

Supplemental Data

Historical intravenous epoetin alfa dose^a

<u>Average Epoetin Alfa Dose (units per session)^b</u>	<u>Hemoglobin (g/dL)</u>
>4000 and ≤6000	≥8.0 and ≤9.5
>6000 and ≤8000	≥8.0 and ≤10.0
>8000 and ≤10000	≥8.0 and ≤10.5
>10000	≥8.0 and ≤11.0

^aFor inclusion, subjects' historical intravenous epoetin alfa dose and hemoglobin levels must be within these ranges for three 4-week periods for a total of 12 weeks concluding within the 2 weeks prior to Week -4.

^bTotal cumulative epoetin dose administered at all hemodialysis sessions over 4 weeks divided by the number of hemodialysis sessions attended

Stopping Criteria

Liver

1. ALT \geq 3 \times ULN and bilirubin \geq 2 \times ULN (>35% direct bilirubin) (or ALT \geq 3 \times ULN and INR >1.5, if INR measured).

NOTE: if serum bilirubin fractionation is not immediately available, withdraw study drug for that subject if ALT \geq 3 \times ULN and bilirubin \geq 2 \times ULN. Serum bilirubin fractionation should be performed if testing is available.

2. ALT \geq 5 \times ULN.

3. ALT \geq 3 \times ULN if associated with symptoms (new or worsening) believed to be related to hepatitis (such as fatigue, nausea, vomiting, right upper quadrant pain or tenderness, or jaundice) or believed to be related to hypersensitivity (such as fever, rash or eosinophilia).

4. ALT \geq 3 \times ULN persists for \geq 4 weeks

5. ALT \geq 3 \times ULN and cannot be monitored weekly for 4 weeks