



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Drotrecogin alfa (activated), Activated protein C

Brand Name: Xigris

Medication Class: Biologic response modifier (Anticoagulant, Profibrinolytic)

FDA Approved Uses: Reduction of mortality from severe sepsis (associated with organ dysfunction) in adults at high risk of death (e.g., APACHE II score ≥ 25)

Available Dosage Forms: Intravenous Powder for Solution: 5 MG, 20 MG

Usual Dose: 24 mcg/kg/hr IV for 96 hours

Duration of Therapy: 96 hours

Approximate Monthly Cost (based on AWP 2006): 96 hr course = \$ 10,548

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patients must have a diagnosis of severe sepsis
- Patients must be at high risk of death due to sepsis-induced organ dysfunction (APACHE II ≥ 25)

Criteria for Continuation of Therapy: There is no data on repeat dosing (efficacy and safety not established)

Cautions:

- Concurrent administration with other blood modifying agents
- Any condition in which bleeding is a significant hazard or would be especially difficult to manage

Monitoring:

- signs and symptoms of bleeding
- hemoglobin/hematocrit
- PT/INR
- platelet count

Contraindications:

- Active internal bleeding
- Intracranial neoplasm or evidence of cerebral herniation or mass lesion
- Known hypersensitivity to drotrecogin alfa (activated) or any of its components
- Recent hemorrhagic stroke (within 3 months)
- Recent intracranial or intraspinal surgery; severe head trauma (within 2 months)
- Presence of an epidural catheter
- Trauma with an increased risk of life-threatening bleeding



Not Approved if:

- Patient is at a low risk of death
- Patient has an APACHE II score <25
- Patient is a child
- Patient's death is imminent due to a preexisting condition.

Special Considerations: Studies have not shown mortality benefit in patients under 18 years, and patients with a low risk of death (e.g., single organ dysfunction or APACHE II <25). There is no data on the efficacy and safety of repeat dosing of Xigris. The mortality benefit of Xigris is highest when treatment is initiated within 48 hrs of organ dysfunction

P&T Approval: _____ Date: _____