Antiandrogen Therapies for Non-Metastatic Castration-Resistant Prostate Cancer: Effectiveness and Value

Draft Questions for Deliberation and Voting: September 13, 2018 Public Meeting

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

Patient Population: For each question, we are considering men with high risk (PSA doubling time $\leq 10$ months) nonmetastatic castration-resistant prostate cancer being treated with androgen deprivation therapy. The comparator is waiting to add antiandrogen therapy with either abiraterone acetate or enzalutamide until the development of detectable metastatic disease.

Clinical Evidence

1) Is the evidence adequate to demonstrate a net health benefit of treating with apalutamide?

   Yes          No

2) Is the evidence adequate to demonstrate a net health benefit of treating with enzalutamide?

   Yes          No

3) Is the evidence adequate to demonstrate a net health benefit of treating with abiraterone acetate?

   Yes          No

4) Is the evidence adequate to distinguish the net health benefits of apalutamide and enzalutamide?

   Yes          No

5) Is the evidence adequate to demonstrate that abiraterone acetate has comparable efficacy to apalutamide and enzalutamide?

   Yes          No
Potential Other Benefits

6) Does treating patients with antiandrogen therapies offer one or more of the following “potential other benefits?” (select all that apply)
   a. This intervention offers reduced complexity that will significantly improve patient outcomes.
   b. This intervention will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
   c. This intervention will significantly reduce caregiver or broader family burden.
   d. This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
   e. This intervention will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.
   f. There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____________.

   Yes    No    Uncertain

7) Are any of the following contextual considerations important in assessing antiandrogen therapies’ long-term value for money? (select all that apply)
   a. This intervention is intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
   b. This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
   c. This intervention is the first to offer any improvement for patients with this condition.
   d. There is significant uncertainty about the long-term risk of serious side effects of this intervention.
   e. There is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
   f. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: __________________________.

   Yes    No    Uncertain
Long-term Value for Money

8) In men with high risk (PSA doubling time ≤10 months) non-metastatic castration resistant prostate cancer being treated with androgen deprivation therapy, given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering potential other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with apalutamide compared with waiting to add antiandrogen therapy with either abiraterone acetate or enzalutamide until the development of detectable metastatic disease?

Low Intermediate High

9) In men with high risk (PSA doubling time ≤10 months) non-metastatic castration resistant prostate cancer being treated with androgen deprivation therapy, given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering potential other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment with enzalutamide compared with waiting to add antiandrogen therapy with either abiraterone acetate or enzalutamide until the development of detectable metastatic disease?

Low Intermediate High