

<b>Case Number:</b>	CM13-0037323		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	01/02/1995
<b>Decision Date:</b>	02/10/2014	<b>UR Denial Date:</b>	09/17/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation 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 physician 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 [REDACTED] employee filed a claim for chronic neck pain, depression, hypertension, ischemic colitis, muscle spasms, shoulder pain, and depression reportedly associated with an industrial injury of 01/02/95. She was treated with analgesic medications; transfer of care to and from various providers and various specialties; prior cervical fusion surgery in 1997 and 2003; topical compounds, blood pressure lowering medications; and the apparent imposition of permanent work restrictions through an Agreed Medical Evaluation. Claimant's restrictions was not accommodated or has returned to work due to 08/20/13 OV noted notable for comments that the claimant reports persistent multi focal 4/10 neck, back, and bilateral arm pain. The claimant has reportedly had previous adverse reactions to Morphine and Exalgo. Currently on baclofen, Cymbalta, Doxepin, Donnatal, Hydrochlorothiazide, topical compounds, Zestril, Lopressor, Norco, Ativan, Soma, and lmitrex. She is somewhat overweight with a BMI of 31. She exhibits a normal cardiopulmonary exam with diffuse abdominal tenderness, decreased cervical range of motion, and a positive Spurling maneuver. Recommendations are made for the claimant to employ Butrans, discontinue baclofen, and employ Prozac and Cymbalta for pain relief. At issue is the request for donnatal, soma, and Ativan.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Donnatal #60 Modified and approved to Donnato #30 for weaning: Overturned**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation DailyMed, an online drug information resource offered by National Institute of Health

**Decision rationale:** CA-MTUS(Effective July 18, 2009) is mute on this subject. According to DailyMed online drug information resource offered by National Institute of Health, Donnatal<sup>®</sup> Elixir - Mint: Each 5 mL (teaspoonful) of elixir (alcohol not more than 23.8%) contains: Phenobarbital, USP/16.2 mg; Hyoscyamine Sulfate, USP/0.1037 mg; Atropine Sulfate, USP/0.0194 mg and Scopolamine Hydrobromide, USP/0.0065 mg INACTIVE

**INGREDIENTS:** Ethyl Alcohol, Glycerin, Purified Water, Saccharin Sodium, Sorbitol, Sucrose, Natural Mint Flavor, FD & C Yellow #5, FD & C Blue #1 and FD&C Red #40. **CLINICAL PHARMACOLOGY:** This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation. **INDICATIONS AND USAGE:** Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the following indications as "possibly" effective: For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. May also be useful as adjunctive therapy in the treatment of duodenal ulcer. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS. **CONTRAINDICATIONS:** Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis. Donnatal<sup>®</sup> Elixir is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom Phenobarbital produces restlessness and/or excitement. **WARNINGS:** In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful. Donnatal<sup>®</sup> Elixir may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work. Phenobarbital may decrease the effect of anticoagulants, and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decrea

**Soma 350mg, #30 Modified and approved to Soma 350mg #15 for weaning:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 29.

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 124 of 127 section on Weaning: Carisoprodol (Soma®): This medication is metabolized to meprobamate, a barbiturate. At the highest levels of barbiturate tolerance, the patient is at risk of delirium, seizures or even death with abrupt discontinuation. There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) (Heacock, 2004) (Washington, 2002) See also Detoxification; & Rapid detox. Therefore the request for Soma 350mg, #30 Modified and approved to Soma 350mg #15 for weaning is medically necessary.

**Lorazepam .5mg, #60 Modified and approved to Lorazepam .5mg #30 for weaning:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 124.

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 124 of 127 section on Weaning: Benzodiazepine: Tapering is required if used for greater than 2 weeks. (Benzon, 2005) (Ashton, 2005) (Kahan, 2006) This is more dangerous than opioid withdrawal, and takes more time, with the following recommendations: (1) The recommended rate of tapering is about 1/8 to 1/10 of the daily dose every 1 to 2 weeks; (2) Rate of withdrawal should be individually tapered; (3) Tapering may take as long as a year; (4) High-dose abusers or those with polydrug abuse may need in-patient detoxification; & (5) Withdrawal can occur when a chronic user switches to a benzodiazepine with a different receptor activity. (Lee, 2002). Based on the foregoing, the request for Lorazepam .5mg, #60 Modified and approved to Lorazepam .5mg #30 for weaning, is medically necessary.

**Baleen 10mg, #90 Modified and approved to Baleen 10mg, 30 for weaning:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 124 of 127 section on Weaning: Baleen (L'Oreal<sup>®</sup>, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baleen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment. Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to maximum dose of 80 mg a day. (See, 2008). Therefore the request of Baleen 10mg, #90 Modified and approved to Baleen 10mg, 30 for weaning is medically necessary.