MAXIMUS Federal Services

Case Number:	CM14-0192471		
Date Assigned:	11/26/2014	Date of Injury:	03/13/1993
Decision Date:	01/12/2015	UR Denial Date:	10/13/2014
Priority:	Standard	Application Received:	11/17/2014

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 Virginia and District of Columbia. 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 76-year old patient who sustained injury on Mar 13 1993. The patient was diagnosed with lumbar radiculitis. The patient had an MRI of the lumbar spine which showed an L2 compression fracture of 25 percent and degenerative disk disease which was found on a prior MRI. . The patient underwent lumbar epidural steroid injection under fluoroscopic guidance.

IMR ISSUES, DECISIONS AND RATIONALES

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

DME: DVT Calf Cuff and Pump 1x rental: 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 Procedure Summary

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) knee and leg procedure summary

Decision rationale: MTUS and ACOEM do not address this intervention. Per ODG, for patients who are at high risk of developing venous thrombosis and providing prophylactic measures such as consideration for anticoagulation therapy is recommended. Minor injuries in the leg are associated with greater risk of venous thrombosis. The relative risk for venous thrombosis is

three fold greater following minor injury, especially if injury occurs in the four weeks prior to thrombosis, is located in the leg and involves multiple injuries or rupture of muscle or ligament. Risk for venous thrombosis is higher in those with leg injury combined with family history of venous thrombosis(12 fold risk), factor V leiden mutation(50 fold risk) or factor 2 20210A mutation(nine fold risk). (von Stralen 2008). A venous thrombosis is a blood clot that forms within a vein. Deep vein thrombosis(DVT) form in the deep veins of the legs, and if a piece of a blood clot formed in the vein breaks it off it can be transported to the right side of the heart and from there into the lungs and is called an embolus and the process is called a venothromboembolism(VTE). Risk factors for DVT/VTE include immobility, surgery, and prothrombotic genetic variants. Studies have addressed the risk for thrombosis following major injury and minor events including travel, minor surgery, and minor trauma are linked to a three fold increased risk for DVT/VTE. VTE is an important condition in hospitalized patients accounting for significant morbidity and mortality. Those at high risk should be considered for anticoagulation therapy during post hospitalization period (Yale 2005). Aspirin may be the most effective choice to prevent pulmonary embolus (PE) and VTE in patient undergoing orthopedic surgery, according to a new study examining a potential role for aspirin in these patients. Patients who received aspirin had a lower VTE risk score than the patients who received warfarin. Patients who received aspirin had a much lower use of sequential compression as needed (bozic 2008). Patients with suspected DVT of the lower extremities are usually investigated with ultrasound either by the proximal veins (2-point ultrasound) or the entire deep vein system (whole leg ultrasonography). The latter approach is thought to be better based on its ability to detect isolated calf vein thrombosis; however it requires skilled operators and is mainly available only during working hours. These two ultrasound based evaluations both with their advantages and disadvantages are about equally effective at guiding the management of patients with suspected DVT, concluded the authors of a large RCT reported in JAMA. But the writer of an accompanying editorial gives the edge to one of the techniques (two point ultrasonography), the one that has been around longer and is simpler and probably more widely available. However the use of a two point ultrasonography to diagnosed DVT frequently requires repeated testing in one week to detect calf DVT which can extend to the proximal veins. Whole leg Doppler ultrasonography generally obviates the requirement, making 1 day testing possible. (bernardi 2008). A systematic review looked at five types of interventions used to prevent VTE in pelvic and acetabular fracture patients: mechanical compression devices, inferior vena cava filters, low molecular weight heparins, ultrasound screening and magnetic resonance venography screening. They concluded that there was limited date to guide which method to choose. (Slobogean 2009). Using data from the prospective million women study in the UK, new research suggest that the risk of VTE after surgery is greater and last for longer than has previously been appreciated. They show that the risk is greatest in the first six weeks following surgery, peaking around three weeks afterward. But most patients receive prophylaxis only for the duration of their hospital stay which averaged around six days. Risk also varied considerably by type of surgery being highest after inpatient surgery for hip and knee replacement (relative risk-221). Overall one in 140 women will be admitted to the hospital with VTE during the 12 weeks after any inpatient surgery, one in 45 after hip or knee replacement surgery and one in 85 after surgery for cancer. This compares with one in 815 after a day case procedure and only one in 6200 women during a twelve week period without surgery. The use of recommended VTE prophylaxis is suboptimal with only 59% of the surgical patients receiving recommended treatment. Current evidence suggests it is needed for inpatients undergoing many orthopedic, general and cancer surgery

