

Case Number:	CM14-0001472		
Date Assigned:	01/22/2014	Date of Injury:	11/01/2012
Decision Date:	06/19/2014	UR Denial Date:	12/17/2013
Priority:	Standard	Application Received:	01/03/2014

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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in California. 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 51-year-old female who reported an injury on 11/01/2012, due to cumulative trauma. The clinical note dated 11/21/2013, presented the injured worker with intermittent head pain, constant shoulder pain with noted weakness, numbness and tingling in her hands and fingers, intermittent pain and numbness in her forearm, wrist, and hands bilaterally, upper and lower back pain and stiffness, and insomnia. The injured worker's physical exam revealed non specific tenderness to the hands, shoulder, elbow, forearm, and wrists bilaterally. There was a positive Phalens, Tinels, and Finkelstein's test bilaterally. The cervical spine exam revealed moderate paraspinal tenderness bilaterally to C1-T1, and the Spurlings, foraminal compression test, and shoulder depressor test reveal pain bilaterally. Evaluation of the cervical spine range of motion revealed 40 degrees of bilateral flexion, 40 degrees of bilateral extension, 60 degrees of bilateral rotation, and 25 degrees of bilateral lateral flexion. The injured worker's diagnoses were thoracic sprain, displacement of lumbar intervertebral disc without myelopathy (per an MRI on 04/30/2013), myalgia, headaches, sprain of unspecified site of the shoulder and upper arm, sprain of other specified sites of elbow and forearm, pain in joint involving forearm, pain in joint involving hand, carpal tunnel syndrome, anxiety, and sleep disturbance. The provider recommended a compounded ketoprofen gel, cyclophene gel, synarpryn 10mg, Tabradol 1mg, Deprizine 15mg, Dicopanol 5mg, and Fanatrax 25mg. The request for authorization form is dated 11/21/2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN 20% PLO GEL 120 GRAMS: 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.

Decision rationale: The Chronic Pain Guidelines indicate that transdermal compounds are largely experimental in use with few randomized controlled trials to determine efficiency or safety. Ketoprofen is currently not FDA approved for topical application. Topical analgesia are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one (1) drug that is not recommended is not recommended. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). The guidelines note there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. It was unclear if the injured worker had a diagnosis which would be congruent with the guideline recommendations for topical NSAIDs. The site at which the requested medication is to be applied was unclear within the request. Therefore, the request is not medically necessary.

CYCLOPHEPENE 5% PLO GEL 120 GRAMS: 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.

Decision rationale: The Chronic Pain Guidelines state that transdermal compounds are largely experimental in use with few randomized controlled trials to determine efficiency or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one (1) drug that is not recommended is not recommended. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment and are recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The guidelines note muscle relaxants are not recommended for topical application. The topical medication contains cyclobenzaprine which is not recommended for topical application. Therefore, the request is not medically necessary.

SYNARPRYN 10MG/1ML ORAL: 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, pain treatment agreement Page(s): 89.

Decision rationale: Synapryn is comprised of tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine. The Chronic Pain Guidelines recommend providing ongoing education on both the benefits and limitations of opioid treatment. The guidelines recommend the lowest possible dose should be prescribed to improve pain and function. The guidelines also recommend ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The 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. The guidelines note that glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The Official Disability Guidelines indicate that compound medications should include at least one (1) drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including over-the-counter (OTC) drugs. The guidelines note that compounded medications should include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have a national drug code (NDC) and should not include a drug that was withdrawn or removed from the market for safety reasons and is not a copy of a commercially available FDA-approved drug product. The guidelines also note that the medications should include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. The documentation lacks evidence of this medication providing desired effects for the injured worker. There was a lack of an adequate and complete pain assessment within the documentation. It was unclear why the injured worker would require compounded oral suspension medications as opposed to non-compounded traditional oral medications. It did appear the injured worker has significant difficulties taking traditional tablet medications which would indicate the injured workers need for the compounded oral suspension medications. Therefore the request is not medically necessary.

TABRADOL 1MG/ML: 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 (Flexeril) Page(s): 41. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic), Compound drugs.

