

Case Number:	CM14-0075076		
Date Assigned:	07/16/2014	Date of Injury:	02/25/2005
Decision Date:	09/22/2014	UR Denial Date:	05/01/2014
Priority:	Standard	Application Received:	05/22/2014

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 Family 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 patient is a 57 year old woman who was injured at work on 2/25/2005. She is requesting review of denial for the following medications: Aspirin (ASA) 81 mg/tablet; one tablet once a day and Hypertensa #60 (2 bottles). The medical records include the Primary and Secondary Treating Physician's Progress Reports (PR-2s). These indicate that the patient has the following Industrial Related Diagnoses: Hypertension, Triggered by Work-Related Injury; Obesity; and Hyperlipidemia. The patient's other diagnoses include: Orthopedic Complaints; Psychiatric Complaints; Gastrointestinal Diagnosis; and Sleep Disorder. Her medications include: Hydrochlorothiazide, Amlodipine, Atenolol, Simvastatin, Aspirin, and Hypertensa. The patient did have a work-up for chest pain with a Lexiscan Stress Test, which was negative for ischemia. It was stated that "there is no evidence that the patient's symptoms are cardiac in nature."

IMR ISSUES, DECISIONS AND RATIONALES

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

Aspirin (ASA) 81mg/tab; 1 tab once a day #45 no refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain Chapter; Aspirin.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical

Evidence: The US Preventive Services Task Force:
<http://www.uspreventiveservicestaskforce.org/uspstf09/aspirincvd/aspcvdrs.htm>.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) American College of Occupational and Environmental Medicine (ACOEM), the Chronic Pain Medical Treatment Guidelines, and the Official Disability Guidelines (ODG) do not comment on the use of aspirin for cardiovascular risk reduction. The US Preventive Services Task Force (referenced above) does provide a Recommendation Statement on the use of Aspirin for the Prevention of Cardiovascular Disease. The summary of recommendations states the following: "The Preventive Services Task Force (USPSTF) recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. In the assessment of risk for gastrointestinal bleeding, the guidelines state that "other risk factors for bleeding include upper gastrointestinal tract pain, gastrointestinal ulcers, and NSAID use." The medical records state that the patient has a "gastrointestinal diagnosis." There is no further description as to the nature of the patient's gastrointestinal disorder. It appears that the patient is pending referral to a GI specialist for further evaluation. Therefore, it is unclear whether the patient meets the USPSTF recommendations for aspirin use and whether the gastrointestinal problem places her at risk of potential harm of a hemorrhage. For this reason the request for aspirin is not considered medically necessary at this time.

Hypertensa #60 2 bottles: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain Chapter; Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Cited below.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) American College of Occupational and Environmental Medicine (ACOEM), Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines do not comment on the use of this agent for the treatment of a disease. A search of www.guidelines.gov does not contain any information on the use of this agent for the treatment of a disease. A search of Pubmed does not contain any information on the use of this agent for the treatment of a disease. The Natural Standard, a reference source for integrative medicine, does not contain any information on the use of this agent for the treatment of a disease. A search of the internet provided the following packet insert for Hypertensa: Hypertensa is classified as a medical food and contains the following ingredients: Hypertensa is a proprietary formulation of amino acids and other dietary factors to support induction, maintenance, and enhancement of the specific neurotransmitter activity involved in the physiology of HT. The formulation consists of nonessential and essential amino acids, L-Arginine HCL, Choline Bitartrate, Whey Protein Isolate (Milk), Cocoa Extract, Cinnamon, Ginseng, L-Leucine, L-Glutamine, L-Histidine HCL, Caffeine, L-Cysteine, and Grape Seed Extract. These ingredients fall into the classification of Generally Recognized as

Safe (GRAS) as defined by the Food and Drug Administration (FDA) (Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). A GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use. The standard for an ingredient to achieve GRAS status requires not only technical demonstration of non-toxicity and safety, but also general recognition of safety through widespread usage and agreement of that safety by experts in the field. Many ingredients have been determined by the FDA to be GRAS, and are listed as such by regulation, in Volume 21 Code of Federal Regulations (CFR) Sections 182, 184, and 186. The medical records indicate that this patient is on a combination of three different medications for treatment of her hypertension; amlodipine, atenolol, and hydrochlorothiazide. The blood pressure readings in the medical records (e.g. 121/77 and 131/71) are within the treatment goals outlined by the Joint National Committee (JNC8) recommendations. Based on the absence of information to support the use of Hypertensa and the evidence in the medical records indicating the patient's blood pressure control on three different antihypertensive agents is well within national consensus guidelines, Hypertensa is not considered as a medically necessary treatment.