VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

INNOHEP® (Tinzaparin)

Effective Date: 7/28/05

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

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, ARCHIVED 1/2/25

NOTE: NOT AVAILABLE IN THE U.S.

Innohep is Low Molecular Weight Heparin (LMWH) similar to Lovenox.. Heparin acts as an anticoagulant by enhancing the inhibition rate of clotting proteases by antithrombin III, impairing normal hemostasis and inhibition of factor Xa. Low molecular weight heparins have a small effect on the activated partial thromboplastin time and strongly inhibit factor Xa. The primary inhibitory activity of tinzaparin is through antithrombin.

~~Pre~~-Authorization Criteria:

Treatment of deep vein thrombosis (DVT) and/or pulmonary embolism (PE).*

Prevention of VTE following orthopedic surgery or following general surgery in patients at high risk of VTE.

*NOTE: Oral anticoagulants are preferred for patients without cancer after initiation of therapy with LMWH

MONITORING PARAMETERS — CBC including platelet count and hematocrit or hemoglobin, and stool for occult blood; the monitoring of PT and/or aPTT is not necessary. Patients receiving both warfarin and tinzaparin should have their INR drawn just prior to the next scheduled dose of tinzaparin.

DOSING: ADULTS —
Treatment of DVT: Dosing Regimen: SubQ: 175 anti-Xa int. units/kg once daily. Warfarin sodium should be started when appropriate. Administer tinzaparin for at least 5-10daysor until patient is adequately anticoagulated with warfarin.

DVT Prophylaxis: 50- 75 anti-Xa units/kg once daily (see product literature for specific procedure coverage)

DOSING: ELDERLY — Refer to adult dosing.

NOTE: Innohep may increase the risk for death, compared to UFH, when administered to elderly patients with renal insufficiency.

NOTE: Safety and efficacy in pediatric patients has not been established.

DOSING: RENAL IMPAIRMENT — Patients with severe renal impairment had a 24% decrease in clearance, use with caution.

DOSING: HEPATIC IMPAIRMENT — No adjustment necessary.

NOTE: . For subcutaneous injection only,

DOSAGE FORMS — Injection, solutions:

10,000 units/mL (0.25 mL, 0.35 mL, 0.45 mL)

10,000 units/mL (2 mL); 20,000 units/mL (2 mL) [contains benzyl alcohol, sodium metabisulfite]

20,000 units/mL (0.4 mL, 0.5 mL, 0.6 mL, 0.7 mL, 0.8 mL, 0.9 mL) [contains sodium metabisulfite]

CONTRAINDICATIONS — Hypersensitivity to tinzaparin sodium, heparin, sulfites, benzyl alcohol, pork products, or any component of the formulation; active major bleeding; current or history of heparin-induced thrombocytopenia

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.

Monitor patient closely for signs or symptoms of bleeding. Risk factors include bacterial endocarditis; congenital or acquired bleeding disorders; active ulcerative or angiodysplastic GI diseases; severe uncontrolled hypertension; hemorrhagic stroke; use shortly after brain, spinal, or ophthalmologic surgery; patients 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. Monitor platelet count closely. Manufacturer recommends discontinuation of therapy if platelets are <100,000/mm3.

PREGNANCY IMPLICATIONS — There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if clearly needed. Pregnant women, or those who become pregnant while receiving tinzaparin, should be informed of the potential risks to the fetus.

LACTATION — Excretion in breast milk unknown/use caution

REFERENCES

1. Hull, RD, Raskob, GE, Pineo, GF, et al. Subcutaneous Low-Molecular-Weight Heparin Compared With Continuous Intravenous Heparin in the Treatment of Proximal- Vein Thrombosis. N Engl J Med 1992; 326:975.
2. Nagge, J, Jackevicius, C, Dzavik, V, et al. Acute Profound Thrombocytopenia Associated With Eptifibatide Therapy. Pharmacotherapy 2003; 23:374.
3. Simonneau, G, Sors, H, Charbonnier, B, et al. A Comparison of Low-Molecular-Weight Heparin With Unfractionated Heparin for Acute Pulmonary Embolism. The THESEE Study Group. Tinzaparine ou Heparine Standard: Evaluations dans l'Embolie Pulmonaire. N Engl J Med 1997; 337:663.
4. Innohep prescribing information, Celgene, December 2008

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