MAXIMUS Federal Services

| Case Number: | CM14-0119577 | | |
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| Date Assigned: | 08/06/2014 | Date of Injury: | 06/08/2012 |
| Decision Date: | 09/11/2014 | UR Denial Date: | 07/10/2014 |
| Priority: | Standard | Application Received: | 07/30/2014 |

## 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 Anesthesiology, has a subspecialty in pain 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:

The injured worker is a 55 year old male who sustained an injury on 01/20/14 while using a backhoe. Assemblage fell striking the injured worker in the head which resulted in a scalp laceration requiring staples. The injured worker was seen on 12/17/13 for continuing complaints of pain in the bilateral lower extremities arms neck feet and head. He was reported to have out of control blood sugar levels. Pain was reported as severe 10/10 without medications and 6 to 8/10 with. He was utilizing multiple medications including Norco, Lyrica, Ketoflex ointment, Cidaflex, Elavil, and Anaprox a natural Gaia herb laxative. There were recommendations for MRI. The requested Trepadone, Theramine, Fluriflex ointment, Anaprox 550 milligrams Gaia herbs and Fentanyl 75 microgram patch quantity ten were denied by utilization review on 07/10/14.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Trepadone #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines offers the definition of a medical food as put forth in section 5(b)of the Orphan Drug Act(21 U.s.c.360ee (b) (3)): "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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder , disease, or condition for which there are distinctive nutritional requirements; and (3) the product must be used under medical supervision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food.

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. In regards to the request for Trepadone quantity 120, given the paucity of current clinical information available for this injured worker, this request is deemed not medically necessary.

**Theramine #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Consulted evidence based guidelines state that medical foods are foods that are 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. Theramine is a proprietary blend of gamma-aminobutyric acid (GABA) and choline bitartrate, L-arginine and L-serine. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food.

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. In regards to the request for Theramine quantity 120, given the paucity of current clinical information available for this injured worker this request is deemed not medically necessary.

**Fluriflex ointment 240gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product.... Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) Topical Analgesics, Compounded.

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

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. Given the paucity of current clinical information available for this injured worker to support the medication, this request for Fluriflex ointment 240gm is deemed not medically necessary.

**Anaprox 550mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Naproxen is a nonsteroidal anti-inflammatory drug(NSAID) for the relief of the signs and symptoms of osteoarthritis. Decision based on Non-MTUS Citation ( U. S . Boxed Warning): for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68.

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. Given the paucity of current clinical information available for the injured worker to support the medication request, the request for Anaprox 550 milligrams quantity of sixty is deemed not medically necessary.

**Fentanyl 75mcg #10:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl is an opioid analgesic with a potency eight times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criterial for Use Page(s): 88-89.

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. Given the paucity of current clinical information available for this injured worker to support the medication request, Fentanyl 75mcg #10 is deemed not medically necessary.

**Gaia Herbs:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Gaia Herbs - Caution is advised since product quality may be uncertain due to the lack of regulations. Short-term treatments with certain herbal medicines (including Devil's claw and willow bark) are effective for relief of acute low back pain, according to the results of a Cochrane review reported in the January 2007 issue of Spine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Foods.

**Decision rationale:** The injured worker utilized medical foods in the past. Otherwise there was no updated clinical information regarding the current clinical condition of this injured worker or requirements for this requested medication. No specific rationale was available for review. In regards to the request for Gaia herbs, given the paucity of current clinical information available for this injured worker, this request is deemed not medically necessary.