

Case Number:	CM14-0132344		
Date Assigned:	10/09/2014	Date of Injury:	08/01/2013
Decision Date:	11/12/2014	UR Denial Date:	08/02/2014
Priority:	Standard	Application Received:	08/19/2014

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. The expert reviewer is Board Certified in Preventative 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:

According to the records made available for review, this is a 60-year-old male with a 8/1/13 date of injury. At the time (8/2/14) of the Decision for 1 prescription of Ketoprofen 20% cream 165 gm, 1 prescription of Cyclobenzaprine 5% cream 100gm, 1 prescription of Synapryn 10mg/1ml oral suspension 500ml #1, 1 prescription of Tabradol 1mg/ml oral suspension 250ml #1, 1 prescription of Deprizine 15mg/ml oral suspension 250ml #1, 1 prescription of Dicopanol 5mg/ml oral suspension 150ml #1, 1 prescription of Fanatrex 25mg/ml oral suspension 420ml #1, Unknown LINT sessions for the cervical spine, and 1 follow-up visit, there is documentation of subjective (neck pain associated with numbness and tingling of the bilateral upper extremities, low back pain radiating to the bilateral lower extremities with numbness and tingling, bilateral knee pain, stress, anxiety, and insomnia) and objective (tenderness to palpation over the suboccipital region, trapezius muscles, and sternocleidomastoid muscles; trigger points over the bilateral upper trapezius; decreased cervical spine range of motion; positive cervical distraction test; decreased sensation over the C5-T1 dermatomes; decreased bilateral knee range of motion; tenderness to palpation over the medial and lateral joint line; positive McMurray's and Lachman's tests; and decreased sensation over the L2-S1 dermatomes) findings, current diagnoses (status post cervical spine fusion, cervicgia, cervical radiculopathy, lumbar radiculopathy, internal derangement of bilateral knees, anxiety, stress, and sleep disorder), and treatment to date (medications (including ongoing treatment with Deprizine, Fanatrex, Dicopanol, Synapryn, and Tabradol)). Medical reports identify that medication offer temporary relief of pain and improve ability to have restful sleep.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Ketoprofen 20% cream 165 gm: 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: MTUS Chronic Pain Medical Treatment Guidelines identifies that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other anti-epilepsy drugs are not recommended for topical applications. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Ketoprofen 20% cream 165 gm is not medically necessary.

1 prescription of Cyclobenzaprine 5% cream 100gm: 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: MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other anti-epilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Cyclobenzaprine 5% cream 100gm is not medically necessary.

1 prescription of Synapryn 10mg/1ml oral suspension 500ml #1: 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, Co-pack drugs and on <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>

Decision rationale: Medical Treatment Guidelines identify Synapryn as Tramadol Hydrochloride, in oral suspension with Glucosamine-compounding kit. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single

package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Synapryn 10mg/1ml oral suspension 500ml #1 is not medically necessary.

1 prescription of Tabradol 1mg/ml oral suspension 250ml #1: 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, Co-pack drugs and on <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>

Decision rationale: Medical Treatment Guidelines identify Tabradol as Cyclobenzaprine Hydrochloride, in oral suspension with MSM - compounding kit. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Tabradol 1mg/ml oral suspension 250ml #1 is not medically necessary.

1 prescription of Deprizine 15mg/ml oral suspension 250ml #1: 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, Co-pack drugs and on <http://www.dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=153097>

Decision rationale: Medical Treatment Guideline identifies Deprizine as Ranitidine Hydrochloride in oral suspension kit. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Deprizine 15mg/ml oral suspension 250ml #1 is not medically necessary.

1 prescription of Dicopanl 5mg/ml oral suspension 150ml #1: 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, Co-pack drugs and on <http://www.drugs.com/pro/dicopanl.html>

Decision rationale: Medical Treatment Guidelines identify Dicopanl as Diphenhydramine Hydrochloride in oral suspension - compounding kit. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of Dicopanl 5mg/ml oral suspension 150ml #1 is not medically necessary.

1 prescription of Fanatrex 25mg/ml oral suspension 420ml #1: 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, Co-pack drugs and on <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=24354>

Decision rationale: Medical Treatment Guidelines identify Fanatrex as Gabapentin in oral suspension kit. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for 1 prescription of 1 prescription of Fanatrex 25mg/ml oral suspension 420ml #1 is not medically necessary.

Unknown LINT sessions for the cervical spine: 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 Neuromuscular Electrical Stimulation Page(s): 121.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines states that neuromuscular electrical stimulation (NMES) is not recommended. In addition, MTUS Chronic Pain Medical Treatment Guidelines states that NMES is primarily used as part of a rehabilitation

program following stroke and there is no evidence to support its use in chronic pain. Therefore, based on guidelines and a review of the evidence, the request for Unknown LINT sessions for the cervical spine is not medically necessary.

1 follow-up visit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Independent Medical Examinations and Consultations, page(s) 127 Official Disability Guidelines (ODG) Pain Chapter, Office visits

Decision rationale: ACOEM guidelines state that the occupational health practitioner may refer to other specialist if a diagnosis is uncertain or extremely complex, when psychosocial facts are present, or when the plan or course of care may benefit from additional expertise. ODG identifies that office visits are based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. Within the medical information available for review, there is documentation of diagnoses of status post cervical spine fusion, cervicgia, cervical radiculopathy, lumbar radiculopathy, internal derangement of bilateral knees, anxiety, stress, and sleep disorder. However, given no documentation of a rationale identifying the medical necessity of the requested follow up visit, and given that the associated requests are not medically necessary, there is no documentation of the medical necessity for a follow-up visit in order to monitor the patient's progress and make any necessary modifications to the treatment plan. Therefore, based on guidelines and a review of the evidence, the request for 1 follow-up visit is not medically necessary.