

## Tranexamic Acid Oral (Lysteda)

### Criteria for Use

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#### VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information. The VA National PBM-MAP-VPE Tranexamic Drug Monograph will be available soon at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov>.

#### EXCLUSION CRITERIA (if ONE is checked, patient is not eligible)

Hypersensitivity

##### **Due to increased thromboembolic risk:**

History of or active thromboembolic disease or intrinsic risk of thrombosis or thromboembolism (including retinal vein or artery occlusion)

Smoker

Obesity

Concomitant use of agents that increase thromboembolic risk including: combined hormonal contraceptives, factor IX complex concentrate or other anti-inhibitor coagulant concentrates, all-trans retinoic acid

#### INCLUSION CRITERIA (ALL must be selected for patient to be eligible)

Patient is not a candidate for any of the following treatment alternatives for heavy menstrual bleeding (e.g., contraindication, intolerance, unsatisfactory response, or patient refusal): combined hormonal contraceptives (i.e., estrogen plus progestin), progestin-only products, non-steroidal anti-inflammatory drugs (NSAIDs), or levonorgestrel-bearing intrauterine device (IUD).\*

#### DOSAGE AND ADMINISTRATION

▪ The FDA approved dose of oral tranexamic acid for heavy menstrual bleeding is 1,300 mg (two 650 mg tablets) three times a day for a maximum of 5 days during monthly menstruation. Tablets may be taken without regard to meals and should be swallowed whole, not chewed or broken. A reduced dose is required for patients with serum creatinine of greater than 1.4 mg/dL. (See Prescribing Information)

#### MONITORING

▪ Patients should be counseled on and monitored for adverse effects and risks (e.g., thromboembolic events, ocular effects).  
▪ Overall, tranexamic acid oral has not been found to significantly improve hemoglobin concentrations in the management of heavy menstrual bleeding.

#### ISSUES FOR CONSIDERATION

- **Indications for use:** Limit the use of oral tranexamic acid to women with cyclical heavy menstrual bleeding unrelated to fibroids or other uterine pathology. Benefits in other patient populations have not been established. Overall, tranexamic acid treatment has not resulted in clinically significant improvements in hemoglobin or complete resolution of menorrhagia (i.e., menstrual blood loss <80 mL per cycle).
- **Thromboembolic risk:** As an antifibrinolytic agent, tranexamic acid can increase thromboembolic risk. Avoid tranexamic acid treatment in women with a history of, increased risk of, or active thromboembolic disease (e.g., genetic predisposition, smoking, obesity, use of combination hormonal contraceptives or other agents that increase thromboembolic risk). FDA review of US post-marketing reports of venous and arterial thrombotic events in women taking oral tranexamic acid led to revised warnings and precautions in the product label in April 2011. In most cases, women were using tranexamic acid concomitantly with combined hormonal contraceptives and/or were obese.
- **Pregnancy:** Oral tranexamic acid (Lysteda) should not be used during pregnancy due to increased thromboembolic risk and no clinical benefit (menorrhagia does not occur during pregnancy). Tranexamic acid is a Category B based on animal studies that showed no adverse embryofetal effects or pregnancy outcomes, and animal studies showed no impaired fertility. . Tranexamic acid crossed the placenta in rats, and cord blood concentrations were similar to maternal concentrations. Counsel women of childbearing potential on benefits and risks of use, and discontinue if the patient becomes pregnant.
- **Lactation:** Based on limited data, tranexamic acid levels in human milk are about 1% of maternal serum concentrations.

\*The levonorgestrel IUD is available through Prosthetics in VA