

<b>Case Number:</b>	CM15-0177156		
<b>Date Assigned:</b>	09/17/2015	<b>Date of Injury:</b>	02/25/2009
<b>Decision Date:</b>	11/10/2015	<b>UR Denial Date:</b>	08/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2015

### 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: Preventive Medicine, Occupational 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:

The injured worker is a 56 year old male with an industrial injury dated 02-05-2009. Review of medical records indicates he is being treated for cervicgia, lumbar sprain, spasm of muscle, myalgia and myositis unspecified, myofascial pain syndrome, fibromyalgia, sprains and strains of shoulder and upper arm, anxiety and depression. The progress note dated 07-21-2015 notes the injured worker is complaining of left shoulder and back pain, neck and right shoulder pain. The pain rating is documented as 7 out of 10 (07-31-2015), maximum as 10 out of 10 and minimum as 6 out of 10. Prior rating of pain in the 05-26-2015 progress note was 6 out of 10. The provider documents the effects of pain as "cannot work, cannot clean home, and can't move the trash outside." "Has trouble falling asleep 1-2 times per week." The provider documents: "With medications he is able to move around the house, walk and do his activities of daily living. Without the medications, (he) cannot walk or do his activities of daily living." "Given his current condition, I doubt he will be able to find gainful employment." "Permanent work restrictions" was documented. His medications include Lyrica, Norco, Docuprene, Flexeril, Prilosec, Fenopofen, Lidoderm (Terocin) patches, Exoten C lotion and Theramine and Sentra. He has been taking Norco and Theramine at least since 08-19-2014, Terocin patches at least since 12-2014 and Exoten C Lotion since at least 04-28-2015. The provider documented regarding Exoten C: "Patient says that cream helps get to area where med does not cover area of allodynia." Physical exam is documented as "diffuse neck and back pain." Other findings are documented as bilateral tenderness and spasms of the cervical paraspinal and trapezius muscles and lumbar paraspinal. Range of motion of the lumbar and cervical spine is documented as

"decreased." The provider documents "He is at low risk for opioid abuse-aberrant behavior per opioid risk tool." The last urine screen is documented as being done on 01-06-2015. The request for authorization dated 08-20-2015 is for: Theramine #90; Terocin patches #30; Norco 5 mg, #60; Exoten C lotion x 2; On 08-28-2015 the request for the medications listed below was non-certified by utilization review: Theramine #90; Terocin patches #30; Norco 5 mg, #60; Exoten C lotion x 2.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Terocin patches #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, compounds containing lidocaine are not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. In addition, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Terocin patches #30 is not medically necessary.

#### **Exoten C lotion x2: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The active ingredients of Exoten C lotion are menthol 4% and lidocaine 4% and is classified as a topical analgesic. The MTUS does not recommend topical analgesics unless trials of antidepressants and anticonvulsants have failed. The medical record does not document failed attempts to alleviate the patient's pain with either antidepressants or anticonvulsants. Exoten C lotion x2 are not medically necessary.

#### **Theramine #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 (Chronic), Medical food.

**Decision rationale:** Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Theramine #90 is not medically necessary.

**Norco 5mg, #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines state that continued or long-term use of opioids should be based on documented pain relief and functional improvement or improved quality of life. Despite the long-term use of Norco, the patient has reported very little, if any, functional improvement or pain relief over the course of the last 6 months. Norco 5mg, #60 is not medically necessary.