Drug Class Review Monograph – GPI Class 84 – Hemostatics

Review Time Frame: January February 2016 – 01 January 2017

Previous Class Review: N/A

Background:
Hemostatics are used as adjuncts or alternatives to standard suturing techniques to control bleeding or for wound closure. Some of the systemic hemostatic agents include:

- **Tranexamic Acid** – a synthetic derivative of the amino acid lysine that exerts its antifibrinolytic effect through the reversible blockade of lysine binding sites on plasminogen molecules.
- **Aminocaproic Acid** – binds to lysine-binding sites within the plasminogen/plasmin molecule.
- **Phytonadione** – promotes the hepatic biosynthesis of vitamin K-dependent clotting factors.
- **Desmopressin** – induces the release of von Willebrand factor from its storage sites in endothelial cells.

New Treatment guideline recommendations pertaining to hemostatics:
- None identified

Newly approved drugs:
- None identified

Newly approved formulations:
- None identified

Newly approved generics:
- None identified

Discontinued drugs:
- None identified

FDA Safety Alert/black box warnings:
- None identified

Pipeline alerts:
Agents pending FDA approval include:
- **Andexanet alfa** – antidote for the oral factor Xa (FXa) inhibitors – a Complete Response Letter was given for andexanet’s BLA. FDA requested Portola Pharmaceuticals to provide additional information primarily related to manufacturing as well as additional data to support inclusion in the label of two additional anticoagulants, edoxaban and enoxaparin.
Summary/Recommendation:

*generic availability