procedures and should be given for at least seven to 10 days. In addition prolonged prophylaxis for four to five weeks also shows a new clinical benefit in high risk patients and procedures. One reason for the poor uptake of VTE prophylaxis is the relative inconvenience of parenteral anticoagulants, such as low molecular weight heparin, the current recommended treatment and previously the only oral options; warfarin was not effective enough for VTE prevention. The UK national institute for health and clinical excellence (NICE) has issues new guidance on the prevention of VTE. They primarily recommend mechanical methods for DVT prophylaxis. Although mechanical methods do reduce the risk of DVT there is no evidence that they reduce the main threat, the risk of PE, fatal PE or total mortality. In contrast, pharmacologic methods reduce significantly all of these outcomes. They recommend stockings for DVT prevention except in stroke patients. The newer oral anticoagulants such as Xarelto and dabigatrin, are indicated as treatment options for specific indications, namely hip- and knee-replacement surgery. In the summary of evidence for knee-replacement surgery, under economic considerations the guidance notes that fondiparinux, dabigatrin, LMWH (low molecular weight heparin) and Xarelto are to be the most cost-effective compared to dabigatran and LMWH as thromboprophylaxis from surgery for four to five weeks (Cohne 2010). A direct comparison of recommendations from AAOS and ACCP for prevention of DVT following total knee and hip replacement surgery found several differences. Neither AAOS nor ACCP recommend routine screening for DVT of PE in asymptomatic patients postoperatively. Warfarin is an acceptable therapy in all patient groups, but recommendations regarding other medications differ. ACCP recommends a 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 or TKR, ACCP recommends the optimal use of mechanical thromboprophylaxis with venous foot pump or 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 concluded that there are inadequate data to make very many recommendations. They did suggest for patients who have undergone major orthopedic surgery, TKR or THR, extending post-surgery use of medications from the standard 7-10 days for 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, LMWH was found to be superior to unfractionated heparin (Soberaj 212). Extended anticoagulation with apixaban or dabigatran reduces VTE or mortality without increasing 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, sot the decisions concerning how long to anticoagulated can be complicated, especially in patients with unprovoked VTE. The two new trials evaluated safety and efficacy of extended anticoagulation treatment with either apixaban (AMPLIFY EXT trial) or dabigatran(RESONATE trial). In AMPLIFY EXT trial, symptomatic or fatal DVT occurred in 1.7% of each apixaban group(2.5mg and 5 mg doses) and in 8.8% in the placebo group($p<.001$, NNT 14). There were no significant differences in the rates of major bleeded among groups (0.1-0.2% with apixaban vs 0.5% with placebo). In the RESONATE trial, recurrent or fatal VTE occurred in 0.4% with

dabigatran vs 5.6% with placebo (P<.001, NNT 22) and with a non-significant reduction in major bleeding (0.9% vs 1.8%). Other options for long term prophylaxis against DVT recurrence include Xarelto and aspirin (Agnelly 2013). While the current surgical care improvement project measures do not include aspirin as an appropriate sole option for the prevention of VTE, in patients undergoing elective TKA or who a contraindication to pharmacologic prophylaxis and undergo a THA or HFS, aspirin in conjunction 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 anticoagulants. (Stewart 2013). Based on the clinical data provided, this intervention would not be indicated. Therefore, DME: DVT Calf Cuff and Pump 1x rental is not medically necessary.