MAXIMUS Federal Services

| Case Number: | CM14-0013064 | | |
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| Date Assigned: | 02/24/2014 | Date of Injury: | 04/20/2009 |
| Decision Date: | 08/07/2014 | UR Denial Date: | 01/07/2014 |
| Priority: | Standard | Application Received: | 01/31/2014 |

## 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 Internal 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:

This is a 73-year-old male with a 4/20/09 date of injury. The mechanism of injury was not noted. In a 11/1/13 progress note, the patient complained of blurred vision for the past four months, has bilateral cataracts, and is scheduled for surgery. The patient also complained that his knees were painful. Physical exam findings showed that the patient was positive for joint pain, he had poor balance, and was positive for memory loss. The diagnostic impression include stroke, sleep apnea, hypertension, coronary artery disease, hypogonadism male, erectile dysfunction, atrial fibrillation, traumatic brain injury, osteoarthritis, hyperlipidemia, overweight, history of prostatectomy, prostate cancer, bilateral cataracts. The treatment to date: medication management, activity modification, physical therapy, aquatic therapy. A utilization review decision dated 1/7/14 denied the request for Provigil and modified the request for Pradaxa to 60 tablets. Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work disorder. In this case, although the patient had been diagnosed with obstructive sleep apnea (OSA) in the past, there are no reports describing the patient's symptoms or continued benefit with use of Provigil. Regarding Pradaxa, it is recommended as an anti-coagulation treatment option for patients with venous thromboembolisms (VTEs) of the leg. Although the patient does not currently present with symptoms or physical examination findings of atrial fibrillation, patients who have chronic atrial fibrillation require chronic anti-coagulation to prevent thromboembolic complications.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Provigil 200mg, #180:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Food and Drug Administration (FDA), Provigil.

**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: Food and Drug Administration (FDA), Provigil.

**Decision rationale:** The Food and Drug Administration (FDA) states that Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work disorder. It is documented in a 12/20/13 progress note that the patient has sleep apnea requiring a continuous positive airway pressure therapy (CPAP). The patient has severe day-time lethargy, somnolence, as well as episodes of narcolepsy. However, the maximum recommended dose of Provigil is 200mg a day and this is a request for 180 tablets, which would be a 6-month supply. An ongoing evaluation of the patient's necessity for and tolerance to the medication is necessary for further certification of the medication. There is no rationale as to why a 6-month supply of this medication would be necessary. Therefore, the request for Provigil 200mg, #180 is not medically necessary.

**Pradaxa 150mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee and Leg, Pradaxa and Venous Thrombosis.

**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: http://www.drugs.com/pro/pradaxa.html.

**Decision rationale:** The CA MTUS and Official Disability Guidelines (ODG) do not address this issue. An online search found that Pradaxa is an oral anticoagulant indicated for the reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation, treatment of Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE), reduction in the risk of recurrence of DVT and PE. In a 12/20/13 progress note, the physician states that the patient is taking Pradaxa to prevent stroke. The patient is at high risk for stroke because of underlying atrial fibrillation. His atrial fibrillation is related to his underlying hypertensive heart disease. However, there is no quantity noted in this request for Pradaxa. In addition, the quantity was not noted in the reports reviewed. Therefore, the request for Pradaxa 150mg is not medically necessary.