

Case Number:	CM13-0041500		
Date Assigned:	04/25/2014	Date of Injury:	03/06/2013
Decision Date:	07/07/2014	UR Denial Date:	10/02/2013
Priority:	Standard	Application Received:	10/14/2013

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 Neurology, has a subspecialty in Neuromuscular Medicine 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:

██████████ is a 38 year old man who sustained a work related injury on March 6 2013. Subsequently, he developed a chronic back pain. According to a notes dated June 14 2013 and September 6 2013, the patient reported chronic back pain radiating to bilateral lower extremities. The patient was subsequently diagnosed with lumbago. The provider requested authorization for the medications prescribed below.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN 20% IN PLO GEL 120GMS: 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: According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111); topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at

least one drug or drug class that is not recommended is not recommended. There is no evidence that Ketoprofen gel is recommended as topical analgesics for chronic pain. Ketoprofen gel, a topical analgesic is not recommended by MTUS guidelines. Furthermore, Ketoprofen was reported to have frequent photocontact dermatitis. Based on the above Ketoprofen 20% In Plo Gel 120gms is not medically necessary.

CYCLOPHENE 5% IN PLO GEL 120 GMS: 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: According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111); topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no evidence that Cyclophene (Cyclobenzaprine) gel is recommended as topical analgesics for chronic pain. There is no documentation of recent spasm in the patient chart. Cyclophene gel, a topical analgesic is not recommended by MTUS guidelines. Based on the above Cyclophene 5% In Plo Gel 120 GMs is not medically necessary.

SYNAPRYN (10MG/1ML ORAL SUSPENSION) 500ML: 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 Tramadol, Criteria for use of opioids Page(s): 113 and 179.

Decision rationale: Synapryn (10mg/1ml Oral Suspension) 500ml Contains Tramadol and Glycosamine. According to MTUS guidelines, Ultram is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. Although, Ultram may be needed to help with the patient pain, it may not help with the weaning process from opioids. Ultram could be used if exacerbation of pain after or during the weaning process. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. There is no clear evidence of objective and recent functional and pain improvement with previous use of opioids (Tramadol). There no clear documentation of the efficacy/safety of previous use of Tramadol. There is no recent evidence of objective monitoring of compliance of the patient with his medication. There is no clear justification for the need to continue the use of Tramadol. Therefore, the prescription of Synapryn (10MG/1ML Oral Suspension) 500ML is not medically necessary at this time.

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 Page(s): 41.

Decision rationale: Tabradol contains Cyclobenzaprine. According to MTUS guidelines, an non sedating muscle relaxants is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic lumbosacral pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The patient in this case does not have clear evidence of acute exacerbation of chronic back pain and spasm and the prolonged use of Tabradol is not justified. The request is not medically necessary.

DEPRIZINE 15MG/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 NSAIDs, GI symptoms & cardiovascular risk Page(s): 102.

Decision rationale: Deprizine 15mg/ML Oral Suspension 250ml contains Ranitidine which is a histamine H2 receptor antagonist. According to MTUS guidelines, Ranitidine is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events . The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no documentation in the patient's chart supporting that she is at intermediate or high risk for

developing gastrointestinal events. Therefore, Deprizine 15mg/ML Oral Suspension 250ML is not medically necessary.

DICOPANOL (DIPHENHYDRAMINE) 58MG/ML ORAL SUSPENSION 150ML: 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. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: < Diphendrydamine > <http://en.wikipedia.org/wiki/Diphenhydramine>.

Decision rationale: Dicopanol contains diphenhydramine, a sedative medication. There is no recent documentation that the patient developed insomnia. Therefore, Dicopanol prescription is not medically necessary.

FANATREX (GABAPENTIN) 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 Gabapentin Page(s): 49.

Decision rationale: Fanatrex contains Gabapentin which is a medication approved for neuropathic pain. According to MTUS guidelines, Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. There is no recent documentation that the patient developed a neuropathic pain. Therefore, the request for Fanatrex (Gabapentin) 25mg/ML Oral Suspension 420ML is not medically necessary.