Original Effective Date: 08/01/2018
Current Effective Date: 08/30/2023
Last P&T Approval/Version: 7/26/2023
Next Review Due By: 07/2024
Policy Number: C14570-A

Hemostatic Agents

PRODUCTS AFFECTED

Amicar (aminocaproic acid), aminocaproic acid, Stimate (desmopressin), desmopressin SOLN 1.5mg/mL, Lysteda (tranexamic acid), tranexamic acid

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Hemophilia A, Von Willebrand disease, Cyclic heavy menstrual bleeding

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. STIMATE (DESMOPRESSIN 1.5MG/ML NASAL) ONLY:
1. (a) Documented diagnosis of mild Hemophilia A
   OR

(b) Documented diagnosis of mild to moderate von Willebrand disease (type I)
AND
2. Request is for control and prevention of bleeding episodes (including management of spontaneous bleeding or trauma-induced hemorrhage), perioperative management, or routine prophylaxis to prevent or reduce frequency of bleeding episodes

B. AMICAR (AMINOCAPROIC ACID) ONLY:
1. (a) Documented diagnosis of congenital or acquired coagulation disorder or member has been on anticoagulation therapy at therapeutic doses
AND
(b) Request is for control or prevention of oral bleeding in a member undergoing dental procedure
OR
2. Documented diagnosis of traumatic hyphema

C. LYSTEDA (TRANEXAMIC ACID) ONLY:
1. (a) Documented diagnosis of cyclic heavy menstrual bleeding
AND
(b) Trial/failure of max tolerated, and acceptable dose of hormonal therapy OR hormonal therapy is clinically inappropriate
OR
2. (a) Documented diagnosis of Hemophilia
AND
(b) Request is for reducing or preventing oral bleeding in a member undergoing dental procedure
AND
(c) Tranexamic acid will be used as part of a treatment plan with factor replacement
OR
3. Documentation of any of the following diagnosis for approved off-labeled use: Hereditary angioedema (HAE) long-term prophylaxis, Post-operative bleeding associated with cervical conization, Transurethral prostatectomy, Prevention of dental procedure bleeding in members on oral anticoagulant therapy, or Traumatic hyphema

CONTINUATION OF THERAPY:
A. FOR ALL CHRONIC THERAPY INDICATIONS (FOR ACUTE TREATMENT REQUESTS, A NEW INITIAL AUTHORIZATION WOULD BE REQUIRED):
1. Prescriber attestation that member continues to respond positively to therapy
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: for up to 12 months

PRESCRIBER REQUIREMENTS:
Hemophilia A, Von Willebrand disease: Prescribed by or in consultation with a board-certified hematologist, a specialist at a Hemophilia treatment center, hematologist or oncologist.
Cyclic heavy menstrual bleeding: Prescribed by or in consultation with a board-certified OB/GYN or another reproductive specialist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Stimate: age ≥11 months
Amicar: No restriction

Drug and Biologic Coverage Criteria

Lysteda: No restriction

QUANTITY:

Stimate

Hemophilia A and von Willebrand disease (type 1): Intranasal (using high concentration spray [1.5 mg/mL]): <50 kg: 150 mcg (1 spray in a single nostril); ≥50 kg: 300 mcg (1 spray each nostril); repeat use is determined by the patient's clinical condition and laboratory work. If using preoperatively, administer 2 hours before surgery.

Lysteda

Cyclic heavy menstrual bleeding: 1,300 mg 3 times daily (3,900 mg/day) for up to 5 days during monthly menstruation

Dental procedure in patients with hemostatic defects: Oral: 25 mg/kg (usual dose range: 1 to 1.5 g) given 2 hours prior to procedure, then 25 mg/kg (usual dose range: 1 to 1.5 g) up to 4 times daily for up to 10 days (Berube 2020; Cyklokapron Canadian product monograph; Hoots 2021; van Galen 2019).

Hereditary angioedema (HAE), long-term prophylaxis (off-label use): Oral: 1,000 to 1,500 mg 2 to 3 times daily

Post-operative bleeding associated with cervical conization (prevention/reduction) (off-label use): Oral: Postoperative regimen: 1500 mg every 8 hours beginning the evening following the procedure and continuing for 12 days

Prevention of dental procedure bleeding in patients on oral anticoagulant therapy (off-label use): Oral rinse: 4.8% solution: Hold 10 mL in mouth and rinse for 2 minutes then spit out. Repeat 4 times daily for 2 days after procedure.

