

Case Number:	CM15-0165782		
Date Assigned:	09/04/2015	Date of Injury:	09/22/2011
Decision Date:	10/19/2015	UR Denial Date:	08/05/2015
Priority:	Standard	Application Received:	08/24/2015

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: New York

Certification(s)/Specialty: Anesthesiology

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 43 year old male injured worker suffered an industrial injury on 9-22-2011. The diagnoses included lumbar microdiscectomy and lumbar radiculopathy. The treatment included surgery and medication. On 5-27-2015 the treating provider reported constant low back pain radiating to the left lower extremity with numbness and tingling rated 9 out of 10. On exam the lumbar spine had restricted range of motion with tenderness and spasms along with positive left straight leg raise. It was not clear if the injured worker had returned to work. The requested treatments included Cyclobenzaprine, Norco, Terocin pain patch, Theramine, Colace, Sentra AM, Sentra PM, and Gabadone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine Hydrochloride 7.5mg Qty: 60: 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): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

Decision rationale: According to the reviewed literature, Cyclobenzaprine (Flexeril) is a skeletal muscle relaxant and a central nervous system (CNS) depressant. It is closely related to the tricyclic antidepressants. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than non-steroidal anti-inflammatory medications alone. Cyclobenzaprine is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. Guidelines state that this medication is not recommended to be used for longer than 2-3 weeks. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. The requested treatment is not medically necessary.

Norco 7.5/325 Qty: 60: 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): Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

Decision rationale: According to the CA MTUS and ODG, Norco 10/325mg (Hydrocodone/Acetaminophen) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is insufficient evidence that the opioids were prescribed according to the CA MTUS guidelines, which recommend prescribing according to function, with specific functional goals, return to work, random drug testing, an opioid contract, and documentation of a prior failure of non-opioid therapy. There is no documentation of significant pain relief or increased function from the opioids used to date. Medical necessity of the requested medication has not been established. Of note, discontinuation of an opioid analgesic should include a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

Terocin pain patch Qty: 30: 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 rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are

compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

Theramine Qty: 180: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Integrated Treatment/ Disability Duration Guidelines Pain (Chronic) (updated July 2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food, Theramine.

Decision rationale: According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Colace 100mg Qty: 120: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

Decision rationale: Opioid-induced constipation is a common adverse effect of long-term opioid use because of the binding of opioids to peripheral opioid receptors in the gastrointestinal tract, resulting in absorption of electrolytes and reduction in small intestine fluid. According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. In this case, there is no documentation of constipation and the requested opioid medication, Norco, has been denied. The medical necessity of Colace has not been established. The requested medication is not medically necessary.

Sentra AM Qty: 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food, Medscape Internal medicine 2014: Sentra AM.

Decision rationale: Sentra AM is a Medical Food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness and memory. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

Sentra PM Qty: 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food, Medscape Internal Medicine 2014: Sentra PM.

Decision rationale: Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

Gabadone Qty: 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food and Other Medical Treatment Guidelines Medscape Internal Medicine (2014).

Decision rationale: Gabadone is a Medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG guidelines do not support the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item was not established. The requested medical food is not medically necessary.