Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 8/24/2022**
Policy Number: PA.CP.MP.179	**Effective Date: 1/1/2020** **Revision Date: 8/24/2022**
Policy Name: Antithrombin III (Thrombate III, Atryn)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☒ **Retiring Policy –** *This option indicates the retirement of an active policy. If there is no indicated replacement, then "NONE" will be listed as the New/Replacement Policy.*
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Please retire this policy – no replacement indicated

Name of Authorized Individual (Please type or print): Carla Huitt, MD MPH	**Signature of Authorized Individual:**

Clinical Policy: Antithrombin III (Thrombate III, Atryn)

Reference Number: PA.CP.MP.179
Effective Date: 1/1/2020
Last Review Date: 2/18/2021

Coding Implications
Revision Log

Description
Medical necessity criteria for Antithrombin III (Thrombate III® and Atryn®).

Policy/Criteria

I. It is the policy of health plans affiliated with PA Health & Wellness® that antithrombin III is **medically necessary** for the following indications:
   A. Diagnosis of hereditary antithrombin deficiency and one of the following:
      1. Treatment or prevention of thromboembolism and human-derived antithrombin III (Thrombate III) is requested;
      2. Prevention of peri-operative and peri-partum thromboembolism and recombinant antithrombin III (Atryn) or Thrombate III is requested.

II. For all Other Diagnosis/Indications: Refer to PA.CP.PMN.53 Off-Label Use of Drugs Not on Statewide Preferred Drug List.

Background
Deficiency of antithrombin III, also known as antithrombin, can be inherited or acquired, and is associated in some patients with a heightened risk of thromboembolism. Antithrombin can be replaced in patients who are deficient, but questions remain regarding the benefits, risks, and appropriate indications for use.

Thrombate
FDA-approved indications for Thrombate include the following:
Patients with hereditary antithrombin deficiency for:
• Treatment and prevention of thromboembolism
• Prevention of peri-operative and peri-partum thromboembolism

Atryn
FDA-approved indications for Atryn include prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients.

Antithrombin for disseminated intravascular coagulation (DIC)
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 contolled trials.[3] 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.[4]

HCPCS Codes	Description
J7196	Injection, antithrombin recombinant, 50 IU
J7197	Antithrombin III (human), per IU

Reviews, Revisions, and Approvals	Date	Approval Date
New Policy developed	10/19	1/16/2019
Annual Review completed, References reviewed and updated. Specialist reviewed.	2/18/2021	
Please retire this policy – no replacement indicated	8/24/2022	**11/10/2022**

References

1. Grifols Therapeutics LLC. Thrombate III prescribing information. Research Triangle Park, NC. January 2019.
2. GTC Biotherapeutics, Inc. ATryn prescribing information. Framingham Massachusetts. November 2010.
3. Levi M1, 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.
4. 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. Warren BL, Eid A, Singer P, et al. Caring for the critically ill patient. High-dose antithrombin III in severe sepsis: a randomized controlled trial. JAMA 2001; 286:1869.
6. Leung L LK. Clinical features, diagnosis, and treatment of disseminated intravascular coagulation in adults. UpToDate. Mannuccio Mannucci P (Ed.) Waltham, MA. Accessed 09/23/20.
7. Schmidt GA, Clardy PF. Investigational and ineffective therapies for sepsis. UpToDate. Parsons PE, Sexton DJ (Eds.) Waltham, MA. Accessed 09/23/20.