



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: _____

- 5) Are any of the following contextual considerations 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