Elagolix for Treating Endometriosis

Draft Questions for Deliberation and Voting: July 12, 2018 Public Meeting

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

Patient Population for all questions: Adult premenopausal women with symptomatic endometriosis and moderate-to-severe symptoms.

Clinical Evidence

1) Is the evidence adequate to demonstrate that the net health benefit of elagolix is superior to that provided by no treatment?
   Yes   No

2) Is the evidence adequate to demonstrate that the net health benefit of elagolix is superior to that provided by the GnRH agonist, leuprorelin acetate?
   Yes   No

3) Is the evidence adequate to demonstrate that the net health benefit of elagolix is superior to that provided by hormonal contraceptive, depot medroxyprogesterone?
   Yes   No

Contextual Considerations/Other Benefits

4) When compared to no treatment, does elagolix offer one or more of the following “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: __________________

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5) Are any of the following contextual consideration important in assessing 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. Compared to no treatment, there is significant uncertainty about the long-term risk of serious side effects of this intervention.
   e. Compared to no treatment, 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: __________________________.

Long-term Value for Money

6) Given the available evidence on comparative clinical effectiveness and the range of values for incremental cost effectiveness for both dysmenorrhea and non-menstrual pelvic pain, and considering other benefits and contextual considerations, what is the long-term value for money of elagolix compared with no active treatment?
   
   Low        Intermediate        High