

Case Number:	CM15-0040070		
Date Assigned:	04/02/2015	Date of Injury:	03/19/2011
Decision Date:	05/26/2015	UR Denial Date:	02/04/2015
Priority:	Standard	Application Received:	03/03/2015

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: Pennsylvania
 Certification(s)/Specialty: Internal Medicine

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 51-year-old male, who sustained an industrial injury on 03/19/2011 due to a fall. The injured worker was diagnosed as having fracture of talus, status post talocalcaneal fusion, headaches, status post open reduction internal fixation of the right ankle with residual pain, and sleep disorder. Medical history also includes hypertension. Treatment to date has included medication, surgery, physical therapy, ankle brace, bone stimulator, CAM walker. Reports from the primary treating physician from 2013- 2015 were submitted. Synapryn, trabadol, fanatrex, and cyclobenzaprine were prescribed in September 2013. Flurbiprofen and capsaicin were prescribed in June 2014. Reports reflect ongoing right ankle pain, headaches, and difficulty sleeping. Medications were noted to offer temporary relief of pain and improved ability to have restful sleep. Work status was noted as temporarily totally disabled. Urine drug screens in December 2014 and January 2015 were positive for cocaine and negative for tramadol (a prescribed medication, component of synapryn); these findings were not addressed. In a progress note dated 01/22/2015 the treating provider notes the injured worker reports complaints of constant, moderate to severe pain to the right ankle that is rated an eight out of ten along with complaints of headaches, high blood pressure, and difficulty sleeping secondary to pain. Examination showed tenderness to palpation of the medial and lateral malleolus, with decreased range of motion of the right ankle and positive anterior drawer, posterior drawer and varus/valgus stress test. Deprizine, dicopanol, fanatrex, synapryn, trabadol, capsaicin, flurbiprofen, menthol, cyclobenzaprine, and gabapentin were continued. Work status remained

temporarily totally disabled. On 2/4/15, Utilization Review non-certified requests for the medications currently under Independent Medical Review, citing the MTUS.

IMR ISSUES, DECISIONS AND RATIONALES

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

Capsaicin (dosage & quantity unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The treating physician's request did not include the concentration or directions for use. The requested prescription is for an unstated quantity and dose, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. There was no documentation of lack of response or intolerance to other treatments. Due to lack of indication and unspecified dose and quantity requested, the request for capsaicin is not medically necessary.

Cyclobenzaprine (dosage & quantity unspecified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants for pain Page(s): 67 and 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42, muscle relaxants p. 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. Tramadol (a form of cyclobenzaprine) has been prescribed for more than one year. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Work status has been temporarily totally disabled for more than one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not

recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple other agents. Limited, mixed evidence does not allow for a recommendation for chronic use. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. The current requests also include a request for trabadol (cyclobenzaprine in oral suspension) which is duplicative and potentially toxic. Due to length of use in excess of the guidelines, unstated quantity requested, duplicative requests for cyclobenzaprine and trabadol with potential for toxicity, and lack of functional improvement, the request for cyclobenzaprine is not medically necessary.

Fanatrex 25mg/ml oral suspension, 420ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): 16-22.

Decision rationale: Fanatrex is a liquid formulation of gabapentin. Fanatrex (gabapentin) has been prescribed for more than one year. Per the MTUS, anti-epilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin has been shown to be effective for treatment of diabetic neuropathy and post-herpetic neuralgia and has been considered a first line treatment for neuropathic pain. This injured worker has chronic ankle pain. There was no documentation of neuropathic pain. A "good" response to the use of AEDs is defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. Lack of at least a 30% response per the MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. There was no documentation of at least 30% pain reduction with use of gabapentin, and no documentation of functional improvement. Work status has been temporarily totally disabled for more than one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. The current requests include a request for gabapentin, which is duplicative and potentially toxic. Due to lack of specific indication, lack of functional improvement, and duplicative requests with potential for toxicity, the request for fanatrex is not medically necessary.

Flurbiprofen (dosage & quantity unspecified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

Decision rationale: Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. This injured worker has chronic ankle pain. Flurbiprofen has been prescribed for at least 8 months. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. No monitoring of blood pressure or blood tests was documented, in spite of documented history of hypertension for this injured worker. There was no documentation of significant pain relief or functional improvement as a result of use of flurbiprofen. Work status has been temporarily totally disabled for more than one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. Due to unspecified quantity requested, length of use not in accordance with the guidelines, lack of functional improvement, and potential for toxicity, the request for flurbiprofen is not medically necessary.

Gabapentin (dosage & quantity unspecified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Neuropathic pain Page(s): 18 and 19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): 16-22.

Decision rationale: Fanatrex (gabapentin) has been prescribed for more than one year. Per the MTUS, anti-epilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin has been shown to be effective for treatment of diabetic neuropathy and post-herpetic neuralgia and has been considered a first line treatment for neuropathic pain. This injured worker has chronic ankle pain. There was no documentation of neuropathic pain. A "good" response to the use of AEDs is defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. Lack of at least a 30% response per the MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any

side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. There was no documentation of at least 30% pain reduction with use of gabapentin, and no documentation of functional improvement. Work status has been temporarily totally disabled for more than one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. The current requests include a request for fanatrex (gabapentin in oral suspension), which is duplicative and potentially toxic. Due to lack of specific indication, lack of functional improvement, and duplicative requests with potential for toxicity, the request for gabapentin is not medically necessary.

Menthol (dosage & quantity unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. Due to lack of recommendation by the guidelines and lack of a sufficiently specific prescription, the request for menthol is not medically necessary.

Synapryn 10mg/1ml oral suspension, 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Analgesic opioid Page(s): 78.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids p. 74-96, glucosamine (and chondroitin sulfate) Page(s): 50, 74-96.

Decision rationale: Synapryn contains tramadol with glucosamine in oral suspension. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally an as-needed medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is illogical and not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address these other recommendations in the MTUS. Work status has been temporarily totally disabled for more than

one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." MTUS also details indications for discontinuing opioid medication, such as serious non-adherence or diversion. Urine drug screens were negative for tramadol, a prescribed medications, and positive for cocaine. The records clearly indicate inconsistent urine drug test and the inconsistent results are not explained by treating provider, which would be necessary for continued usage. Concurrent use of alcohol or other illicit drugs is considered adverse behavior. Immediate discontinuation of opioids has been suggested for use of illicit drugs and/or alcohol. The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. Should there be any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol which are habituating. Synapryn is not medically necessary based on the MTUS recommendations for use of glucosamine, inconsistent urine drug screens/urine drug screens positive for cocaine, lack of functional improvement, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS. The request IS NOT medically necessary.

Tabradol 1mg/ml oral suspension, 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42, muscle relaxants p. 63-66.

Decision rationale: Tabradol is cyclobenzaprine in an oral suspension. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic ankle pain with no evidence of prescribing for flare-ups. Trabadol (a form of cyclobenzaprine) has been prescribed for more than one year. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Work status has been temporarily totally disabled for more than one year, there was not documentation of improvement in activities of daily living, medications were not reduced, and office visits have continued at the same frequency. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple other agents. Limited, mixed evidence does not allow for a recommendation for chronic use. The current requests also include a request for cyclobenzaprine, which is duplicative and potentially toxic. Due to length of use in excess of the guidelines, duplicative

requests for cyclobenzaprine and tramadol with potential for toxicity, and lack of functional improvement, the request for tramadol is not medically necessary.