

STANDARD MEDICARE PART B MANAGEMENT

ATryn (antithrombin [recombinant])

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

ATryn is a recombinant antithrombin indicated for the *prevention* of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients.

B. Compendial Use

Management of heparin resistance during cardiopulmonary bypass (CPB)

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

Authorization of 1 month may be granted for prevention of peri-operative or peri-partum thromboembolic events in hereditary antithrombin deficient members.

B. Heparin Resistance

Authorization of 1 month may be granted for management of heparin resistance during cardiopulmonary bypass.

III. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for ATryn.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

Reference number(s)
4368-A

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for ATryn are covered in addition to management of heparin resistance during cardiopulmonary bypass.

IV. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using ATryn for the management of heparin resistance during cardiopulmonary bypass can be found in 2 randomized trials. In 2 randomized, double-blind, placebo-controlled, multicenter studies in patients with heparin resistance undergoing CPB, ATryn effectively restored heparin responsiveness and reduced markers of coagulation activation. In these studies, heparin resistance was defined as an activated clotting time (ACT) less than 480 seconds following administration of a total heparin dose of 400 units/kg. Treatment with ATryn was associated with reduced requirements for fresh frozen plasma and heparin during CPB.

V. REFERENCES

1. ATryn [package insert]. Framingham, MA: GTC Biotherapeutics, Inc.; December 2013.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 17, 2022.