

Case Number:	CM15-0193678		
Date Assigned:	10/07/2015	Date of Injury:	07/11/1991
Decision Date:	11/19/2015	UR Denial Date:	09/14/2015
Priority:	Standard	Application Received:	10/01/2015

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: Texas, California
 Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 67 year old female patient with an industrial injury date of 07-11-1991. The diagnoses include facet syndrome, lumbar 4-5 post-operative -laminectomy lumbar 4-5, painful lumbar disc- lumbar 4-5 and herniated disc - lumbar 4-5 postoperative. Per the doctor's note dated 08-20- 2015, she had back pain that was "constant" and rated as 4 and leg pain described as "intermittent" and rated as 3. Work status was documented as "permanent and stationary." The physical examination revealed normal gait and normal posture, lumbar flexion 100% with no pain, painful palpation over the facets of lumbar 4-5 bilaterally, normal strength and sensation in the legs and negative Straight leg raising in sitting at 90 degrees. Her medications included Flector patches, Voltaren gel and Celebrex. Per the progress note dated 07-24-2014, she has gastric reflux at times with medication but has been able to tolerate Celebrex in the past. The treatment note dated 07-24-2014 indicated the patient's medications were Voltaren cream, Flector patches and Celebrex at that time. Per the patient's note dated 10/17/15, her past surgical history includes back surgery and her past medical history includes Barrett's esophagus. She has had GI endoscopy on 6/12/2008 with findings of Barrett's esophagus. Prior treatment is documented as epidural steroid injection and physical therapy (03-23-1994 note.) On 09-14-2015 utilization review issued the following decision regarding the requested treatments: Voltaren cream tube with 11 refills: non-certified, Flector patch #30 with 11 refills: non-certified, Celebrex #30 200 mg with 11 refills: modified to Celebrex 200 mg # 30 with 2 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Celebrex #30 200mg with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

Decision rationale: Celebrex contains Celecoxib which is a non steroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. According to CA MTUS chronic pain medical treatment guidelines "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. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective non steroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. (Schnitzer, 2004) 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." Per the records provided patient had chronic back and leg pain with history of lumbar surgery. Per the patient's note dated 10/17/15, her past medical history includes Barrett's esophagus and per the progress note dated 07-24-2014, she has gastric reflux at times with medication but has been able to tolerate Celebrex in the past. An NSAID like COX-2 inhibitor, Celebrex, is appropriate in this patient with a history of Barrett's esophagus, to manage chronic pain. However the rationale for the daily long term use of Celecoxib, along with 11 refills is not specified in the records provided. This does not allow for a re evaluation to check the response and monitor for side effects of this medication. The medical necessity of Celebrex #30 200mg with 11 refills is not fully established for this patient at this time. Therefore, the request is not medically necessary.

Voltaren cream tube with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/09/15) Voltaren® Gel (diclofenac).

Decision rationale: The cited Guidelines regarding topical analgesics state, "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. 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." Intolerance or contraindication to oral medications other than NSAIDs is not specified in the records provided. Failure of an antidepressant or anticonvulsant is not specified in the records provided. In addition, per the ODG cited above voltaren gel is "Not recommended as a first-line treatment. See Diclofenac Sodium (Voltaren), where Voltaren Gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral

dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations." The medical necessity of Voltaren cream tube with 11 refills is not fully established for this patient at this time.

Flector patch #30 with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/09/15) Flector® patch (diclofenac epolamine).

Decision rationale: Flector patch contains diclofenac. The MTUS Chronic Pain Guidelines regarding topical analgesics state, "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." Any intolerance or contraindication to oral medications other than NSAIDs is not specified in the records provided. Failure of an antidepressant or anticonvulsant is not specified in the records provided. In addition, according to the ODG guidelines, Flector patch is "Not recommended as a first-line treatment". Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. (FDA, 2007) On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver." The medical necessity of Flector patch #30 with 11 refills is not fully established for this patient at this juncture. Therefore, the request is not medically necessary.