

STANDARD MEDICARE PART B MANAGEMENT

THROMBATE III (Antithrombin III [Human])

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Indicated in patients with hereditary antithrombin deficiency for treatment and prevention of thromboembolism
2. Indicated in patients with hereditary antithrombin deficiency for prevention of peri-operative and peri-partum thromboembolism

B. Compendial Uses

1. Acquired antithrombin III deficiency
2. Heparin resistance prior to and during cardiopulmonary bypass (CPB)
3. Sickle cell-thalassemia, treatment of chronic leg ulcers

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. **Hereditary Antithrombin Deficiency**

1. Authorization of 12 months may be granted for treatment of hereditary antithrombin deficiency when the requested medication will be used for any of the following indications:
 - a. Treatment of thromboembolism
 - b. Prevention of thromboembolism

2. Authorization of 1 month may be granted for the treatment of hereditary antithrombin deficiency when the requested medication will be used for any of the following indications:

- a. Prevention of peri-operative (i.e., surgical procedures) thromboembolism
- b. Prevention of peri-partum (i.e., obstetrical procedures) thromboembolism

B. Acquired Antithrombin Deficiency

Authorization of 6 months may be granted for treatment of acquired antithrombin deficiency when both of the following criteria is met:

1. The member has a condition associated with low levels of antithrombin III (e.g., disseminated intravascular coagulation (DIC) associated with sepsis or trauma, liver failure, asparaginase-induced antithrombin deficiency)
2. The requested medication will be used for the treatment or prophylaxis of thromboembolism

C. Heparin Resistance

Authorization of 1 month may be granted for treatment of heparin resistance prior to and during cardiopulmonary bypass (CPB).

D. Sick cell beta thalassemia

Authorization of 3 months may be granted for treatment of chronic leg ulcers in patients with sickle cell beta thalassemia

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Hereditary antithrombin deficiency (excluding prevention of peri-operative and peri-partum thromboembolism)

Acquired antithrombin deficiency

Sickle cell beta thalassemia

Authorization for 12 months may be granted for hereditary antithrombin deficiency (excluding prevention of peri-operative and peri-partum thromboembolism), acquired antithrombin deficiency, and sickle cell beta thalassemia when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication
- B. The member is receiving benefit from therapy

IV. REFERENCES

1. Thrombate III [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2019.

2. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/01/2020).
3. Hunault-Berger M, Chevallier P, Delain M, et al. Changes in antithrombin and fibrinogen levels during induction chemotherapy with L-asparaginase in adult patients with acute lymphoblastic leukemia or lymphoblastic lymphoma. Use of supportive coagulation therapy and clinical outcome: the CAPELAL study. Haematologica. 2008;93(10):1488-1494.