

Case Number:	CM15-0029042		
Date Assigned:	02/23/2015	Date of Injury:	04/22/2013
Decision Date:	04/24/2015	UR Denial Date:	01/20/2015
Priority:	Standard	Application Received:	02/17/2015

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: District of Columbia, Virginia
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 injured worker is a 62-year-old male, who sustained an industrial injury on 4/22/13. The injured worker has complaints of left knee and left shoulder pain. Magnetic Resonance Imaging (MRI) left shoulder on 10/24/13 and left knee on 5/16/13 were done. The diagnoses have included chronic pain syndrome; left shoulder pain; left shoulder strain; labral tear; degenerative joint disease; tendinosis, left knee; medial meniscus tear; anterior cruciate ligament tear; chondromalacia patella; lateral meniscus tear; joint effusion and myalgia. Treatment to date has included aquatic and land therapy; ice and home exercise program and medications. According to the utilization review performed on 1/20/15, the requested Xarelto 10mg #14 has been non-certified. Official Disability Guidelines Knee and Leg Chapter were used in the utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xarelto 10mg #14: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Knee and Leg.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Venous thrombosis ODG (knee and leg chapters).

Decision rationale: Recommend identifying subjects who are at a high risk of developing venous thrombosis and providing prophylactic measures such as consideration for anticoagulation therapy. Warfarin is an acceptable therapy in all patient groups, but recommendations regarding other medications differ. ACCP recommends an LMWH or fondaparinux. AAOS, in contrast to ACCP, stratifies patients into four categories based on VTE risk and risk of major bleeding. Recommendations regarding mechanical prophylaxis differ slightly. According to AAOS, unless contraindicated, mechanical compression should be utilized for both total hip and knee arthroplasty for all patients in the recovery room and during the hospital stay for patients undergoing THR and TK, ACCP recommends the optimal use of mechanical thromboprophylaxis with the venous foot pump (VFP) or IPC (intermittent pneumatic compression) for patients with high risk of bleeding. When the high bleeding risk decreases, ACCP recommends that pharmacologic thromboprophylaxis be substituted for or added to the mechanical thromboprophylaxis (AAOS/ACCP 2010). The latest AHRQ comparative effectiveness review of VTE in orthopedic surgery conclude that there was inadequate data to make very many recommendations. They did suggest, for patients who have undergone major orthopedic surgery such as hip or knee replacement, extending post surgery use of medications from the standard seven to 10 days to 28 days or longer, to prevent blood clots may be beneficial. While there is not enough evidence to determine which type of anti clotting medication is best, within the heparin class of medications, LMHW was found to superior to un-fractionated heparin (Sobieraj 2012). Extended anticoagulation with apixaban or dabigatran reduces recurrent VTE and mortality without increasing major bleeding anticoagulation treatment decreases the risk of recurrence but can increase the risk of major bleeding anticoagulation treatment for patients with VTE is generally recommended for at least three months, but there is a high risk of recurrence. Extended treatment decreases the risk of recurrence but can increase the risk of major bleeding, so the decision concerning how long to continue anticoagulation can be complicated, especially if patients have unprovoked VTE. Two new trials evaluated the safety and efficacy of extended anticoagulation with eighter apixaban (AMPLIFY Ext trial) or dabigatran (RE sonate trial). In the AMPLIFY trial, symptomatic or fatal VTE occurred in one point seven percent of each apixaban group and in 8.8 percent in the placebo group (p less than .001, NNT 20). Clinically relevant bleeding occurred in 6.3 % vs 18% (p=.001, NNH 28). But there was no significant difference in the rates of major bleeding. An additional non-inferiority trial comparing dabigatran to warfarin showed that rates of recurrent or fatal VTE were similar for the two active drugs, but dabigatran was associated with reduced risk of clinically relevant bleeding (5.6% vs 10.2 %, P LESS than .001, NNT 22) and with a non-significant reduction in major bleeding (0.9 percent vs 1.8%) other options for long term prophylaxis against a VTE recurrence include rivaroxaban and aspirin. (Agnelli 2013) while current surgical care improvement project measures do not included aspirin as an appropriate sole options for the prevention of VTE, in patients undergoing elective TKA or who have a contradiction to pharmacologic prophylaxis and undergo a THA or HFS, aspirin In conjunctions with compression devices as part of a multimodal approach, would meet these measures. Data do not support the hypothesis that aspirin is less likely to cause adverse bleeding events than more potent anticoagulation (steward 2013). This patient has not had recent surgery, nor any medical condition such as atrial fibrillation or recurrent DVT, which would warrant this medication. As per guidelines above and review of the clinical documentation provided, it would not be indicated. Therefore, the request is not medically necessary.