

Case Number:	CM14-0093331		
Date Assigned:	07/25/2014	Date of Injury:	12/03/2013
Decision Date:	06/24/2015	UR Denial Date:	06/10/2014
Priority:	Standard	Application Received:	06/19/2014

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:

This 31 year old man sustained an industrial injury on 12/3/2013 after falling off of a ladder and landing on concrete. Diagnoses include rule out cervical disc displacement, cervical radiculopathy, rib sprain, left elbow sprain, long finger injury, rule out long finger internal derangement, thoracic spine sprain/strain, rule out thoracic spine intervertebral disc displacement, lumbar intervertebral disc displacement, radiculopathy, hip sprain/strain, and left ankle ligament disorder. Treatment has included oral and topical medications and acupuncture. Initial primary treating physician report dated 1/28/2014 show complaints of pain to the neck rated 7/10, left elbow rated 6/10, left long finger rated 7/10, left ribs rated 6-7/10, mid back rated 6-7/10, low back pain rated 8/10, bilateral hip pain rated 4-6/10, and left ankle rated 4-5/10. Examination showed widespread tenderness. Medications prescribed included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclophene, Ketoprofen cream, and Terocin patches. A urine drug screen on 1/28/14 was negative for all substances assayed. Office visits from February to May 2014 note ongoing pain unchanged in severity. Medications were noted to offer temporary relief of pain and improve ability to have restful sleep. Work status in this timeframe was noted as temporarily totally disabled. On 6/10/14, Utilization Review (UR) non-certified requests for the items currently under Independent Medical Review, citing the MTUS, ACOEM, ODG and National Guidelines Clearinghouse.

IMR ISSUES, DECISIONS AND RATIONALES

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

Unknown prescription of Terocin Patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine, topical.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113. 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: This injured worker has chronic multifocal pain. Terocin patches have been prescribed for four months. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There was no documentation of trial and failure of antidepressants and anticonvulsants for this injured worker. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Terocin patch contains lidocaine and menthol. The site of application and directions for use were not specified. 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. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. There is no documentation that this injured worker has neuropathic pain or post-herpetic neuralgia. 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. As the compound contains medication that is not recommended, the compound is not recommended. In addition, there was no documentation of trial and failure of antidepressant and anticonvulsant medication. As such, the request for Terocin patches is not medically necessary.

1 Urine drug screen: 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 drug testing, opioids Page(s): 43, 77-78, 89, 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: urine drug testing.

Decision rationale: This injured worker has chronic multifocal pain. He has been prescribed tramadol for four months. An initial urine drug screen at onset of treatment on 1/28/14 was negative. Per MTUS chronic pain medical treatment guidelines, urine drug screens are recommended as an option to assess for the use or the presence of illegal drugs, in accordance with a treatment plan for use of opioid medication, and as a part of a pain treatment agreement for opioids. Per the ODG, urine drug testing is recommended as a tool to monitor compliance

with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. Urine drug testing is recommended at the onset of treatment when chronic opioid management is considered, if the patient is considered to be at risk on addiction screening, or if aberrant behavior or misuse is suspected or detected. Ongoing monitoring is recommended if a patient has evidence of high risk of addiction and with certain clinical circumstances. Frequency of urine drug testing should be based on risk stratification. Patients with low risk of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. Patients at moderate risk for addiction/aberrant behavior should be tested 2-3 times per year. Patients at high risk of adverse outcomes may require testing as often as once a month. Random collection is recommended. Results of testing should be documented and addressed. There was no documentation of risk stratification for aberrant behavior, which would be necessary to determine the frequency of urine drug testing. In addition, the associated opioid has been determined to be not medically necessary. As such, the request for urine drug screen is not medically necessary.

Unknown prescription of Ketoprofen cream: Upheld

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

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

Decision rationale: Ketoprofen, a non-steroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photo contact dermatitis. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. The site of application and directions for use were not specified. As topical ketoprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. 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 FDA approval, unstated site of application, and unstated quantity requested, the request for ketoprofen is not medically necessary.

