



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Thrombate III [Antithrombin III (Human)]-Medicare Advantage Only

Policy Number: 5.02.585.MA
Origination: 01/2021

Last Review: 01/2024
Next Review: 01/2025

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Thrombate III [Antithrombin III (Human)]** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Thrombate III [Antithrombin III (Human)] may be considered **medically necessary** when the following criteria are met:

1) Hereditary Antithrombin Deficiency. Approve for 1 year if patient meets the following:

- a) Diagnosis of hereditary antithrombin deficiency; **AND**
- b) Thrombate III will be used for treatment of thromboembolism **OR** prevention of perioperative or peri-partum thromboembolism

Off Label

- 1) Intraoperative heparin resistance during cardiopulmonary bypass.**

When Policy Topic is not covered

Thrombate III [Antithrombin III (Human)] is considered **not medically necessary** when the above criteria are not met and **investigational** for all other uses.

Centers for Medicare and Medicaid Services (CMS)

When reviewing for a Medicare beneficiary, guidance from National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) supersede the Medical Policies of Blue KC. Blue KC Medical Policies are used in the absence of guidance from an NCD or LCD.

In general, Medicare covers outpatient (Part B) drugs that are furnished 'incident to' a physician's service provided that the drugs are not usually self-administered

by the patients who take them. Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#).

NCDs

<https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all>

LCDs

<https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all>

Considerations

Thrombate III [Antithrombin III (Human)] requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

Thrombate III [antithrombin III (human)] is a serine protease inhibitor that plays a major role in the regulation of hemostasis.

Thrombate III [antithrombin III (human)] is important in mediating the major antithrombotic effect of heparin and neutralizes Factor Xa by forming a complex that is rapidly removed from the circulation.

Thrombate III [antithrombin III (human)] is indicated in patients with hereditary antithrombin deficiency for:

- treatment of thromboembolism
- prevention of peri-operative and peri-partum thromboembolism.

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Thrombate III [antithrombin III (human)] while maintaining optimal therapeutic outcomes.

Warnings and Precautions

- Hypersensitivity reactions: Hypersensitivity reactions, including severe hypersensitivity reactions (eg, anaphylaxis), may occur; monitor closely during infusions. If hypersensitivity symptoms occur, discontinue immediately and institute supportive emergency care.

- **Infections:** Thrombate III: Thrombate III is AT collected from pooled human plasma (hpAT). A product of human plasma, it may potentially contain infectious agents which could transmit disease, including the Creutzfeldt-Jakob Disease (CJD) agent; screening of donors, as well as testing and/or inactivation or removal of certain viruses, reduces this risk. Infections suspected to be transmitted by this product should be reported to the manufacturer.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2020. URL: <http://www.clinicalpharmacology.com> Accessed November 2020.
2. Lexicomp [database online]. Hudson, OH Lexi-comp, Inc.: URL <http://online.lexi.com> Accessed November 2020.
3. Micromedex Healthcare Series: Thomson Micromedex, Greenwood Village, CO. 2020. Accessed November 2020
4. Thrombate III [package insert]. Research Triangle Park, NC: Grifols Therapeutic Inc.; Revised January 2019

Billing Coding/Physician Documentation Information

J7197	Antithrombin III (human), per IU
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Policy Implementation/Update Information

01/2021	New Policy titled "Thrombate III – MA Only"
01/2022	Annual review – no changes made
01/2023	Annual review – added Off Label use, added Warnings and Precautions
01/2024	Annual review – no changes made

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.