

# Drotrecogin alfa (activated) Patient Selection Evaluation

Patient Name: \_\_\_\_\_  
 Date of Admission: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_

Medical Record Number: \_\_\_\_\_  
 Attending Physician/Resident: \_\_\_\_\_  
 Date: \_\_\_\_\_

CRITERIA	RESPONSE	CRITERION MET	COMMENTS
<b>Inclusion Criteria (Patient must meet inclusion criteria 1,2 and 3 for treatment consideration.)</b>			
1. Patient has known or suspected infection defined as: a. Positive culture or b. White cells in a normally sterile body fluid or c. Perforated viscus or d. Radiographic evidence of pneumonia in association with the production of purulent sputum	<input type="checkbox"/> yes <input type="checkbox"/> no	Patient meets criterion 1 if the answer is "YES" to the stated descriptors.  <input type="checkbox"/> Meets <input type="checkbox"/> Does not meet	
2. Patient has three or more signs of SIRS defined as: a. Core temperature of $\geq 38^{\circ}\text{C}$ (100.4°F) or $\leq 36^{\circ}\text{C}$ (96.8°F) b. Heart rate of $\geq 90$ beats/minute except in patients with a medical condition known to increase the heart rate or those receiving treatment that would prevent tachycardia c. Respiratory rate $\geq 20$ breaths/minute or a $\text{PaCO}_2 \leq 32$ mm Hg or the use of mechanical ventilation for an acute respiratory process d. White-cell count of $\geq 12,000/\text{mm}^3$ or $< 4,000/\text{mm}^3$ or a differential showing $>10$ percent immature neutrophils	<input type="checkbox"/> yes <input type="checkbox"/> no	Patient meets criterion 2 if the answer is "YES" to the stated descriptors.  <input type="checkbox"/> Meets <input type="checkbox"/> Does not meet	
3. Patient has at least one organ or system dysfunction defined as: a. Cardiovascular dysfunction: Arterial systolic blood pressure $\leq 90$ mm Hg or the mean arterial pressure $\leq 70$ mm Hg for at least one hour despite adequate fluid resuscitation, adequate intravascular volume status or the use of vasopressors in an attempt to maintain a systolic blood pressure of $\geq 90$ mm Hg or a mean arterial pressure of $\geq 70$ mm Hg or b. Kidney dysfunction: Urine output $< 0.5$ ml/kg of body weight/hour for $> 1$ hour, despite adequate fluid resuscitation or c. Respiratory dysfunction: Ratio of $\text{PaO}_2$ to $\text{FiO}_2 \leq 250$ in the presence of other dysfunctional organs or systems or $\leq 200$ if the lung was the only dysfunctional organ or d. Hematologic dysfunction: Platelet count $< 80,000/\text{mm}^3$ or decreased by 50 percent in the 3 days preceding enrollment or e. Unexplained metabolic acidosis: $\text{pH} \leq 7.30$ or the base deficit had to be $\geq 5.0$ mmol/liter in association with a plasma lactate level that was $> 1.5$ times the upper limit of the normal value for the reporting laboratory	<input type="checkbox"/> yes <input type="checkbox"/> no	Patient meets criterion 3 if the answer is "YES" to the stated descriptors.  <input type="checkbox"/> Meets <input type="checkbox"/> Does not meet	
<b>Exclusion Criteria (If the patient meets exclusion criterion 4, treatment is not recommended.)</b>			
4. Patient has one or more of the following: a. Active internal bleeding or b. Recent (within 3 months) hemorrhagic stroke or c. Recent (within 2 months) intracranial or intraspinal surgery, or severe head trauma or d. Trauma with an increased risk of life-threatening bleeding anesthesia or e. Presence of an epidural catheter or f. Intracranial neoplasm or mass lesion or evidence of cerebral herniation	<input type="checkbox"/> yes <input type="checkbox"/> no  <input type="checkbox"/> yes <input type="checkbox"/> no  <input type="checkbox"/> yes <input type="checkbox"/> no  <input type="checkbox"/> yes <input type="checkbox"/> no  <input type="checkbox"/> yes <input type="checkbox"/> no  <input type="checkbox"/> yes <input type="checkbox"/> no	Patient meets criterion 4 if the answer is "YES" to at least one of the stated descriptors.  <input type="checkbox"/> Meets <input type="checkbox"/> Does not meet	



# Drotrecogin alfa (activated) Patient Selection Evaluation (continued)

## EVALUATION SUMMARY

<b>Patient <i>must</i> meet inclusion criteria 1,2 and 3 for treatment consideration.</b>		
Criterion 1: Inclusion	<input type="checkbox"/> Meets	<input type="checkbox"/> Does not meet
Criterion 2: Inclusion	<input type="checkbox"/> Meets	<input type="checkbox"/> Does not meet
Criterion 3: Inclusion	<input type="checkbox"/> Meets	<input type="checkbox"/> Does not meet
<b>If the patient meets exclusion criterion 4, treatment is not recommended.</b>		
Criterion 4: Exclusion	<input type="checkbox"/> Meets	<input type="checkbox"/> Does not meet
<b>If the patient meets specific considerations within criterion 5, individualized evaluation is required prior to treatment consideration regardless of compliance to inclusion criteria.</b>		
Criterion 5: Special Considerations	<input type="checkbox"/> Meets	<input type="checkbox"/> Does not meet
<b>Other situations not specified in criterion 4 or 5 where individualized evaluation is required prior to treatment consideration regardless of compliance to inclusion criteria.</b>		
Other situations:	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## TREATMENT RECOMMENDATION

<input type="checkbox"/> Patient a candidate for drotrecogin alfa (activated) therapy <input type="checkbox"/> Patient <i>not</i> a candidate for drotrecogin alfa (activated) therapy
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