Unknown prescription of Cyclophene: Upheld

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

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

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There was no documentation of

trial and failure of antidepressants and anticonvulsants for this injured worker. Topical muscle relaxants are not recommended per the MTUS; Cyclophene is topical cyclobenzaprine. 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 treating physician has also prescribed oral cyclobenzaprine, which is duplicative and potentially toxic. Due to lack of recommendation by the guidelines, unstated quantity requested, and potential for toxicity, the request for cyclophene is not medically necessary.

Unknown prescription of Synapryn (Tramadol): 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 opioids, glucosamine (and chondroitin sulfate) Page(s): 50, 77-80, 93-94.

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. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. 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." 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. 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. Synapryn is not medically necessary based on the MTUS, unspecified quantity requested, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

Unknown prescription of Tabradol (Cyclobenzaprine): 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. This patient has chronic pain with no evidence of prescribing for flare-up. Cyclobenzaprine has been prescribed for four months. There was no documentation of improvement in pain or function as a result of use of cyclobenzaprine; pain severity ratings were unchanged, work status remains temporarily totally disabled, there was no documentation of improvement in activities of daily living, and office visits have continued at the same frequency. The MTUS states that treatment with cyclobenzaprine should be brief, and that the addition of cyclobenzaprine to other agents is not recommended. In this case, cyclobenzaprine is added to other agents. Prescribing was not for a short term exacerbation. The treating physician has also prescribed topical cyclobenzaprine, which is duplicative and potentially toxic. 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 duration of use in excess of the guidelines, lack of functional improvement, unstated quantity requested, and potential for toxicity, the request for cyclobenzaprine is not medically necessary.

Unknown prescription of Deprizine (Ranitidine): 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 NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: This injured worker has been prescribed ketoprofen cream, a non-steroidal anti-inflammatory agent, and deprizine (ranitidine) a histamine 2 (H2) receptor antagonist. The MTUS recommends co-therapy of NSAIDs with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. There is no recommendation for H2 receptor antagonists for gastric protection from NSAID use. A H2-receptor antagonist may be considered for treatment of dyspepsia secondary to NSAID therapy. Deprizine is ranitidine in an oral suspension. Ranitidine is prescribed without any rationale provided. If ranitidine is prescribed as cotherapy with an NSAID, ranitidine is not the best drug. Note the MTUS recommendations cited. There are no medical reports which adequately describe any relevant signs and symptoms of possible GI disease. There is no examination of the abdomen on record. Cotherapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this case. 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 specific indication, and unstated quantity requested, the request for deprizine is not medically necessary.

Unknown prescription of Dicopanor (Diphenhydramine): 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 Official Disability Guidelines (ODG) pain chapter: insomnia.

Decision rationale: Dicopanor contains diphenhydramine and other unnamed ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanor is not medically necessary on this basis alone. The documentation suggests that the reason for prescription of dicopanor was for insomnia, although specific complaint of insomnia was not noted. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Note the Official Disability Guidelines citation above. That citation also states that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. 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. Dicopanor is not medically necessary based on lack of a sufficient analysis of the patient's condition, unspecified quantity requested, the ODG citation, and lack of information provided about the ingredients.

Unknown prescription of Fanatrex (Gabapentin): 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 (antiepilepsy drugs (AEDs) Page(s): 16-22.

Decision rationale: Fanatrex is a formulation of gabapentin in oral suspension. Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. There was no documentation of neuropathic pain for this injured worker. The MTUS notes the lack of evidence for treatment of radiculopathy. 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. In this case, fanatrex has been prescribed for four months, with no change in pain severity ratings. There was no documentation of functional improvement as a result of use of fanatrex. Work status remains temporarily totally disabled, there was no documentation of improvement in activities of daily living, 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 lack of documentation neuropathy, lack of improvement in pain or function, and unstated quantity requested, the request for fanatrex is not medically necessary.