

<b>Case Number:</b>	CM15-0030692		
<b>Date Assigned:</b>	02/25/2015	<b>Date of Injury:</b>	04/03/2013
<b>Decision Date:</b>	04/08/2015	<b>UR Denial Date:</b>	02/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/19/2015

### 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: Internal 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 47 year old female, who sustained a work/ industrial injury on 4/3/13 as a strawberry picker. She has reported symptoms of lumbar spine pain, left lower extremity numbness, and cervical pain with numbness and tingling. Pain was 10/10 without medication and 8-9/10 with medication. Prior medical history included arthritis, migraine, and depression. The diagnoses have included sacroiliitis, pain in joint, pelvis region and thigh and degenerative lumbar lumbosacral intervertebral disc. Treatments to date included medication, physical therapy, acupuncture, chiropractic care, epidural steroid injections, Transcutaneous Electrical Nerve Stimulation (TENS) unit. Diagnostics included a Magnetic Resonance Imaging (MRI) dated 5/2013 that noted disc protrusions at L3-4 and bulges at L4-5 and L5-S1. Medications included Percocet, Amitriptyline, Benadryl, Pinnacle compounding cream, and Gabapentin. Examination noted tenderness over the paraspinal muscles of the lumbar spine with a positive left sided straight leg raise. There was decreased strength in the left/right lower extremities. The treating physician requested a Pinnacle compounding cream. On 2/18/15, Utilization Review non-certified a Pinnacle compounding cream, noting the California Medical treatment Utilization Schedule (MTUS) Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pinnacle compounding cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs and is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Pinnacle compounding cream was requested. The active ingredients were not specified. The components of the Pinnacle compounding cream were not documented. The request for a compounding cream, with unknown ingredients, cannot be endorsed. ODG guidelines require that compound products include at least one drug substance, or active ingredient, that is the sole active ingredient in an FDA-approved prescription drug. Topical analgesics in general are not supported by MTUS guidelines. Therefore, the request for Pinnacle compounding cream is not medically necessary.