REQUEST FOR APPROVAL
Form #EMSA-0391 **Revised 03/18/03**
Check One: □ Local Optional Scope of Practice **X <u>Trial Study</u>**
TXA Use in Trauma Patients by Paramedics in the Pre- Hospital Setting

1. <u>Description of the procedure or medication requested:</u>

Tranexamic acid – TXA (trade name Cyklokapron, Lysteda) is a synthetic derivative of the amino acid lysine. TXA blocks the formation of plasmin from plasminogen and, at high concentrations, noncompetitively inhibits plasmin. Plasmin is a molecule that triggers clot breakdown. TXA is excreted renally. The use of TXA as a supplement has been successful in the control of bleeding in hemophilia, preoperatively, gastric hemorrhage, menorrhagia, traumatic hyphema and in the treatment of hereditary angioedema. TXA is supplied in 1000mg ampules in 10mL normal saline.

Side effects:

- Acute gastrointestinal disturbances (nausea, vomiting and diarrhea; generally dose-related).
- Visual disturbances (blurry vision and changes in color perception, especially with prolonged use).
- Thromboembolic events (deep venous thrombosis, pulmonary embolism).
- Dizziness, fatigue, headache, and hypersensitivity reaction.

Administration and route:

- Administer 1 gram of TXA in 100 ml of 0.9% Normal Saline, intravenous or via interosseous device over 10 minutes as soon as possible but no later than three hours after injury (given by paramedics in the prehospital setting).
- Infuse a second gram of TXA IV or IO over 8 hours in 0.9% Normal Saline (given by RN's in the trauma centers). *See ICEMA Attachment A.*
- TXA SHOULD NOT to be administered through same line as blood products, rfactor VIIa, or Hexend.
- DO NOT administer as IV push, may cause hypotension.
- Drug must be stored at 59-86 degrees Fahrenheit.

Patients who receive TXA will be clearly identified with an approved wristband prior to transporting to a regional trauma center participating in the study.

2. <u>Description of the medical conditions for which the procedure/medication will be utilized:</u>

Patients must meet trauma triage criteria related to anatomic, physiologic, and mechanism of injury as established by REMSA. Refer to REMSA Policy #5301 - Trauma Triage Indicators and Destination.

- Additionally, patient must be: at least 18 years or older, less than three hours post injury, and meet any of the criteria listed below:

  - Blunt or penetrating trauma to the torso with signs and symptoms of hemorrhagic shock including a systolic blood pressure (SBP) of less than 90 mmHg.
  - Major amputation of any extremity, proximal to the wrist and ankle.
  - Bleeding uncontrolled by direct pressure or tourniquet.
  - Estimated external blood loss (EBL) of 500 ml or more in the field.

3. Alternatives (Please describe any alternate therapy[ies] considered for the same conditions and any advantages and disadvantages):

Other antifibrinolytic agents are available; however, we do not believe any are superior to TXA for EMS use.

4. An estimate of frequency of utilization:

5-10 patients per month

5. Other factors or exceptional circumstances:

None.

6. Any supporting data, including relevant studies and medical literature:

See ICEMA Attachment B.

7. Recommended policies/procedures to be instituted regarding:

TXA will be administered to blunt and trauma patients:

- Blunt or penetrating trauma to the torso with signs and symptoms of hemorrhagic shock including a systolic blood pressure (SBP) of less than 90 mmHg.
- Major amputation of any extremity, proximal to the wrist and ankle.
- Bleeding uncontrolled by direct pressure or tourniquet.
- Estimated external blood loss (EBL) of 500 ml or more in the field.

Medical Control:

Trauma Center base hospital will provide the medical control.

Treatment Protocols:

See REMSA Attachment A.

Quality assurance of the procedure or medication:

- All paramedic provider agencies participating in this study must use the REMSA ePCR system.
- REMSA will generate a daily list via ePCR and do the initial QA.
- Concurrently, paramedics participating in the TXA trial study will be required to notify the EMS Coordinator when TXA is administered upon completion of the incident. Each EMS coordinator will be required to QA the incident.
- Once a month the QA Leadership (EMS Coordinators, Principal Investigators, Trauma Medical Directors, ED Medical Directors, TPM's and EMS Agency) will meet and review all TXA administration cases, paying special attention to safety issues and fallouts.
- Severe adverse events (SAE) will be reported to EMSA and IRB within 24 hours of the incident.
- Adverse effects (AE) will be reported within 30 days.
- EMSA will receive a progress report at 6 months from the start of the trial and every 6 months until completion or as requested.
  See Attachment D.

Description of the training and competency testing required to implement the procedure or medication.

A training video will be developed to distribute to the EMS providers, MICN's and nurses and MD's. The video will contain an overview of the TXA, inclusion criteria for the study, protocol information, documentation, data collection and reporting process. This educational offering will be *minimally* 1.5 hours long. A written post-test will be required. Participating EMS agencies will have a 3 month period to educate the EMS providers before the official start of the trial study. (Enclosed is a draft of the educational PowerPoint presentation, this will be developed into a training video.) *See ICEMA Attachment E.*

9. <u>Copy of the local EMS System Evaluation and Quality Improvement Program plan for this request:</u>

See REMSA Attachment B.