



## Tinzaparin Sodium

### DESCRIPTION

Tinzaparin sodium is the sodium salt of a low molecular weight heparin. It is prepared from porcine intestinal mucosa by controlled enzymatic depolymerization using heparinase from *Flavobacterium heparinum*. Clinically, tinzaparin inhibits reactions that lead to the formation of fibrin clots. Its activity is mediated through the plasma protease inhibitor antithrombin.

An example of a preparation of tinzaparin sodium is Innohep®.

### REFER TO DECISION SUPPORT TREE

### POLICY

**Proposal is to add the following statement in blue and delete the following statement with strikethrough.**

- Tinzaparin sodium for the treatment of the following is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Deep vein thrombosis (DVT)
  - Pulmonary embolism (PE)
- Tinzaparin sodium for the prevention of deep vein thrombosis is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Tinzaparin sodium for the treatment of other conditions/diseases, including, but not limited to, the treatment of stroke is considered **investigational**.
  - Treatment of stroke
  - Prevention of clotting in indwelling intravenous lines for hemodialysis and extracorporeal circulation
  - Treatment of deep vein thrombosis as a monotherapy

### MEDICAL APPROPRIATENESS

**Proposal is to delete the following statement with strikethrough and add the following statements in blue.**

- Tinzaparin sodium for the treatment of **ANY ONE** of the following is considered **medically appropriate** if the following criteria are met:
  - ~~As an adjunctive treatment of acute symptomatic deep vein thrombosis with or without pulmonary embolism~~  
Deep vein thrombosis (DVT) if **ALL** of the following:
    - DVT is objectively confirmed
    - Creatinine clearance greater than or equal to 30 mL/minute (e.g., adequate renal function)
    - Administered in conjunction with a vitamin K antagonist [e.g., warfarin sodium (Coumadin®)]
  - Pulmonary embolism (PE) if **ALL** of the following:
    - PE is objectively confirmed
    - Creatinine clearance greater than or equal to 30 mL/minute (e.g., adequate renal function)
    - Administered in conjunction with a vitamin K antagonist [e.g., warfarin sodium (Coumadin®)]
- Tinzaparin sodium for the prevention of deep vein thrombosis (DVT) is considered **medically appropriate** if the individual meets **ANY ONE** of the following criteria:
  - Undergoing general surgery with risk factors for DVT (e.g., over 40 years of age, obesity as defined by body mass index (BMI) greater than or equal to 30, will undergo general anesthesia lasting longer than 30 minutes, diagnosis of malignancy, history of DVT or PE)
  - Undergoing orthopedic surgery with risk factors for DVT (e.g., over 40 years of age, obesity (e.g., body mass index (BMI) greater than or equal to 30), general anesthesia lasting longer than 30 minutes, diagnosis of malignancy, history of DVT or PE)



- Pregnant with **ANY ONE** of the following:
  - Current venous thromboembolism
  - History of venous thromboembolism
- Acute spinal cord injury once primary hemostasis is evident

### APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

### Proposal is to delete the following statement with strikethrough and add the following statements in blue.

~~In addition to the FDA approved indication, a single pharmacy compendium, the 2006 USP DI Drug Information for the Health Care Professional, also recognized the use of tinzaparin sodium for the treatment of the following:  
Treatment of deep vein thrombosis as a monotherapy  
Treatment of pulmonary embolism~~

- Drugdex recognizes the use of tinzaparin sodium in the anticoagulation of chronic hemodialysis patients.
- The NCCN Drugs & Biologics Compendium recognizes the use of tinzaparin sodium for additional uses beyond the FDA-approved labeling in the treatment of cancer patients with failure of anticoagulation therapy (Refer to the NCCN Drugs & Biologics Compendium or NCCN Clinical Practice Guidelines for detailed recommendations).
- Two open-label prospective randomized clinical trials recognized the use of tinzaparin sodium as monotherapy for the treatment of deep venous thrombosis.

### ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

No additional controlled studies were found in the published literature that validate the use of tinzaparin sodium for the treatment or prevention of any other conditions/diseases.

### SOURCES

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## Pharmaceutical Decision Support Tree

### Tinzaparin Sodium (Innohep<sup>®</sup>)

1. Is the medication being requested for **ANY ONE** of the following?
  - Prevention of clotting in indwelling intravenous lines for hemodialysis and/or extracorporeal circulation
  - Treatment of deep vein thrombosis as a monotherapy
  - Treatment of stroke

If yes, this does not meet medical necessity and/or medical appropriateness criteria  
If no, go to question #2
2. Does the individual have a diagnosis of deep vein thrombosis with **ALL** of the following?
  - DVT is objectively confirmed
  - Creatinine clearance greater than or equal to 30 mL/minute (e.g., adequate renal function)
  - Administration is in conjunction with a vitamin K antagonist [e.g., warfarin sodium (Coumadin<sup>®</sup>)]

If yes, this satisfies medical necessity and medical appropriateness criteria  
If no, go to question #3
3. Does the individual have a diagnosis of pulmonary embolism with **ALL** of the following?
  - PE is objectively confirmed
  - Creatinine clearance greater than or equal to 30 mL/minute (e.g., adequate renal function)
  - Administration is in conjunction with a vitamin K antagonist [e.g., warfarin sodium (Coumadin<sup>®</sup>)]

If yes, this satisfies medical necessity and medical appropriateness criteria  
If no, go to question #4
4. Does the individual have a need to prevent deep vein thrombosis after orthopedic or general surgery?

If yes, go to question #5  
If no, go to question #6
5. Does the individual show evidence of increased risk for deep vein thrombosis with **ANY ONE** of the following?
  - Over 40 years of age
  - Obesity as defined by body mass index (BMI) greater than or equal to 30
  - To undergo general anesthesia lasting longer than 30 minutes
  - Diagnosis of malignancy
  - History of deep vein thrombosis
  - History of pulmonary embolism
  - Other condition/disease associated with increased risk for deep vein thrombosis

If yes, this satisfies medical necessity and medical appropriateness criteria  
If no, this does not meet medical necessity and/or medical appropriateness criteria
6. Is the individual pregnant with **ANY ONE** of the following?
  - Current venous thromboembolism
  - History of venous thromboembolism

If yes, this satisfies medical necessity and medical appropriateness criteria  
If no, go to question #7
7. Has the individual experienced an acute spinal cord injury with evidence of primary hemostasis?



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## Pharmaceutical Decision Support Tree

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria