Clinical Policy: Antithrombin III (Thrombate III, Atryn)

Reference Number: LA.CP.MP.179 Coding Implications
Last Review Date: 08/2020 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections 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. It is the policy of Louisiana Healthcare Connections that Antithrombin III (Thrombate III or Atryn) is not medically necessary for all other indications, including but not limited to, disseminated intravascular coagulation (DIC) associated with sepsis or trauma.

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
Converted corporate to local policy.	08/15/2020	

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.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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