

Interim Drotrecogin Alfa Administration Policy:

Drotrecogin alfa (recombinant human activated protein C, rhAPC) is recommended in patients at high risk of death and with no absolute contraindication related to bleeding risk or relative contraindication that outweighs the potential benefit of rhAPC. Specific decisions on rhAPC use must be based on a given patient's clinical situation.

This document establishes a standardized, rationale use policy for rhAPC. All three questions must be answered consecutively to administer rhAPC.

1. Inclusion Criteria (calculated at the time of rhAPC consideration):

A. Infection: does this patient have a known or suspected infection? ____ Yes ____ No

B. Systemic inflammation: patients *must meet 3 of 4 criteria*, check all that apply.

- | | |
|--|---|
| <input type="checkbox"/> Fever: ≥ 38.0 °C (100.4 °F) | <input type="checkbox"/> PCO ₂ ≤ 32 |
| <input type="checkbox"/> Hypothermia ≤ 36.0 °C (96.8 °F) | <input type="checkbox"/> WBC: $\geq 12,000$ |
| <input type="checkbox"/> Heart rate: ≥ 90 bpm | <input type="checkbox"/> WBC: $< 4,000$ |
| <input type="checkbox"/> Respiratory rate: ≥ 20 or ventilated | <input type="checkbox"/> $> 10\%$ immature forms |

C. Acute organ dysfunction: patients *must meet 1 or more* of the following:

- | | |
|--|---|
| <input type="checkbox"/> SBP < 90 or MAP < 70 .* | <input type="checkbox"/> PaO ₂ /FiO ₂ < 300 . |
| <input type="checkbox"/> Continued use of vasopressors to maintain SBP > 90 or MAP > 65 .* | <input type="checkbox"/> Platelet count $< 100,000$. |
| <input type="checkbox"/> Urine output < 0.5 mL/kg/hr x 2 hrs.* | <input type="checkbox"/> Acidosis with serum lactate > 2 mmol/L. |

* *despite minimum fluid resuscitation as directed in the resuscitation bundle.*

Are all inclusion criteria (A, B, C) met?

____ **Yes. Continue to question 2.**
____ **No. Stop evaluation for rhAPC.**

2. Relative Contraindications:

- | | |
|--|--|
| <input type="checkbox"/> Current use of therapeutic anticoagulation (ex: full dose heparin or LMWH, warfarin, IIB/IIIA inhibitors, recent thrombolysis). | <input type="checkbox"/> Recent (within 2 months) cranial procedure, spinal procedure or head trauma |
| <input type="checkbox"/> Active bleeding or coagulopathy | <input type="checkbox"/> Trauma with increased risk of bleeding |
| <input type="checkbox"/> Platelet count $< 30,000$ | <input type="checkbox"/> Epidural catheter |
| <input type="checkbox"/> Recent major surgery | <input type="checkbox"/> Intracranial mass or neoplasm |
| <input type="checkbox"/> Recent (within 3 months) hemorrhagic stroke | <input type="checkbox"/> Known hypersensitivity to rhAPC |
| | <input type="checkbox"/> Other: _____ |

Are there any relative contraindications that prohibit the use of rhAPC?

____ **Yes. Stop evaluation for rhAPC.**
____ **No. Continue to question 3.**

3. Severity of Illness:

In the efficacy trial cited above, the mortality benefit from rhAPC was almost entirely in the 50% of patients who were most ill. Markers for demonstrated benefit included 2 or more organ system failures and/or APACHE II scores ≥ 25 .

Is the patient at high risk of death due to severe sepsis?

____ **Yes. Administer rhAPC.**
____ **No. Do not administer rhAPC.**

Date: ____/____/____ (circle: dd/mm/yy or mm/dd/yy)

Time: ____: ____ (24 hr. clock)