

Case Number:	CM13-0070826		
Date Assigned:	01/08/2014	Date of Injury:	03/29/2005
Decision Date:	04/25/2014	UR Denial Date:	12/17/2013
Priority:	Standard	Application Received:	12/26/2013

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 Physical Medicine and Rehabilitation, 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:

The patient is a 43 year old female who was injured on 03/29/2005. The patient stated several tables fell on her and she sustained an injury to her lower back and fractured her left heel. Prior treatment history has included trigger point injections, a total of 6 sites. The patient underwent anterior lumbar interbody fusion at L4-5 and L5-S1 and placement of intervertebral biomechanical device at L4-5 and L5-S1 on 12/11/2012. 12/10/2013 Medications Include: Celexa 40 mg Theophylline ER 300 mg Ventolin HFA Keflex Prilosec 20 mg Omeprazole 20 mg Amitiza 24 mcg Ambien 10 mg Donnatal 16.2 mg Fentanyl 25 mcg Lidocaine 5% Vicodin ES 7.5 mg Topamax 50 mg Diagnostic studies reviewed include CT of the lumbar spine with and without contrast performed on 08/23/2013 revealed 1) status post anterior and posterior fusion at L4-L5, L5-S1, along with left laminotomies as described below. There is solid bony fusion at both levels and no central stenosis; 2) Mild degenerative changes in the mid to lower lumbar spine; and 3) Mild multilevel foraminal narrowing. MRI of lumbar spine with and without Gadolinium performed on 09/26/2012 revealed: 1) L5-S1: There is a 2 mm degenerative anterior spondylolisthesis of L5 with respect to S1. There is a 2-3 mm left paracentral protrusion, which mildly fattens the left anterolateral thecal sac; however, there is no canal or lateral recess stenosis. There has been a left hemilaminectomy; Disc bulge extending into the neural foraminal mildly narrow the neural foramina. These findings are similar to the previous examination. 2) L4-5: There is a 1 mm retrolisthesis, a 2 mm disc bulge, without canal or lateral recess stenosis. There has been a left hemilaminectomy; disc bulge with loss of disc height extending into the right neural foramen mild to moderately narrow the right neural foramen without impingement of the exiting right L4 nerve root. PR2 dated 12/10/2013 documented the patient to have complaints of increased pain in her right hip and right shoulder pain. She indicates that the right hip pain increases with weight bearing activities and pain at

night when she lies on the right lateral side. She also admits to right shoulder pain with overhead activities. There is no associated numbness in that hand; however, there is pain with that activity. She has had subacromial bursitis and an injection into the subacromial bursa with significant pain relief. She continues to take her medications and denies any side effects. She states that the combination of Fentanyl and Vicodin ES does significantly improve her pain and allow her to continue her activities of daily living. She states that it helps her approximately 50%. Objective findings on exam revealed moderate scar tenderness of the lumbar spine. There is pain to palpation of the lumbar facet on both sides at L3-S1 region. There is pain noted over the lumbar intervertebral spaces on palpation. The patient's gait appears to be antalgic; anterior lumbar flexion causes pain. There is pain noted with lumbar extension and left lateral flexion causes pain; right lateral flexion reveals pain as well. She has pain with hip rotation and Patrick's test is positive on the right and negative on the left. Motor strength is grossly normal. The patient has tenderness to palpation in the right trochanteric bursa.

IMR ISSUES, DECISIONS AND RATIONALES

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

VICODIN ES 7.5/750MG #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: As per CA MTUS guidelines, Vicodin is recommended for moderate to moderately severe pain. Guidelines indicate "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)." In this case, records review indicates that this patient has chronic lower back pain and has been prescribed Vicodin chronically. There is subjective documentation that this patient's pain level with medications is 50 % less with subjective reports of functional improvement. However, guidelines recommend urine drug screening to monitor prescribed substance and issues of abuse, addiction or poor pain control. There is no documentation submitted that there is ongoing monitoring of the use of opioids with urine drug screening done. Thus, the request is non-certified.

DONNATAL 16.20.1037-0.0194MG #90: 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 Belladonna Alkaloid Combinations and Phenobarbital; <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601024.html>.

Decision rationale: Brand names of combination products - Donnatal[®] Tablets (containing Atropine, Hyoscyamine, Phenobarbital, Scopolamine) - Donnatal[®] Elixir (containing Atropine, Hyoscyamine, Phenobarbital, Scopolamine) Belladonna alkaloid combinations and phenobarbital are used to relieve cramping pains in conditions such as irritable bowel syndrome and spastic colon. They also are used with other medicine to treat ulcers. These medicines decrease the motion of the stomach and intestines and the secretion of stomach fluids, including acid. Belladonna alkaloid combinations and phenobarbital come as a regular tablet, a slow-acting tablet, capsule, and liquid to take by mouth. The regular tablet, capsule, and liquid are usually taken three or four times a day, 30 minutes before meals and at bedtime. The slow-acting tablet usually is taken two or three times a day at evenly spaced intervals. According to the references, this medication is a combination drug obtaining belladonna alkaloid and phenobarbital, used to relieve cramping pains in conditions such as IBS and spastic colon, and may be used with other medications in treatment of ulcers. The medical records do not appear to document a history, diagnosis and/or clinical findings that establish the patient has any of these gastrointestinal conditions for which this medication is indicated to treat. Without a relevant documented clinical history and findings that establish this medication is appropriate for the treatment of this patient, the medical necessity of Donnatal has not been established.