

Case Number:	CM14-0160049		
Date Assigned:	10/03/2014	Date of Injury:	09/14/2005
Decision Date:	12/26/2014	UR Denial Date:	08/25/2014
Priority:	Standard	Application Received:	09/29/2014

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 Occupational 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:

58-year-old male who has submitted a claim for lumbar postlaminectomy syndrome and lumbar radiculopathy associated with an industrial injury date of 9/14/2005. Medical records from 2014 were reviewed. The patient reported pain reduction with intake of Anaprox and tramadol. Intake of medications allowed him to work 5 to 6 hours per day. Back pain was rated 8-9/10 in severity, and relieved to 3-4/10 with medications. Pain radiated to the left calf area. Physical examination of the lumbar spine showed tenderness, muscle spasm, restricted motion, positive left FABER sign, and positive sacroiliac compression test. Straight leg raise test was positive on the left. Progress report from 5/20/2014 cited that Ketoprofen cream was started because of discontinuation of Anaprox tablet. Treatment to date has included laminectomy and discectomy, physical therapy, and medications such as Sentra AM, Sentra PM, Theramine (since April 2014), gabapentin, tramadol, Anaprox, Prilosec, Ketoprofen cream, and Sprix nasal spray (since May 2014). The utilization review from 8/25/2014 modified the request for tramadol ER 150mg, #90 into 10% quantity monthly reduction for the purpose of weaning because of no supporting evidence of objective functional benefit with medication use; denied Anaprox 500mg bid #60 because long-term use was not recommended; denied Ketoprofen cream 20% tid #2 because of limited published studies concerning its efficacy and safety; denied Sprix 1-2 sprays for breakthrough pain because of limited published studies concerning its efficacy and safety; denied Theramine tid #90, Sentra PM bid #60, and Sentra AM bid #60 because of no evidence of extenuating circumstances in the patient's case to warrant these medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg #90: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

Decision rationale: As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, the patient was prescribed tramadol since at least May 2014. Intake of medications allowed him to work 5 to 6 hours per day. Back pain was rated 8-9/10 in severity, and relieved to 3-4/10 with medications. The guideline criteria for continuing opioid management were met. Therefore, the request for tramadol ER 150mg #90 was medically necessary.

Anaprox 500mg bid #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 46.

Decision rationale: As stated on page 46 of the California MTUS Chronic Pain Medical Treatment guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. In this case, the patient was prescribed Anaprox since at least May 2014. Intake of medications allowed him to work 5 to 6 hours per day. Back pain was rated 8-9/10 in severity, and relieved to 3-4/10 with medications. However, progress report from 5/20/2014 cited that Ketoprofen cream was started because of discontinuation of Anaprox tablet. There is no clear rationale for resuming Anaprox tablet at this time. The medical necessity cannot be established due to insufficient information. Therefore, the request for Anaprox 500mg bid #60 is not medically necessary.

Ketoprofen cream 20% tid #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Ketoprofen is not recommended for topical use as there is a high incidence of photo contact dermatitis. In this case, topical cream is prescribed as adjuvant therapy to oral medications. Progress report from 5/20/2014 cited that Ketoprofen cream was started because of discontinuation of Anaprox tablet. However, the prescribed medication is not recommended for topical use. Therefore, the request for Ketoprofen cream 20% tid #2 is not medically necessary.

Sprix 1-2 sprays for break through pain: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: US Food and Drug Administration (Sprix)

Decision rationale: CA MTUS and ODG do not address the use of Sprix; however, the US Food and Drug Administration states that Sprix is indicated for short term (up to 5 days) management of moderate to moderately severe pain. In this case, the earliest progress reporting stating the patient's use of Sprix nasal spray is dated May 2014; which is beyond the duration of time recommended for use. Moreover, there are no documented functional gains derived from the use of this medication. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Sprix 1-2 sprays for break through pain is not medically necessary.

Theramine tid #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 Official Disability Guidelines (ODG) Pain Chapter, Sentra

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines, Pain section was used instead. ODG states that Theramine is a medical food that is a proprietary blend of GABA (gamma-aminobutyric acid) and choline bitartrate, L-arginine and L-serine that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. However, it remains not recommended by the guidelines. In this case, patient has been on Theramine since April 2014. However, this medication is not recommended

by the guidelines. There is no documented nutritional deficiency to corroborate use of this medication. Therefore, the request for Theramine tid #90 is not medically necessary.

Sentra PM bid #60: 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, Sentra

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline Bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra PM since March 2014. However, this medication is not recommended by the guidelines. There is no documented nutritional deficiency to corroborate use of this medication. Therefore, the request for Sentra PM bid, #60 is not medically necessary.

Sentra AM bid #60: 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, Sentra

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline Bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety

disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra AM since March 2014. However, this medication is not recommended by the guidelines. There is no documented nutritional deficiency to corroborate use of this medication. Therefore, the request for Sentra AM bid, #60 is not medically necessary.