



Oral Immunotherapy and Viaskin[®] Peanut for Peanut Allergy: Effectiveness and Value

Questions for Deliberation and Voting: June 11, 2019 Public Meeting

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

Patient Population for questions:

- **AR101:** Children between the ages of four and 17 years with peanut allergy.
- **Viaskin Peanut:** Children between the ages of four and 11 years with peanut allergy.

Clinical Evidence

1. Is the evidence adequate to demonstrate that the net health benefit of AR101 plus strict peanut avoidance is superior to continued avoidance alone?

Yes No

2. Is the evidence adequate to demonstrate that the net health benefit of Viaskin Peanut plus strict peanut avoidance is superior to continued avoidance alone?

Yes No

3. Is the evidence adequate to distinguish the net health benefit of AR101 and Viaskin Peanut?

Yes No

3a. If the answer to Q3 is Yes: Based on the available evidence, which therapy has greater net health benefit: (a) AR101 plus strict peanut avoidance, or (b) Viaskin Peanut plus strict peanut avoidance?

a. AR101 b. Viaskin Peanut

4. Is the evidence adequate to demonstrate that the net health benefit of AR101 is superior to oral immunotherapy as practiced currently?

Yes No

Potential Other Benefits and Contextual Considerations

5. Does desensitizing patients with Viaskin Peanut offer one or more of the following potential “other benefits” in comparison to strict peanut avoidance alone? (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, school, 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 Viaskin Peanut: _____

6. Does desensitizing patients with AR101 offer one or more of the following potential “other benefits” in comparison to strict peanut avoidance alone? (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, school, 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 AR101: _____

7. Are any of the following contextual considerations important in assessing the long-term value for money for Viaskin Peanut in comparison to strict peanut-avoidance alone? (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. There is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - c. There is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - d. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

8. Are any of the following contextual considerations important in assessing the long-term value for money for AR101? (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. There is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - c. There is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - d. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

Long-Term Value for Money¹

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 AR101 plus strict peanut avoidance compared with continued avoidance alone?
- a. Low long term value for money
 - b. Intermediate long term value for money
 - c. High long term value for money
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 Viaskin Peanut plus strict peanut avoidance compared with continued avoidance alone?
- a. Low long term value for money
 - b. Intermediate long term value for money
 - c. High long term value for money

¹ Note: AR101 and Viaskin Peanut value votes will only be taken if the prices have been announced by the time of the June 11 public meeting.