



Additive Therapies for Cardiovascular Disease

Questions for Deliberation and Voting: September 26th Public Meeting

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

Patient population for all questions relating to:

- **Rivaroxaban:** Adults with established cardiovascular disease who are currently being treated with optimal medical management
- **Icosapent Ethyl:** Adults with either established cardiovascular disease or at high risk for cardiovascular disease who are currently being treated with optimal medical management (including statins).

Clinical Evidence

1. Is the evidence adequate to demonstrate that the net health benefit of rivaroxaban plus ASA is superior to that provided by ASA alone?

Yes No

2. Is the evidence adequate to demonstrate that the net health benefit of rivaroxaban plus ASA is superior to that provided by ASA as part of dual antiplatelet therapy (DAPT) with an oral P2Y₁₂ inhibitor (e.g. ticagrelor or clopidogrel)?

Yes No

3. Is the evidence adequate to demonstrate that the net health benefit of icosapent ethyl added to optimal medical management (including statin therapy) is superior to that provided by optimal medical management (including statin therapy) alone?

Yes No

Potential Other Benefits and Disadvantages and Contextual Considerations

4. Does treating patients with rivaroxaban plus ASA offer one or more of the following potential “other benefits or disadvantages” compared to ASA alone? (Select all that apply.)
 - a. This intervention will significantly reduce caregiver or broader family burden.
 - b. 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.
 - c. This intervention will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.
 - d. There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____.

5. Does treating patients with icosapent ethyl offer one or more of the following potential “other benefits or disadvantages” compared to optimal medical management (including statin therapy) alone? (Select all that apply.)
 - a. This intervention will significantly reduce caregiver or broader family burden.
 - b. 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.
 - c. This intervention will have a significant impact on improving patients’ ability to return to work and/or their overall productivity.
 - d. There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____.

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

Long-Term Value for Money

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 rivaroxaban plus ASA versus ASA alone?
 - a. Low long-term value for money at current pricing
 - b. Intermediate long-term value for money at current pricing
 - c. High long-term value for money at current pricing
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 rivaroxaban plus ASA versus ASA as part of DAPT with clopidogrel?
 - a. Low long-term value for money at current pricing
 - b. Intermediate long-term value for money at current pricing
 - c. High long-term value for money at current pricing
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 icosapent ethyl in addition to optimal medical management (including statin therapy) versus optimal medical management (including statin therapy) alone?
 - a. Low long-term value for money at current pricing
 - b. Intermediate long-term value for money at current pricing
 - c. High long-term value for money at current pricing