Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Chronic or Episodic Migraine: Effectiveness and Value

Draft Questions for Deliberation and Voting
June 14, 2018 Public Meeting

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

Clinical Evidence

Patient Population for questions 1-3: Adult patients who experience 15 or more headache days per month (i.e., chronic migraine) for whom other preventive therapies have failed.

1. Is the evidence adequate to distinguish the net health benefits among the CGRP inhibitors erenumab, fremanezumab, and galcanezumab?
   Yes  No

2. Is the evidence adequate to demonstrate a net health benefit for treatment with CGRP inhibitors versus no treatment?
   Yes  No

3. Is the evidence adequate to distinguish the net health benefit between treatment with CGRP inhibitors and onabotulinum toxin A (Botox®, Allergan)?
   Yes  No

Patient Population for questions 4-5: Adult patients with migraine not classified as chronic (i.e., “episodic” migraine) for whom other preventive treatment has failed.

4. Is the evidence adequate to distinguish the net health benefits among the CGRP inhibitors erenumab, fremanezumab, and galcanezumab?
   Yes  No

5. Is the evidence adequate to demonstrate a net health benefit for treatment with CGRP inhibitors versus no treatment?
   Yes  No
Contextual Considerations/Other Benefits

*Patient population for questions 6-7: Adult patients who experience 15 or more headache days per month (i.e., chronic migraine) for whom other preventive therapies have failed AND adult patients with migraine not classified as chronic (i.e., “episodic” migraine) for whom other preventive treatment has failed.*

6. Does treating patients with CGRP inhibitors 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: ________________

7. Are any of the following contextual considerations important in assessing CGRP inhibitors’ 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: __________________________.

Long-term Value for Money

*Patient Population for questions 8-11: Adult patients who experience 15 or more headache days per month (i.e., chronic migraine) for whom other preventive therapies have failed.*

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 with erenumab versus no treatment?
   a. Low          b. Intermediate          c. High
9. 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 with fremanezumab versus no treatment?
   a. Low   b. Intermediate   c. High

10. 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 with erenumab versus onabotulinum toxin A?
    a. Low   b. Intermediate   c. High

11. 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 with fremanezumab versus onabotulinum toxin A?
    a. Low   b. Intermediate   c. High

**Patient Population for questions 12-13: Adult patients with migraine not classified as chronic (i.e., “episodic” migraine) for whom other preventive treatment has failed.**

12. 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 with erenumab versus no treatment?
    a. Low   b. Intermediate   c. High

13. 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 with fremanezumab versus no treatment?
    a. Low   b. Intermediate   c. High