Lidocaine. Flurbiprofen, used as a topical NSAID, has been shown to be superior to placebo during the first two weeks of treatment for osteoarthritis, but either not afterward, or with diminishing effect over another two-week period. 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. There was no documentation of intolerance to other previous medication. Medical necessity for the requested topical medication was not established. The requested treatment is not medically necessary.

**Gabapentin powder, Amitriptyline, Capsaicin, Versapro base dispensed 3/10/15:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical.
**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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, the topical compound contains Gabapentin, Amitriptyline and Capsaicin. Amitriptyline and Gabapentin are not FDA approved for topical application. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. There was no documentation of intolerance to other previous oral medications. The medical necessity of the requested topical medication was not established. The requested topical analgesic is not medically necessary.

**Cyclobenzaprine powder, Lidocaine, Versapro base dispensed 3/10/15:** Upheld

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