

Case Number:	CM13-0044957		
Date Assigned:	12/27/2013	Date of Injury:	08/09/2007
Decision Date:	03/11/2014	UR Denial Date:	10/07/2013
Priority:	Standard	Application Received:	10/31/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Orthopedic Surgery, 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 physician 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:

58 year old female with industrial injury 8/9/07. Exam note from 9/9/13 demonstrates complaint of radicular neck pain, bilateral shoulder pain and radiating pain down fingers and bilateral knee pain. Positive Spurling's sign noted with lumbar spine tenderness. Bilateral knees demonstrates decreased range of motion. Diagnosis of cervical spine pain, radiculopathy and lumbar radiculopathy. Additional diagnosis of bilateral shoulder pain and bilateral knee pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound Ketoprofen 20% in PLO Gel, three times a day for Inflammations, 120 Grams:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Per the CA MTUS regarding topical analgesics: Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many

agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." There is insufficient evidence in the records to support medical necessity and lack of support by the guidelines. Therefore the determination is for non-certification.

Compound Cyclophene 5% in PLO gel, TID for Neuropathic Pain and Muscle Spasms, 120 Grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Per the CA MTUS regarding topical analgesics, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." There is insufficient evidence in the records to support medical necessity and lack of support by the guidelines. Therefore the determination is for non-certification.

Synapryn 10MG/1ML Oral Suspension, three times a day as directed, 500 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Synapryn is a oral suspension of Tramadol with Glucosamine, with regards to compounded medication such as Synapryn the CA MTUS/Chronic Pain Medical Treatment Guidelines state,"Any compounded product that contains at least one drug (or drug class) that isnot recommended is not recommended." Therefore the determination is non-certification as it is not medically necessary per the guidelines.

Tabradol 1MG/ML Oral Suspension, 2 - 3 Times a Day for Muscle Spasms, 250 ML:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Tabradol is an oral suspension of Cyclobenzaprine with MSM, with regards to compounded medication such as Tabradol the CA MTUS/Chronic Pain Medical Treatment Guidelines state, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the determination is non-certification as it is not medically necessary per the guidelines.

Deprizine 15 MG/ML Oral Suspension, 2 Teaspoons Once Daily, 250 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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. In this case there is insufficient evidence to support use of Ranitidine (Deprizine) as the patient has no history of peptic ulcer disease, GI bleeding or perforation. Therefore the determination is non-certification as it is not medically necessary.

Dicopanol 5 MG/ML Oral Suspension, 1 ML at bedtime a day, 150 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the determination is non-certification as it is not medically necessary per the guidelines.

Fanafrex (Gabapentin) 25 MG/ML Oral Suspension, 1 Teaspoon three times a day for Chronic Neuropathic Pain, 420 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 18, 50, 78, 93, 94 111, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the determination is non-certification as it is not medically necessary per the guidelines.