

Case Number:	CM15-0128075		
Date Assigned:	07/14/2015	Date of Injury:	01/25/1994
Decision Date:	08/25/2015	UR Denial Date:	06/09/2015
Priority:	Standard	Application Received:	07/02/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 53 year old male, who sustained an industrial injury on 1/25/94. He reported pain in his lower back. The injured worker was diagnosed as having failed lumbar back syndrome, muscle spasms, lumbosacral radiculopathy and fibromyalgia. Treatment to date has included trigger point injections on 8/1/12, Voltaren 1%, Celebrex, Omeprazole and Duexis since at least 7/8/14. As of the PR2 dated 4/3/15, the injured worker reports pain in his low back and right leg. Objective findings include facet pain at L3-S1, no trigger points and normal gait. The treating physician requested Duexis 800mg/26.6mg #90 x 1 refill, Omeprazole 20mg #60 x 1 refill, Voltaren 1% #5 x 1 refill and Celebrex 200mg #30 x 1 refill.

IMR ISSUES, DECISIONS AND RATIONALES

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

Duexis 800mg/26.6mg 1 tab 3 times a day for 30 days #90 with 1 refill: 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 Anti-inflammatories NSAIDs, GI symptoms & cardiovascular risk, Famotidine Page(s): 22, 68-69.

Decision rationale: The patient presents with pain in the lower back and right lower extremity. The request is for Duexis 800 mg/26.6 mg tab 3 times a day for 30 days # 90 with 1 refill. Physical examination to the lumbar spine on 04/31/15 revealed tenderness to palpation at L3-S1 on the right side. Patient received trigger point injections on 07/08/14. Per 04/09/13 progress report, patient's diagnosis include failed back synd, lumb, radiculopathy L/S, and fibromyalgia/myositis. Patient's medications, per 04/03/15 progress report include Oxycodone-Acetaminophen, Omeprazole, Voltaren Gel, and Duexis. Patient's work status was not specified. Per FDA label indication, Duexis is a combination of the NSAID Ibuprofen and the histamine H2-receptor antagonist famotidine indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. MTUS Guidelines page 22 states "anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long term use may not be warranted." For Famotidine, MTUS page 68 and 69 state, "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors." MTUS recommends determining risk for GI events before prescribing prophylactic PPI or omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. Treater has not discussed this request. Patient received prescriptions for Duexis on 07/08/14 and 04/03/15. MTUS does not recommend routine use of PPI's for prophylactic use without a proper GI risk assessment. Review of medical records do not show GI risk assessment, or documentation of GI issues such as GERD, gastritis or peptic ulcer, for which histamine H2-receptor antagonist such as Famotidine would be indicated. Treater has not discussed why a combination medication is required, either. Therefore, the request is not medically necessary.

Omeprazole 20mg capsule delayed release, 2 capsules once a day for 30 days #60 with 1 refill: 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): 68-69.

Decision rationale: The patient presents with pain in the lower back and right lower extremity. The request is for Omeprazole 20 mg capsules delayed release, 2 capsules once a day for 30 days # 60 with 1 refill. Physical examination to the lumbar spine on 04/31/15 revealed tenderness to palpation at L3-S1 on the right side. Patient received trigger point injections on 07/08/14. Per 04/09/13 progress report, patient's diagnoses include failed back synd, lumb, radiculopathy L/S, and fibromyalgia/ myositis. Patient's medications, per 04/03/15 progress report include Oxycodone- Acetaminophen, Omeprazole, Voltaren Gel, and Duexis. Patient's work status was not specified. MTUS pg 69 states , "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)." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." The patient has received prescriptions for Omeprazole from 12/18/12 and 04/03/15. In this case, the treater does not document any gastrointestinal upset or irritation. There is no history of ulcers, either. The treater does not provide GI risk assessment required to make a determination based on MTUS. Therefore, the request Omeprazole is not medically necessary.

Voltaren 1% topical gel 1gm every 8 hours for 30 days #5 tube with 1 refill: 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 patient presents with pain in the lower back and right lower extremity. The request is for Voltaren 1% topical gel 1 gm every 8 hours for 30 days # 5 tube with 1 refill. Physical examination to the lumbar spine on 04/31/15 revealed tenderness to palpation at L3-S1 on the right side. Patient received trigger point injections on 07/08/14. Per 04/09/13 progress report, patient's diagnosis include failed back synd, lumb, radiculopathy L/S, and fibromyalgia/myositis. Patient's medications, per 04/03/15 progress report include Oxycodone-Acetaminophen, Omeprazole, Voltaren Gel, and Duexis. Patient's work status was not specified. The MTUS has the following regarding topical creams (p111, chronic pain section): "Topical Analgesics: Recommended as an option as indicated below. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder." MTUS Chronic Pain Medical Treatment Guidelines, pg 9 under Pain Outcomes and Endpoints states: "All therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement" Patient has received prescriptions for Voltaren Gel on 107/08/14 and 04/03/15. In this case, the treater has not discussed how Voltaren Gel decreases pain and significantly improves patient's activities of daily living. MTUS page 60 require recording of pain and function when medications are used for chronic pain. While the patient does present with peripheral joint problems for which topical NSAIDs may be indicated, given the lack of documentation of it's efficacy, the request is not medically necessary.

Celebrex 200mg 1 capsule once a day for 30 days #30 with 1 refill: 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 Selective COX-2 NSAIDS, for Celecoxib (Celebrex) Page(s): 22, 70-73.

Decision rationale: The patient presents with pain in the lower back and right lower extremity. The request is for Celebrex 200 mg 1 capsule once a day for 30 days # 30 with 1 refill. Physical examination to the lumbar spine on 04/31/15 revealed tenderness to palpation at L3-S1 on the right side. Patient received trigger point injections on 07/08/14. Per 04/09/13 progress report, patient's diagnosis include failed back synd, lumb, radiculopathy L/S, and fibromyalgia/myositis. Patient's medications, per 04/03/15 progress report include Oxycodone-Acetaminophen, Omeprazole, Voltaren Gel, and Duexis. Patient's work status was not specified. MTUS guidelines page 22 supports NSAIDs for chronic LBP but for Celebrex, it states, "COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost." MTUS Chronic Pain Medical Treatment Guidelines, pg. 70-73 Selective COX-2 NSAIDS, for Celecoxib (Celebrex), states this is the only available COX-2 in the United States and that the Recommended Dose is 200 mg a day (single dose or 100 mg twice a day). Treater does not discuss this request. Patient has received prescriptions for Celebrex from 12/18/12 and 04/03/15. MTUS guidelines state that Celebrex is indicated in patients with a history of GI complications and not recommended for the majority of patients owing to high cost. In this case, treater has not discussed GI complications, nor are there any indications that the patient has failed generic NSAID therapy. Therefore, the request is not medically necessary.