

Clinical Policy: Antithrombin III (Thrombate III)

Reference Number: PA.CP.PHAR.564

Effective Date: 01/2022

Last Review Date: 01/2026

Description

Antithrombin III (Thrombate III[®]) is a human antithrombin product.

FDA Approved Indication(s)

Thrombate III is indicated in adult and pediatric patients with hereditary antithrombin deficiency for:

- Treatment and prevention of thromboembolism
- Prevention of peri-operative and peri-partum thromboembolism

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Thrombate III is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hereditary Antithrombin Deficiency (must meet all):

1. Diagnosis of hereditary antithrombin deficiency;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following (a or b):
 - a. Treatment or prevention of thromboembolism;
 - b. Prevention of peri-operative or peri-partum thromboembolism.

Approval duration:

**Acute thrombosis or peri-operative/peri-partum prevention: 3 months or
Prevention: 12 months**

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Hereditary Antithrombin Deficiency (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
2. Member is responding positively to therapy.

Approval duration:

**Acute thrombosis or peri-operative/peri-partum prevention: 3 months or
Prevention: 12 months**

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy PA.CP.PMN.53 or evidence of coverage documents;
- B. Disseminated intravascular coagulation (DIC).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DIC: disseminated intravascular coagulation

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- None reported

Appendix D: General Information

- In addition to the FDA-approved indications, antithrombin has been suggested for treatment of patients with DIC associated with trauma or sepsis. However, 2009 British guidelines for the diagnosis and management of DIC do not recommend antithrombin in patients with DIC without further prospective evidence in randomized controlled trials. More recent studies have not found clear benefit of antithrombin in treatment of DIC. A 2016 Cochrane review of antithrombin administration in critically ill patients concluded that there is insufficient evidence to support its use in any category of such patients, including those with sepsis and DIC. A 2022 statement from the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis (ISTH) on sepsis-induced coagulopathy in the management of sepsis concluded that although antithrombin is a candidate for anticoagulation, it has not proven to be effective with robust evidence, and future trials are warranted.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hereditary antithrombin deficiency	Individualize dose to achieve antithrombin level of 80% to 120% of normal human plasma. <u>Loading dose (IV infusion):</u> 120% - baseline % x body weight (kg) / 1.4%	Varies per baseline and target antithrombin levels

Indication	Dosing Regimen	Maximum Dose
	<u>Adjustment (as needed, IV infusion):</u> Target % - trough % x body weight (kg) / 1.4% <u>Maintenance:</u> Loading dose x 0.6 IV every 24 hours as needed	

VI. Product Availability

Single-dose vial: approximately 500 units

VII. References

1. Thrombate III Prescribing Information. Research Triangle Park, NC: Grifols Therapeutics LLC; July 2025. Available at: www.thrombate.com. Accessed October 23, 2025.
2. Levi M, Toh CH, Thachil J, Watson HG. Guidelines for the diagnosis and management of disseminated intravascular coagulation. British Committee for Standards in Haematology. Br J Haematol. 2009 Apr;145(1):24-33.
3. Allingstrup M, Wetterslev J, Ravn FB, Møller AM, Afshari A. Antithrombin III for critically ill patients. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD005370. 5.
4. Iba T, Levi M, Thachil J, et al. Communication from the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis on sepsis-induced coagulopathy in the management of sepsis. J Thromb Haemost. 2023;21(1):145-153
5. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at: <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents>. Accessed November 24, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7197	Antithrombin III (human), per IU

Reviews, Revisions, and Approvals	Date
Policy created	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: no significant changes; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025
1Q 2026 annual review: Atryn was discontinued and removed from criteria; RT4: updated Thrombate III indication for pediatric extension and removed requirement for age \geq 18 years; revised approval durations for prevention from 6 months to 12 months; references reviewed and updated.	01/2026

