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| Case Number: | CM14-0194849 | | |
| Date Assigned: | 12/02/2014 | Date of Injury: | 10/02/2002 |
| Decision Date: | 02/19/2015 | UR Denial Date: | 11/17/2014 |
| Priority: | Standard | Application Received: | 11/20/2014 |

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. 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 patient is an injured worker with a history of neck, back, and shoulder conditions. The patient was injured on 10/02/2002 due to motor vehicular accident. The patient was diagnosed with lumbago, cervicalgia, cervical and lumbar intervertebral disc displacement, lumbosacral neuritis radiculitis, and cervicocranial syndrome. The patient previously underwent left shoulder arthroscopy, subacromial decompression, distal clavicle resection/repair, and debridement of the humeral head and labrum on 7/11/05; and right shoulder arthroscopy, subacromial decompression, distal clavicle resection/repair, and debridement of the humeral head and labrum on 1/9/06. The most recent testosterone laboratory test was dated August 12, 2013 and demonstrated that free testosterone was 34 pg/mL with a normal range of 35 - 155. The progress report dated 11/10/2014 documented a history of work related injury. He has been able to return to the workforce. He has been back at work for approximately two years. He was involved in a motor vehicle accident. He had headaches. He had neck pain with sharp shooting pains toward the right here which were then mirrored on the left side. He had low back pain. He reports that he has had diffuse low back pain in the lumbar region with a warm sensation into the right lateral thigh. Since the motor vehicle accident he has had increase in intensity of his typical low back pain with new sharp, shooting pain with a deep ache in the lateral aspect of the right thigh and completely new similar complaints in the medial thigh to the groin on the right. He has been walking with a limp but denies any focal weakness. He denies any bowel or bladder dysfunction. Medications included Testosterone, Valium, Soma, Ambien, and Norco 10/325. Diagnoses were lumbago, displacement of lumbar intervertebral disc, cervicalgia, displacement of cervical

intervertebral disc, pain in thoracic spine, lumbosacral neuritis radiculitis, spasm of muscle, cervicocranial syndrome, headache, and hypogonadism. Utilization review determination date was November 17, 2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 tube of compounded Testosterone, Thony and Verabase Cream 30 grams: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110-111. 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 (Page 110-111) states that testosterone replacement for hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. 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. 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. The most recent testosterone laboratory test was dated August 12, 2013 which is over one year before the request for authorization date November 4, 2014. Free testosterone was 34 pg/mL with a normal range of 35 - 155. No PSA prostate specific antigen was documented. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should not be a copy of a commercially available FDA-approved drug product. Testosterone is a commercially available FDA-approved drug. AndroGel is a FDA-approved topical testosterone product. Therefore, a compounded Testosterone cream is a copy of the commercially available FDA-approved drug topical testosterone product AndroGel. The request for compounded Testosterone cream is not supported by MTUS or ODG guidelines. Therefore, the request for 1 tube of compounded Testosterone, Thony and Verabase Cream 30 grams is not medically necessary.

