Sotatercept for Pulmonary Arterial Hypertension

Questions for Deliberation and Voting: December 1, 2023 Public Meeting

These questions are intended for the deliberation of the Midwest CEPAC voting body at the public meeting.

Patient Population for all questions: Adults with World Health Organization WHO Functional Class (WHO-FC) II and III pulmonary arterial hypertension (PAH) who are on background therapy.

Clinical Evidence

1. Is the evidence adequate to demonstrate that the net health benefit of sotatercept added to background therapy is superior to that provided by background therapy alone?

   Yes  No

Contextual Considerations and Potential Other Benefits or Disadvantages

Please vote on the following contextual considerations:

When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for PAH, on the basis of the following contextual considerations:

1=Very low priority; 2=Low priority; 3=Average priority; 4=High priority; 5=Very high priority

2. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability.
3. Magnitude of the lifetime impact on individual patients of the condition being treated.
Please vote on the following potential other benefits or disadvantages:

What are the relative effects of sotatercept added to background therapy versus background therapy alone on the following outcomes that inform judgement of the overall long-term value for money of sotatercept?

1=Major negative effect; 2=Minor negative effect; 3=No difference; 4=Minor positive effect; 5=Major positive effect

4. Patients’ ability to achieve major life goals related to education, work, or family life.
5. Caregivers’ quality of life and/or ability to achieve major life goals related to education, work, or family life.
6. Patients’ ability to manage and sustain treatment given the complexity of regimen.
7. Society’s goal of reducing health inequities.

Long-Term Value for Money

8. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with sotatercept added to background therapy versus background therapy alone?
   a. Low long-term value for money at assumed pricing.
   b. Intermediate long-term value for money at assumed pricing.
   c. High long-term value for money at assumed pricing.

*This vote will only be taken if a price becomes available for sotatercept.