

Case Number:	CM15-0166252		
Date Assigned:	09/29/2015	Date of Injury:	09/07/2010
Decision Date:	12/07/2015	UR Denial Date:	08/04/2015
Priority:	Standard	Application Received:	08/24/2015

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 55 year old female who sustained an industrial injury September 7, 2010. According to a secondary treating physician's progress report dated June 25, 2015, the injured worker presented for evaluation with complaints of acid reflux for the past three weeks. She reported sleeping 6 hours nightly due to pain and anxiety. She did not bring her glucose monitor but reported her average fasting blood glucose at home is 100mg-dL. She reported unchanged shortness of breath, unchanged chest pain, and unchanged diabetes mellitus. Physical examination revealed; blood pressure 122-109, heart rate 77; 5'1" and 210 pounds; lungs are clear to auscultation; regular heart rate and rhythm without rubs, murmurs or gallops; abdomen is soft with normoactive bowel sounds, no distention, guarding, or tenderness to palpation, unable to assess hepatosplenomegaly; extremities, no edema. The physician noted no other significant findings on physical examination. Diagnoses are constipation-diarrhea, rule out irritable bowel syndrome; gastritis per EGD report (report not present in the record); weight gain, unsubstantiated at this time; sleep disorder, rule out obstructive sleep apnea; diabetes mellitus. Treatment plan included urine toxicology performed (report present in the medical record), labs pending, body composition study performed (report present in the medical record), and to continue to follow a low fat, low acid diet. At issue, is a request for authorization for body composition study, sudoscan, AppTrim, and Xenical. According to utilization review dated August 4, 2015, the request for Metformin 500mg #60 with 2 refills and Victoza 1.2mg with 2 refills are certified. The request for (1) prescription for AppTrim #120 3 bottles, (1) sudoscan, (1) body composition study, and (1) prescription for Xenical 120mg #90 with 2 refills are non-

certified. The prospective requests for Dexilant, Gaviscon, Simethicone, Probiotics, and urine toxicology are conditionally non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription for Appttrim #120 3 bottles: 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: Appttrim is 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 medical documents provided do not clearly specify the disease or condition for which the requested distinctive nutritional ingredient is intended to treat, nor is there evidence that testing of the nutritional ingredient using recognized scientific principles has been completed. One prescription for Appttrim #120 3 bottles is not medically necessary.

1 Sudoscan: 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 Blue Cross and Blue Shield Association Corporate Medical Policy Subject: Autonomic Testing Policy #: MED. 00112 Current Effective Date: 10/14/2014 Status: Revised Last Review Date: 08/14/2014.

Decision rationale: According to the MTUS, for all conditions or injuries not addressed in the MTUS, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community pursuant to section 9792.25(b). The MTUS and Official Disability Guidelines are silent regarding autonomic nervous system function testing device, the SudoScan; consequently, the Blue Cross and Blue Shield Association Corporate Medical Policy regarding Autonomic Testing was referenced. The policy states: The use of autonomic nervous system function testing for sudomotor function using quantitative sudomotor axon reflex test (QSART), the

thermoregulatory sweat test (TST), silastic sweat imprint, sympathetic skin response (SSR), quantitative direct and indirect reflex test of sudomotor function (QDIRT), or SudoScan are considered investigational and not medically necessary for all indications. The use of autonomic nervous system function testing for cardiovagal innervations is considered investigational and not medically necessary for all indications. The use of autonomic nervous system function testing for vasomotor adrenergic innervations is considered investigational and not medically necessary for all indications. 1 SudoScan is not medically necessary.

1 Body Composition Study: 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 Blue Cross Medical Coverage Guidelines Bioelectrical Impedance Analysis to Determine Body Composition Effective Date: 05/13/2014.

Decision rationale: The medical record states that the patient underwent a body composition evaluation with an RJL Systems portable bioelectrical impedance analyzer. According to the MTUS, for all conditions or injuries not addressed in the MTUS, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community pursuant to section 9792.25(b). The MTUS and Official Disability Guidelines are silent on the issue of body composition analysis. Alternative guidelines were referenced from Blue Cross. According to Blue Cross Medical Coverage Guidelines, Bioelectrical Impedance Analysis to Determine Body Composition, Bioelectrical impedance analysis to determine whole body composition is considered experimental or investigational based upon: 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and 2. Insufficient evidence to support improvement of the net health outcome, and 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and 4. Insufficient evidence to support improvement outside the investigational setting. The above Guidelines state that insufficient evidence exists to support the use of Bioelectrical Impedance Analysis to determine body composition outside the investigational setting. The treating physician does not provide documentation of extenuating circumstances which would substantiate deviating from the Guidelines. Body Composition Study is not medically necessary.

1 prescription for Xenical 120mg #90 with 2 refills: 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 Aetna Clinical Policy Bulletin: Weight Reduction Medications and Programs, Number: 0039, last reviewed: 03/21/2014.

Decision rationale: The MTUS and the Official Disability Guidelines are silent on the topic of Xenical. The Aetna Clinical Policy Bulletin: Weight Reduction Medications and Programs was referenced in regard to the request. This policy is supported by NHLBI Guidelines on Diagnosis and Management of Obesity. Weight reduction medications are considered medically necessary for members who have failed to lose at least one pound per week after at least 6 months on a weight loss regimen that includes a low calorie diet, increased physical activity, and behavioral therapy. Other criteria are also listed, but the medical record fails to document the above steps, which are the minimum for authorization of weight loss medications. 1 prescription for Xenical 120mg #90 with 2 refills is not medically necessary.