VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

FRAGMIN® (Dalteparin)

Effective Date: 7/28/05

Date Developed: 7/19/05 by C. Wilhelmy MD

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Fragmin is a low molecular weight heparin analog which is similar to Lovenox (enoxaparin). While dalteparin has been shown to inhibit both factor Xa and factor IIa (thrombin), the antithrombotic effect of dalteparin is characterized by a higher ratio of antifactor Xa to antifactor IIa activity (2.7:1)

Pre-Authorization Criteria:

Non-ST elevation acute coronary syndromes: Prevention of ischemic complications in patients with unstable angina or non-Q-wave myocardial infarction in combination with an appropriate antiplatelet regimen.

Venous thromboembolism prophylaxis: Prevention of DVT which may lead to PE, in patients requiring abdominal surgery who are at risk for thromboembolism complications (eg, >40 years, obesity, malignancy, history of DVT or PE, surgical procedures requiring general anesthesia lasting >30 minutes); patients undergoing total hip arthroplasty; or in patients who are at risk for thromboembolism complications due to severe immobility during an acute illness.

Venous thromboembolism treatment in patients with active cancer: Extended treatment (6 months) of acute symptomatic VTE (ie, DVT and/or PE) to reduce the recurrence of VTE in cancer patients.

Venous thromboembolism treatment in pediatric patients: Treatment of symptomatic VTE (ie, DVT and/or PE) to reduce the recurrence of VTE in infants ≥1 month of age, children, and adolescents.

Off-Label:

Deep vein thrombosis and/or pulmonary embolism treatment; Hemodialysis, intermittent, anticoagulation of circuit; Mechanical heart valve, bridging anticoagulation; Periprocedural bridging anticoagulation for patients at high risk of thromboembolism, with atrial fibrillation, venous thromboembolism, or other high-risk conditions; Superficial vein thrombosis, acute symptomatic; Venous thromboembolism

prophylaxis, nonorthopedic surgery; Venous thromboembolism prophylaxis, pregnancy; Venous thromboembolism prophylaxis, total knee arthroplasty; Venous thromboembolism treatment in pregnancy

ADMINISTRATION

Refer to product literature for dosing in specific cases.

or non- Q-wave MI undergoing regional anesthesia; not for I.M. or I.V. use

WARNINGS / PRECAUTIONS — Patients with recent or anticipated neuraxial anesthesia (epidural or spinal anesthesia) are at risk of spinal or epidural hematoma and subsequent paralysis

Not to be used interchangeably (unit for unit) with heparin or any other low molecular weight heparins

Use with caution in patients with history of heparin- induced thrombocytopenia (HIT). Monitor platelet count closely

Certain patients are at increased risk of bleeding. Risk factors include bacterial endocarditis; congenital or acquired bleeding disorders; active ulcerative or angiodysplastic GI diseases; severe uncontrolled hypertension; hemorrhagic stroke; or use shortly after brain, spinal, or ophthalmology surgery; in patient treated concomitantly with platelet inhibitors; recent GI bleeding; thrombocytopenia or platelet defects; severe liver disease; hypertensive or diabetic retinopathy; or in patients undergoing invasive procedures.

Can cause hyperkalemia possibly by suppressing aldosterone production.

DRUG INTERACTIONS

Drugs which affect platelet function (eg, aspirin, NSAIDs, dipyridamole, ticlopidine, clopidogrel) may potentiate the risk of hemorrhage.

Thrombolytic agents increase the risk of hemorrhage.

Warfarin: Risk of bleeding may be increased during concurrent therapy. Dalteparin is commonly continued during the initiation of warfarin therapy to assure anticoagulation and to protect against possible transient hypercoagulability.

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