Decision rationale: Tabradol is comprised of cyclobenzaprine hydrochloride 1 mg/mL, in an oral suspension with MSM. The Chronic Pain Guidelines recommend Flexeril as an option for a

short course of therapy. The greatest effect of this medication is in the first four (4) days of treatment, suggesting that shorter courses may be better. The Official Disability Guidelines indicate that compound medications should include at least one (1) drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including over-the-counter (OTC) drugs. The guidelines note that compounded medications should include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have a national drug code (NDC) and should not include a drug that was withdrawn or removed from the market for safety reasons and is not a copy of a commercially available FDA-approved drug product. The guidelines also note the medications should include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. It appears the injured worker has been prescribed the medication since at least 11/07/2013. The request for additional use of the medication would exceed the guideline recommendations. The efficacy of the medication was unclear. It was unclear why the injured worker would require compounded oral suspension medications as opposed to non-compounded traditional oral medications. It did appear the injured worker has significant difficulties taking traditional tablet medications which would indicate the injured workers need for the compounded oral suspension medications. Therefore, the request is not medically necessary.

DEPRIZINE 15MG/ML: 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 NSAID's, GI symptoms & cardiovascular risk Page(s): 69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic), Compound drugs.

Decision rationale: Deprizine is ranitidine hydrochloride 16.8 mg/mL (Zantac). The Chronic Pain Guidelines recommend H2-receptor antagonists for the treatment of dyspepsia secondary to non-steroidal anti-inflammatory drug (NSAID) therapy. The Official Disability Guidelines indicate that compound medications should include at least one (1) drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including over-the-counter (OTC) drugs. The guidelines note compounded medications should include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have a national drug code (NDC) and should not include a drug that was withdrawn or removed from the market for safety reasons and is not a copy of a commercially available FDA-approved drug product. The guidelines also note that the medications should include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. The medical documents lack evidence of the injured worker presenting with any symptoms or a significantly increased risk for gastrointestinal events. It did not appear the injured worker has a history of gastrointestinal (GI) bleed, peptic ulcer, or perforation. It was unclear why the injured worker would require compounded oral suspension medications as opposed to non-compounded traditional oral medications. It did appear that the

injured worker has significant difficulties taking traditional tablet medications which would indicate the injured worker's need for the compounded oral suspension medications. Therefore, the request is not medically necessary.

DICOPANOL 5MG/ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.nhm.nih.gov

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Insomnia treatment

Decision rationale: Dicopanol is diphenhydramine hydrochloride 5 mg/mL, in an oral suspension. The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids, and tolerance seems to develop within a few days and next-day sedation has been noted as well as impaired psychomotor and cognitive function. Sedating antihistamines has been shown to build tolerance against its sedation effectiveness very quickly. The Guidelines further state that compound medications should include at least one (1) drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including over-the-counter (OTC) drugs. The guidelines note compounded medications should include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have a national drug code (NDC) and should not include a drug that was withdrawn or removed from the market for safety reasons and is not a copy of a commercially available FDA-approved drug product. The guidelines also note the medications should include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. The provider's rationale for the use of this medication is unclear. It was unclear why the injured worker would require compounded oral suspension medications as opposed to non-compounded traditional oral medications. It did appear that the injured worker has significant difficulties taking traditional tablet medications, which would indicate the injured worker's need for the compounded oral suspension medications. Therefore, the request is not medically necessary.

FANATREX 25MG/ML: 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 Specific Anti-epilepsy Drugs Page(s): 18. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

Decision rationale: Fanatrex is gabapentin 25 mg/mL, in an oral suspension. The Chronic Pain Guidelines indicate that relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain

relief in relationship to improvements in function and increased activity. The guidelines also indicate that Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia. The Official Disability Guidelines indicate that compound medications should include at least one (1) drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including over-the-counter (OTC) drugs. The guidelines note that compounded medications should include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have a national drug code (NDC) and should not include a drug that was withdrawn or removed from the market for safety reasons and is not a copy of a commercially available FDA-approved drug product. The guidelines also note that the medications should include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. The providers rationale for the use of this medication is unclear. It was unclear why the injured worker would require compounded oral suspension medications as opposed to non-compounded traditional oral medications. It did appear that the injured worker has significant difficulties taking traditional tablet medications which would indicate the injured worker's need for the compounded oral suspension medications. The injured worker has been prescribed Gabapentin since at least 11/07/2013. There is a lack of evidence in the medical documents that include decreased pain and increased function in relation to Gabapentin. Therefore, the request is not medically necessary.