



Additive Therapies for Cardiovascular Disease

Draft 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 on September 26th in Saint Louis, MO.

Patient population for all questions relating to:

- **Rivaroxaban:** Adults with established cardiovascular disease
- **Icosapent Ethyl:** Adults with either established cardiovascular disease or at high risk for cardiovascular disease

Clinical Evidence

1. For patients currently receiving optimal medical management, 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. For patients currently receiving optimal medical management, 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., clopidogrel)?

Yes

No

3. For patients currently receiving statin therapy, is the evidence adequate to demonstrate that the net health benefit of adding icosapent ethyl is superior to that provided by optimal medical management alone?

Yes

No

Potential Other Benefits and Disadvantages and Contextual Considerations

4. For patients currently receiving optimal medical management, 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. For patients currently receiving statins, does treating patients with icosapent ethyl offer one or more of the following potential “other benefits or disadvantages” compared to optimal medical management 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. For patients currently receiving optimal medical management, are any of the following contextual considerations important in assessing the long-term value for money for rivaroxaban plus ASA compared to ASA 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. 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. For patients currently receiving statins, are any of the following contextual considerations important in assessing the long-term value for money for icosapent ethyl compared to optimal medical management 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. 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
 - b. Intermediate long-term value for money
 - c. High long-term value for money
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 as part of DAPT with an oral P2Y12 inhibitor (e.g. clopidogrel)?
 - 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 icosapent ethyl in addition to optimal medical management (including statins) versus optimal medical management alone?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money