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 Physical Medicine & Rehabilitation, has a subspecialty in Sports Medicine and is licensed to practice in Texas. 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 injured worker is a 58-year-old male who reported an injury on November 30, 2007 secondary to a fall. The clinical note dated January 16, 2014 reported the injured worker complained of severe pain to his lower back with tingling in the right lower extremity from the knee to the foot and numbness of the left forefoot ascending into the leg. The injured worker underwent a caudal lumbar epidural injection as well as a left L5 transforaminal selective nerve root epidural injection on February 13, 2012, in which he reportedly stated it, did not provide him relief. The injured worker also reportedly complained of severe knee pain, left greater than right, and the patient is status post left knee meniscectomy and was awaiting further left and right knee surgical interventions. The injured worker reportedly characterized his symptoms as tingling, severe, shooting, sharp, and numbing and exacerbation occurred with sitting, walking, and standing, bending, rising from a chair, and driving. Lying prone and the side, stretching, ice, heat, and massage are palliative. The physical examination of the lumbar spine revealed a healed postsurgical scar consistent with laminectomy over discectomy and there was paralumbar tenderness bilaterally from L3 through S1. The physical examination of the lower extremities revealed tenderness to the bilateral medial and lateral collateral ligaments and significant shortness of bilateral hamstrings. The neurological evaluation noted tingling corresponding to the right L4, L5, and S1 dermatomes from the knee to the foot with numbness corresponding to the left L4, L5, and S1 dermatomes of the forefoot and ascending into the leg. The deep tendon reflexes were 2+ at the bilateral patellar tendons and 1+ at the Achilles tendons. The pathological reflexes were absent and motor strength was 5/5 globally throughout the bilateral lower extremities. The diagnoses included failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and bilateral knee arthropathies. The treatment plan included recommendations for hydrocodone, naproxen, Lyrica, Senokot, compounded topical analgesic creams, and Tercocin,
as well as acupuncture and aquatic therapy. The Request for Authorization was submitted January 16, 2014.

**IMR ISSUES, DECISIONS AND RATIONALES**

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

**RETROSPECTIVE HYDROCODONE 5/500MG #120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Opioids, criteria for use, Page(s): 78.

**Decision rationale:** The request for retrospective hydrocodone 5/500 mg #120 is not medically necessary. The injured worker has a history of lumbar facet joint pain, lumbar neuralgia, and bilateral knee pain treated with injections and medications. The California MTUS Guidelines recommend ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines note a pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Within the clinical information provided for review, there is a lack of documentation indicating the injured worker had significant quantifiable objective functional improvement with this medication as well as the requesting physician did not include an adequate and complete assessment of the injured worker's pain. In addition, there is a lack of documentation addressing whether the injured worker displayed aberrant drug behavior or side effects of this medication. The request as submitted failed to provide a frequency for the medication. Therefore, the request is not medically necessary.

**RETROSPECTIVE NAPROXEN 550MG #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, NSAIDs (non-steroidal anti-inflammatory drugs), Page 67.

**Decision rationale:** The request for retrospective naproxen 550 mg #90 is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and chronic knee pain which has been treated with injections, medications, and surgery. The California MTUS guidelines recommend the use of NSAIDs for injured workers with osteoarthritis (including knee and hip) and patients with acute exacerbations of chronic low back pain. The guidelines recommended NSAIDs at the lowest dose for the shortest period in injured workers with moderate to severe pain. Acetaminophen may be considered for initial therapy for injured workers with mild to moderate pain, and in
particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. In injured workers with acute exacerbations of chronic low back pain, the guidelines recommend NSAIDs as an option for short-term symptomatic relief. Based on the documentation, provided for review, it is unclear how long the injured worker has been utilizing this medication. As per the guidelines, NSAIDs are recommended at the lowest doses for the shortest period in injured workers. However, there is no documentation of pain relief or improved function with the medication. Also, the request as submitted failed to provide the frequency of the medication. Therefore, the request is not medically necessary.

**LYRICA 100MG, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTI-EPILEPSY DRUGS (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Antiepilepsy drugs (AEDs), Page(s): 16.

**Decision rationale:** The request for Lyrica 100 mg #60 is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and bilateral knee pain treated with surgery, injections, and medications. The California MTUS Guidelines state anti-epilepsy drugs are recommended for neuropathic pain and Lyrica has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia and is considered first-line treatment for both. The clinical information, provided for review, stated the injured worker has evidence of neuropathic pain to include radiating pain, numbness and tingling; however, there is no clear evidence stating how long the injured worker has been utilizing this medication or the efficacy of this medication. The request as submitted failed to provide the frequency of the medication. Therefore, the request is not medically necessary.

**RETROSPECTIVE SENOKOT:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Veterans Health Administration, Department of Defense, Clinical Practice Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Opioids, criteria for use Page(s): 77.

**Decision rationale:** The request for retrospective Senokot is not medically necessary. The California MTUS Guidelines state a prophylactic treatment of constipation should be initiated upon opioid therapy. Within the clinical information, provided for review, the physician noted there were no signs of opioid toxicity or side effects to include gastrointestinal events or constipation. In addition, the request as submitted failed to provide the frequency of the medication or a quantity. Therefore, the request for retrospective Senokot is not medically necessary.

**RETROSPECTIVE TRAMADOL COMPOUND CREAM:** Upheld
Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Effectiveness of topical administration of opioids in palliative care: a systematic review B LeBon, G Zeppetella, IJ Higginson - Journal of pain and symptoms, 2009 - Elsevier

Decision rationale: The request for retrospective tramadol compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and bilateral knee pain treated with surgery, injections, and medications. The California MTUS Guidelines do not specifically address opioid analgesics in topical formulations. However, peer reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. In addition, it was unclear why the injured worker would require tramadol in a cream form as opposed to an oral medication. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.

