

<b>Case Number:</b>	CM14-0128463		
<b>Date Assigned:</b>	10/08/2014	<b>Date of Injury:</b>	04/03/2006
<b>Decision Date:</b>	11/17/2014	<b>UR Denial Date:</b>	07/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/11/2014

### 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. The expert reviewer is Board Certified in Occupational Medicine 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 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/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:

Patient is a 51 year-old male with date of injury 04/03/2006. The medical document associated with the request for authorization, a primary treating physician's progress report, dated 06/20/2014, lists subjective complaints as insomnia and acid reflux. Objective findings: No physical examination was documented on the PR-2. Diagnosis: 1. Diabetes mellitus, industrial aggravation 2. Gastroesophageal reflux disease, secondary to NSAIDs 3. Gastric ulcer, secondary to NSAIDs 4. Hypertension, industrial aggravation 5. Irritable bowel syndrome 6. Sleep disorder 7. Erectile dysfunction. The medical records supplied for review document that the patient has been taking the following medications for at least as far back as the dated provided below. Medications: 1. Androgel Pump 1.62% (taking for at least three months) 2. Topical Cream (Flurbiprofen 20%, Tramadol 20%) (prescribed 06/20/2014) 3. Topical Cream (Gabapentin 10%, Amitriptyline 10%, Dexamethasone 10%) (prescribed 06/20/2014) 4. Hypertensa, #60 (taking for at least three months).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Androgel Pump 1.62 Percent 2 Refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement for Hypogonadism (Related to Opioids) Pag.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 110-111.

**Decision rationale:** The MTUS recommends testosterone replacement for hypogonadism in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. There is no documentation of hypogonadism related to long-term high dose opioid use. Androgel Pump 1.62 Percent 2 Refills is not medically necessary.

**Topical Cream 210 Gram (Flurbiprofen 20 Percent, Tramadol 20 Percent):** 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 Page(s): 111.

**Decision rationale:** According to the MTUS, 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. The use of tramadol and a compounded topical formulations is not supported by the Guides. Topical Cream 210 Gram (Flurbiprofen 20 Percent, Tramadol 20 Percent) is not medically necessary.

**Topical Cream 210 Gram (Gabapentin 10 Percent, Amitriptyline 10 Percent, Dexamethasone 10 Percent):** 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 Page(s): 111-113.

**Decision rationale:** According to the MTUS, 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. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Topical Cream 210 Gram (Gabapentin 10 Percent, Amitriptyline 10 Percent, Dexamethasone 10 Percent) is not medically necessary.

**Hypertensa #60 3 Bottles:** Overturned

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

**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:** Hypertensa is considered a medical food. 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. The request is medically necessary.