Erythopoiesis Stimulating Agents (ESA) in Anemia Related to Kidney Disease

CMS Office of Clinical Standards and Quality
Coverage and Analysis Group
Division of Items and Devices

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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Purpose of the Meeting

CMS has called this meeting of the panel to review the available evidence on the use of erythropoiesis stimulating agents (ESAs) to manage anemia in patients who have chronic kidney disease (CKD).

Questions To Answer

1. **How confident are you that there is sufficient evidence to determine whether using a medical intervention (e.g., blood transfusion, iron therapy, or ESAs) to maintain or raise the hemoglobin or hematocrit levels of anemic CKD patients affects each of the health outcomes below?**

Questions To Answer

Question 1 (Cont'd)

- **Exercise (activity) tolerance**
- **Vascular events (stroke, myocardial infarction, congestive heart failure)**
- **Patient perceived quality of life**
- **Survival**

Questions To Answer

2. For any health outcome listed in Question 1 for which the panel indicates at least intermediate confidence (mean score ≥ 2.5) in the sufficiency of evidence, how confident are you that maintaining or raising hemoglobin or hematocrit levels of anemic CKD patients improves each such health outcome?

Questions To Answer

3a. For any health outcome addressed in Question 2 for which the panel indicates at least intermediate confidence (mean score ≥ 2.5), how confident are you that there is sufficient evidence to determine whether the use of ESAs to maintain or raise hemoglobin or hematocrit levels of CKD patients improves each such health outcome?

Questions To Answer

3b. For any health outcome addressed in Question 3.a. for which the panel indicates at least intermediate confidence (mean score ≥ 2.5), how confident are you that the use of ESAs to maintain or raise hemoglobin or hematocrit levels of CKD patients improves each such health outcome?

Questions To Answer

4a. How confident are you that there is sufficient evidence to determine whether the use of ESAs to maintain or raise the hemoglobin or hematocrit levels of anemic CKD patients worsens any health outcome listed in Question 1?

Questions To Answer

4b. For any health outcome addressed in Question 4.a. for which the panel indicates at least intermediate confidence (mean score ≥ 2.5), how confident are you that the use of ESAs to maintain or raise hemoglobin or hematocrit levels of CKD patients worsens each such health outcome?

Questions To Answer

5. Please discuss any impact of the following factors on the conclusions reached above.

   a. Whether the CKD patient is undergoing chronic dialysis or is in pre-dialysis status.

   b. Whether the CKD patient has pretreatment baseline hemoglobin levels:

   - < 7 g/dL
   - ≥7g/dL to < 9 g/dL
   - ≥9 g/dL to <12g/dL
   - ≥ 12 g/dL

Questions To Answer

Question 5 (Cont'd)

5c. Whether an appropriate target hemoglobin or hematocrit has been set for the CKD patient

5d. Whether the ESA dosing strategy has been implemented to minimize the rapidity of hemoglobin or hematocrit rise and/or oscillations in their levels

Questions To Answer

Question 5 (Cont'd)

5e. Whether the CKD patient has demonstrated a blunted or "non-response" to interventions to raise hemoglobin or hematocrit

5f. Whether the CKD patient has been evaluated to determine the etiology (cause) of the anemia

Questions To Answer

Question 5 (Cont'd)

5g. Whether the CKD patient demonstrates cardiac, cerebral or other vascular comorbidities

5h. Other

Questions To Answer

6. What clinical trials designs would be most desirable to fill in any identified evidence gaps?

Background

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