

<b>Case Number:</b>	CM15-0122066		
<b>Date Assigned:</b>	07/06/2015	<b>Date of Injury:</b>	08/15/1991
<b>Decision Date:</b>	08/04/2015	<b>UR Denial Date:</b>	06/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/24/2015

### 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: California  
 Certification(s)/Specialty: Emergency Medicine

### 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 is a 66 year old male with an August 15, 1991 date of injury. A progress note dated June 2, 2015 documents subjective complaints (left greater than right bilateral upper extremity pain; difficulty sleeping due to pain; increased symptoms with weather fluctuations; average pain since last visit was 7/10), objective findings (symptoms consistent with complex regional pain syndrome; no new neurological deficits noted), and current diagnoses (left greater than right upper extremity complex regional pain syndrome; status post ulnar nerve transposition in the left; status post bilateral carpal tunnel release; poor sleep hygiene; deconditioning and withdrawal of left upper extremity; left knee pain, status post recent arthroscopy). Treatments to date have included medications, surgeries, magnetic resonance imaging of the cervical spine that showed small disc lesions; normal electromyogram/nerve conduction studies, and activity as tolerated. The medical record indicates that medications are not helping much at this time. The treating physician documented a plan of care that included PC5001 cream (Flurbiprofen 20%, Baclofen 2%, Cyclobenzaprine 2%, Gabapentin 6%, Lidocaine 5%) and Belsomra.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**PC5001 cream (Flurbiprofen 20%, Baclofen 2%, Cyclobenzaprine 2%, Gabapentin 6%, Lidocaine 5%) qty 1.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical NSAIDs/analgesics Page(s): 111.

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

**Decision rationale:** As per MTUS guidelines "Any compound product that contains a drug or drug class that is not recommended is not recommended". 1) Flurbiprofen: Topical NSAIDs are shown to be superior to placebo. It should not be used long term. It may be useful. Flurbiprofen is not FDA approved for topical application. There is no justification by the provider as to why the patient requires a non-FDA approved compounded NSAID when there are multiple other approved products including over the counter medications on the market. Flurbiprofen is not medically necessary. 2) Baclofen is not FDA approved for topical use. It is not recommended. There is no evidence for efficacy as a topical product. 3) Cyclobenzaprine is not FDA approved for topical use. It is not recommended. There is no evidence for efficacy as a topical product. 4) Gabapentin is not FDA approved for topical use. It is not recommended. There is no evidence for efficacy as a topical product. 5) Lidocaine: Topical lidocaine is recommended for post-herpetic neuralgia only although it may be considered as off-label use as a second line agent for peripheral neuropathic pain. It may be considered for peripheral neuropathic pain only after a trial of 1st line agent. Patient has no documented medication failure. Not recommended. This non-evidence based compounded product contains multiple non-FDA approved applications of various medications leading to significant risk of medication interactions and toxicity. This compounded cream is not medically necessary

**Belsomra 10mg Qty 30.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC, Mental Illness & Stress, Suvorexant (Belsomra).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain(Chronic), Insomnia Treatment; Mental; Suvorexant (Belsomra).

**Decision rationale:** There is no specific sections in the MTUS chronic pain or ACOEM guidelines that relate to this topic. Ambien is a benzodiazepine agonist approved for insomnia. As per ODG guidelines, it recommends treatment of underlying cause of sleep disturbance and recommend short course of treatment. Long-term use may lead to dependency. There is no documentation of other conservative attempts at treatment of sleep disturbance or sleep studies. Provider documents source of patient's insomnia is pain. ODG specifically does not recommend Belsomra as a first line agent. The lack of conservative treatment and lack of 1st line treatment does not support treatment with a 2nd line, new generation medication with limited data to support safety or efficacy. Belsomra is not medically necessary.