RETROSPECTIVE FLURBIPROFEN COMPOUND CREAM: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Topical analgesics Page(s): 111-112.

Decision rationale: The request for retrospective flurbiprofen compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, bilateral knee pain treated with surgeries, injections, and medications. The California MTUS Guidelines state topical NSAIDs may be useful for chronic musculoskeletal pain but there are no long term studies of their effectiveness or safety. In addition, topical NSAIDs are not recommended for neuropathic pain, as there is no evidence to support their use. The guidelines also note topical NSAIDs are recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment; however, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The guidelines also state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note gabapentin is not recommended for topical application. The clinical information provided for review, failed to provide evidence the injured worker gained pain relief or improved function with this medication. In addition, the specific site at which the topical medication would be utilized was unclear within the provided documentation. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.
RETROSPECTIVE CYCLOBENZAPRINE COMPOUND CREAM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): TOPICAL ANALGESICS.

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

Decision rationale: The request for retrospective cyclobenzaprine compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, bilateral knee pain treated with surgeries, injections, and medications. The current California MTUS Guidelines states any compounded product that contains at least one drug or drug class that is not recommended is not supported. The guidelines also state there is no evidence for use of the muscle relaxant cyclobenzprine as a topical product. The clinical information, provided for review, failed to provide evidence the injured worker gained pain relief or improved function with this medication. In addition, the specific site at which the topical medications will be utilized was unclear within the provided documentation. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.

HYDROCODONE 5/500MG, #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 78.

Decision rationale: The request for hydrocodone 5/500 mg #120 is not medically necessary. The injured worker has a history of lumbar facet joint pain, lumbar neuralgia, and bilateral knee pain treated with injections and medications. The California MTUS Guidelines recommend ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines note a pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Within the clinical information, provided for review, there is a lack of documentation indicating the injured worker had significant quantifiable objective functional improvement with this medication as well as the requesting physician did not include an adequate and complete assessment of the injured worker's pain. In addition, there is a lack of documentation addressing whether the injured worker displayed aberrant drug behavior or side effects of this medication. The request as submitted failed to provide a frequency for the medication. Therefore, the request is not medically necessary.

NAPROXEN 550MG, #90: Upheld
Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67.

Decision rationale: The request for naproxen 550 mg #90 is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and chronic knee pain which has been treated with injections, medications, and surgery. The California MTUS guidelines recommend the use of NSAIDs for injured workers with osteoarthritis (including knee and hip) and patients with acute exacerbations of chronic low back pain. The guidelines recommended NSAIDs at the lowest dose for the shortest period in injured workers with moderate to severe pain. Acetaminophen may be considered for initial therapy for injured workers with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. In injured workers with acute exacerbations of chronic low back pain, the guidelines recommend NSAIDs as an option for short-term symptomatic relief. Based on the documentation, provided for review, it is unclear how long the injured worker has been utilizing this medication. As per the guidelines, NSAIDs are recommended at the lowest doses for the shortest period in injured workers. However, there is no documentation of pain relief or improved function with the medication. The request failed to provide the frequency of the medication. Therefore, the request is not medically necessary.

SENOKOT: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Veterans Health Administration, Department of Defense, Clinical Practice Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 77.

Decision rationale: The request for Senokot is not medically necessary. The California MTUS Guidelines state a prophylactic treatment of constipation should be initiated upon opioid therapy. Within the clinical information, provided for review, the physician noted there were no signs of opioid toxicity or side effects to include gastrointestinal events or constipation. In addition, the request as submitted failed to provide the frequency of the medication or a quantity. Therefore, the request for Senokot is not medically necessary.

TRAMADOL COMPOUND CREAM: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Effectiveness of topical administration of opioids in

**Decision rationale:** The request for tramadol compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, and bilateral knee pain treated with surgery, injections, and medications. The California MTUS Guidelines do not specifically address opioid analgesics in topical formulations. However, peer reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. In addition, it was unclear why the injured worker would require tramadol in a cream form as opposed to an oral medication. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.

**FLURBIPROFEN COMPOUND CREAM:** 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:** The request for flurbiprofen compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, bilateral knee pain treated with surgeries, injections, and medications. The California MTUS Guidelines state topical NSAIDs may be useful for chronic musculoskeletal pain but there are no long term studies of their effectiveness or safety. In addition, topical NSAIDs are not recommended for neuropathic pain, as there is no evidence to support their use. The guidelines also note topical NSAIDs are recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment; however, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The guidelines also state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note gabapentin is not recommended for topical application. The clinical information, provided for review, failed to provide evidence the injured worker gained pain relief or improved function with this medication. In addition, the specific site at which the topical medication would be utilized was unclear within the provided documentation. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.

**CYCLOBENZAPRINE COMPOUND CREAM:** 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:** The request for cyclobenzaprine compound cream is not medically necessary. The injured worker has a history of failed back surgery syndrome, lumbar facet joint pain, lumbar neuralgia, bilateral knee pain treated with surgeries, injections, and medications. The current California MTUS Guidelines states any compounded product that contains at least one drug or drug class that is not recommended is not supported. The guidelines also state there is no evidence for use of the muscle relaxant cyclobenzprine as a topical product. The clinical information, provided for review, failed to provide evidence the injured worker gained pain relief or improved function with this medication. In addition, the specific site at which the topical medications will be utilized was unclear within the provided documentation. The request as submitted failed to provide the frequency or quantity of the medication. Therefore, the request is not medically necessary.