

Case Number:	CM15-0012667		
Date Assigned:	01/30/2015	Date of Injury:	03/14/2001
Decision Date:	03/23/2015	UR Denial Date:	12/19/2014
Priority:	Standard	Application Received:	01/22/2015

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: Family Practice

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 46-year-old man reported an industrial left knee injury dated 3/14/01. Although the available records are somewhat scanty, it appears that he subsequently developed bilateral lower extremity deep vein thromboses followed by post-phlebotic syndrome on the left. Current diagnoses include chronic pain syndrome, diabetes mellitus, atherosclerotic cardiovascular disease, dyspnea and respiratory abnormalities, morbid obesity (BMI 67.2), deep vein thrombosis, edema, and post-phlebotic syndrome. He was recently hospitalized for pneumonia, which has resolved. Treatments to date were not noted in documentation. In a progress note from his treating pulmonologist dated 10/16/14 the provider reports the patient has ongoing leg pain and swelling. He continues to have falls. He has had low INRs due to inability to get Coumadin after denials by UR. The plan included having the patient take Coumadin 5 mg 1.5 per day. A request for authorization for Coumadin 5 mg, brand-name, non-generic for lifetime appears to have been submitted on 10/15/14. An item of note contained in the records is a 9/19/12 FDA report that was apparently printed from the FDA website by a pharmacy reviewer, which states that generic and brand-name drugs differ in quantity absorbed by an average of 3.5%. On 12/19/14 Utilization Review non-certified the request for Coumadin 5mg (unknown quantity). The California Medical Treatment Utilization Schedule Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Coumadin 5mg (unknown quantity): Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines- Knee & Leg

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Overview of the causes of venous thromboembolus; and Rationale and indications for indefinite anticoagulation in patients with venous thromboembolism

Decision rationale: The UptoDate articles cited above state that the rationale for indefinite anticoagulation for patients who have had a deep venous thrombosis with or without a pulmonary embolus is based on the patient's risk for a major bleed versus the risk for thrombosis. The overall 5-year risk for recurrent pulmonary embolus in patients who stop anticoagulation after a first event is approximately 30%. Risk factors for thrombosis include previous episode of thrombosis; post-thrombotic syndrome especially with edema; obesity (hazard ratio 2.7 for BMI over 40); immobility; hypertension; atherosclerotic disease; diabetes; congestive heart failure especially if right-sided; smoking; cancer; and inherited hypercoagulable states. Risk factors for increased risk for major bleed include advanced age, previous bleed, frequent falls, diabetes, end-stage liver and kidney disease, and concomitant use of NSAIDs or other antiplatelet therapy. The clinical findings in this case support the use of lifelong Coumadin. This patient has multiple risk factors for another thrombotic event. These include two previous episodes of thrombosis (if in fact he had thromboses in both legs), extreme obesity (a BMI of 40 nearly triples the risk of thrombosis, and his BMI is 67.2), post-thrombotic syndrome with edema, diabetes, atherosclerotic disease and hypertension. It appears possible that he may have right-sided congestive heart failure, given his symptoms of dyspnea and edema. Although he also has some risk factors for a major bleed, his pulmonologist feels they are outweighed by his very high risk for recurrent thrombosis, and I would agree with him. It has been customary for clinicians to choose brand-name medications in situations where dosage must be fine-tuned, due to the variability that may occur when generic medications are changed willy nilly. This practice would be somewhat supported by the FDA article cited in the case summary, which notes some variation in the dose that reaches the patient from generic to brand-name medication. The requesting physician is essentially asking for a lifelong supply of brand-name Coumadin, and the UR physician is not to be faulted for non-certifying the request. The provider has not documented clear rationales, and it is certainly conceivable that the patient's situation could change, making the request untenable. However, I feel that the the risks (i.e. thrombosis, pulmonary embolism and death) of making it difficult for this patient to achieve a steady state of anticoagulation at an appropriate level should be avoided at all costs. There are three sub-optimal INR values recorded in this patient's records, which the pulmonologist states occurred because the patient's Coumadin had been denied. Although the request for Coumadin is not worded ideally, I do not feel it is reasonable to create further delays in providing this medication to this patient by forcing the physician to word his request appropriately, document his rationales, and wait through one or more UR processes. Taking into account the evidence-based citations above and the clinical information provided for my review, an indefinite supply of brand-name Coumadin for this patient IS medically necessary. It is necessary because he is

likely to have a high lifelong risk for venous thrombosis and pulmonary embolism, and the risk should not be increased by making it more difficult for him to achieve optimal anticoagulation.