MAXIMUS Federal Services

Case Number:	CM14-0173869		
Date Assigned:	10/27/2014	Date of Injury:	09/15/2003
Decision Date:	12/03/2014	UR Denial Date:	09/22/2014
Priority:	Standard	Application Received:	10/21/2014

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 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:

This 48 year-old patient sustained an injury on 9/15/2003 while employed by [redacted] The request(s) under consideration include Amitiza 24 mcg, # 60 with 3 refills and Suboxone 24 mcg 8 mg- 2mg SI film 8-2, # 60 with 3 refills. The s/p thoracic discectomy, partial corpectomy and fusion with instrumentation of T7-8 on 11/11/04 were deemed P&S on 11/2/05. The patient continued to treat with pain management to include medications, T7-8 selective nerve blocks (August and October 2008), therapy and modified activities/rest. The patient has not worked since 10/31/04. On report of 1/13/09 from pain management provider noted the patient with diagnoses of s/p T8 rib resection; chronic pain syndrome; and neuropathic pain at T7-8 distribution. Medications listed Fentanyl patch, Oxy IR, Lyrica, Amitiza, and Nonalon with proposed radiofrequency ablation procedure. Orthopedic AME report of 6/17/09 had diagnoses of s/p T7-8 anterior discectomy with partial corpectomy and fusion. It was noted the patient "exhibited pain that is quite severe and in excess of what one would expect, given nature of problem." "This is not explainable by etiologies related to this spinal surgery, but probably much more related to the excessive use of narcotic analgesics." Long discussion with patient and wife regarding down sides and problems with chronic narcotic sue related to chronic pain. Future medical care "does not appear to be indicated other than a focused weaning program off of narcotic analgesics." No further investigation studies, injections, formal therapy, acupuncture, chiropractic treatment or surgery are indicated. Report of 9/4/14 from the provider noted the patient had been taking Suboxone that "does not help with his pain" with pain in the left shoulder and mid back; difficulty sleeping and complains of constipation. Medications list Duragesic, Oxycodone, Xanax, and Suboxone. Exam only documented vitals without any other clinical findings or neurological exam. Treatment plan included medication refills and trial of Amitiza. The request(s) for Amitiza 24 mcg, # 60 with 3 refills was modified for #60 with 1 refill

and Suboxone 24 mcg 8 mg- 2mg SI film 8-2, # 60 with 3 refills was modified for #60 and 1 refill on 9/22/14 citing guidelines criteria and lack of medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 24 mcg, # 60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid-Initiating Therapy and Long-term users of Opioids Page(s): 77, 88.

Decision rationale: Amitiza (lubiprostone) is a chloride channel activator for oral use indicated for treatment of irritable bowel syndrome and chronic idiopathic constipation; however, the effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking opioids has not been established in clinical studies. The patient continues to treat for chronic symptoms for this chronic 2003 injury; however, reports have no notation regarding any subjective functional improvement from long term narcotics use especially not recommended per AME and was without any clinical findings related to GI side effects. Although chronic opioid use is not supported, Amitiza medication may be provided for constipation, a common side effect with opioid medications may be provided for short-term relief as long-term opioid use is supported. The patient was provided supplies with refills; however, has not shown efficacious benefit from its use. The submitted documents have not adequately addressed or demonstrated the indication of necessity for this medication over other failed trials of laxative or stool softeners. The Amitiza 24 mcg, # 60 with 3 refills is not medically necessary and appropriate.

Suboxone 24 mcg 8 mg- 2mg SI film 8-2, # 60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 26,27 and 78.

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

Decision rationale: Per the MTUS Guidelines cited, opioid use in the setting of chronic, non-malignant, or neuropathic pain is controversial. Patients on opioids should be routinely monitored for signs of impairment and use of opioids in patients with chronic pain should be reserved for those with improved functional outcomes attributable to their use, in the context of an overall approach to pain management that also includes non-opioid analgesics, adjuvant therapies, psychological support, and active treatments (e.g., exercise). Submitted documents show no evidence that the treating physician is prescribing opioids in accordance to change in pain relief, functional goals with demonstrated improvement in daily activities, decreased in medical utilization or change in work status. There is no evidence presented of random drug testing or utilization of pain contract to adequately monitor for narcotic safety, efficacy, and

compliance. The MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain. The Suboxone 24 mcg 8 mg- 2mg SI film 8-2, # 60 with 3 refills is not medically necessary and appropriate.