Transurethral prostatectomy, blood loss reduction (off-label use): Oral: 2,000 mg 3 times daily on the operative and first postoperative day

Traumatic hyphema (off-label use): Oral: 25 mg/kg administered 3 times daily for 5 to 7 days

Amicar

Acute bleeding in patients with hemostatic defects: Oral: Loading dose: 4 to 5 g during the first hour, followed by 1 g/hour for 8 hours (or 1.25 g/hour using oral solution) or until bleeding controlled (maximum daily dose:30 g)

Control of oral bleeding in congenital and acquired coagulation disorder (off-label use): Oral: 50 to 60 mg/kg every 4 hours

Prevention of dental procedure bleeding in patients on oral anticoagulant therapy (off-label use): Oral rinse: Hold 4 g/10 mL in mouth for 2 minutes then spit out. Repeat every 6 hours for 2 days after procedure

Traumatic hyphema (off-label use): Oral: 50 mg/kg/dose every 4 hours (maximum daily dose: 30 g) for 5 days

PLACE OF ADMINISTRATION:

The recommendation is that oral and intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral or Intranasal

DRUG CLASS:
Hemostatics - Systemic

FDA-APPROVED USES:
Stimate (desmopressin acetate): indicated for patients with hemophilia A with Factor VIII coagulant activity levels greater than 5%. Stimate Nasal Spray is also indicated for patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%.

Lysteda (tranexamic acid) is indicated for the treatment of cyclic heavy menstrual bleeding in females of reproductive potential.

Amicar (aminocaproic Acid) is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, transfusion of appropriate blood products and other emergency measures may be required.

COMPENDIAL APPROVED OFF-LABELED USES:
Hereditary angioedema (HAE), long-term prophylaxis, Post-operative bleeding associated with cervical conization, Transurethral prostatectomy, or Traumatic hyphema. Prevention of dental procedure bleeding in patients on oral anticoagulant therapy, Traumatic hyphema, Control of oral bleeding in congenital and acquired coagulation disorder

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of hemostatic agents are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Stimate (desmopressin) include: No labeled contraindications. AMICAR should not be used when there is evidence of an active intravascular clotting process. When there is uncertainty as to whether the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC), this distinction must be made before administering AMICAR. The following tests can be applied to differentiate the two conditions: Platelet count is usually decreased in DIC but normal in primary fibrinolysis. Protamine Para coagulation test is positive in DIC; a precipitate forms when protamine sulfate is dropped into citrated plasma. The test is negative in the presence of primary fibrinolysis. The euglobulin clot lysis test is abnormal in primary fibrinolysis but normal in DIC. AMICAR must not be used in the presence of DIC without concomitant heparin. Contraindications to Lysteda (tranexamic acid) include: use with combination hormonal contraception, active thromboembolic disease, or a history or intrinsic risk of thrombosis or thromboembolism, including retinal vein or artery occlusion, and hypersensitivity to tranexamic acid.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Amicar SOLN 0.25GM/ML
Amicar TABS 500MG
Amicar TABS 1000MG
Aminocaproic Acid SOLN 0.25GM/ML
Aminocaproic Acid TABS 500MG
Aminocaproic Acid TABS 1000MG
Stimate SOLN 1.5MG/ML
Desmopressin Acetate SOLN 1.5MG/ML
Lysteda TABS 650MG
Tranexamic Acid Tab 650 MG

REFERENCES

1. Amicar (aminocaproic acid) [prescribing information]. Gurnee, IL: Akorn Operating Company LLC; March 2022.
2. Lysteda (tranexamic acid) (prescribing information). Parsippany, NJ: Ferring Pharmaceuticals Inc.; December 2020.
3. Stimate (desmopressin acetate) nasal spray [prescribing information]. King of Prussia, PA: CSL Behring; June 2013.
4. Brewer, A and Correa, ME. Guideline for Dental Treatment of Patients with Inherited Bleeding Disorders. Treatment of Hemophilia. 2006; 40:1-13.
5. Chauncey JM, Wieters JS. (2021). Tranexamic Acid. StatPearls. Accessed August 17, 2021, from: https://www.ncbi.nlm.nih.gov/books/NBK532909/

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Continuation of Therapy Prescriber Requirements FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Products Affected Required Medical Information Prescriber Requirements References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file