



Inclisiran and Bempedoic Acid for Patients with Heterozygous Familial Hypercholesterolemia and for Secondary Prevention of ASCVD: Effectiveness and Value

Draft Questions for Deliberation and Voting at the February 5, 2021 Public Meeting

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

Clinical Evidence

Patient population for questions 1 and 2: All adult patients with established ASCVD and/or HeFH who have elevated LDL-C levels despite treatment with maximally tolerated oral lipid-lowering therapy.

1. Given today's evidence, is the evidence adequate to demonstrate that the net health benefit of adding **bempedoic acid** (Nexletol™) to usual care is superior to that provided by usual care alone?

Yes

No

2. Given today's evidence, is the evidence adequate to demonstrate that the net health benefit of adding **inclisiran** to usual care is superior to that provided by usual care alone?

Yes

No

Potential Other Benefits and Contextual Considerations

With ICER's 2020 value assessment framework update, ICER now uses a three-item Likert scale voting format.

- Please vote 1, 2, or 3 on the following potential other benefits and contextual considerations as they relate to **bempedoic acid** (Nexletol™). When an active comparator is mentioned please consider statin therapy. Refer to the table below.
- Please vote 1, 2, or 3 on the following potential other benefits and contextual considerations as they relate to **inclisiran**. When an active comparator is mentioned please consider inclisiran versus PCSK9 inhibitor drugs. Refer to the table below.

Likert Scale of Potential Other Benefits and Contextual Considerations		
1 (Suggests Lower Value)	2 (Intermediate)	3 (Suggests Higher Value)
Uncertainty or overly favorable model assumptions creates significant risk that base-case cost-effectiveness estimates are too optimistic.		Uncertainty or overly unfavorable model assumptions creates significant risk that base-case cost-effectiveness estimates are too pessimistic.
Very similar mechanism of action to that of other active treatments.		New mechanism of action compared to that of other active treatments.
Delivery mechanism or relative complexity of regimen likely to lead to much lower real-world adherence and worse outcomes relative to an active comparator than estimated from clinical trials.		Delivery mechanism or relative simplicity of regimen likely to result in much higher real-world adherence and better outcomes relative to an active comparator than estimated from clinical trials.
This intervention will not differentially benefit a historically disadvantaged or underserved community.		This intervention will differentially benefit a historically disadvantaged or underserved community.
Small health loss without this treatment as measured by absolute QALY shortfall.		Substantial health loss without this treatment as measured by absolute QALY shortfall.
Small health loss without this treatment as measured by proportional QALY shortfall.		Substantial health loss without this treatment as measured by proportional QALY shortfall.
Will not significantly reduce the negative impact of the condition on family and caregivers vs. the comparator.		Will significantly reduce the negative impact of the condition on family and caregivers vs. the comparator.
Will not have a significant impact on improving return to work and/or overall productivity vs. the comparator.		Will have a significant impact on improving return to work and/or overall productivity vs. the comparator.
Other		Other

Long-Term Value for Money

Patient population for question 5: All adult patients with established ASCVD and/or HeFH who have elevated LDL-C levels despite treatment with maximally tolerated statin therapy.

5. 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 at current pricing of adding **bempedoic acid with ezetimibe** to usual care versus usual care with **ezetimibe**?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

Patient population for question 6: All adult patients with established ASCVD and/or HeFH who have elevated LDL-C levels despite treatment with maximally tolerated oral lipid-lowering therapy.

6. 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 at current pricing of adding **inclisiran** to usual care versus **usual care alone**?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money

Patient population for questions 7 and 8: All adult patients with established ASCVD – with or without HeFH – who have elevated LDL-C levels and have statin-associated side effects (“statin intolerant”).

7. 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 at current pricing of adding **bempedoic acid with ezetimibe** to usual care versus usual care with **ezetimibe**.
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High 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 at current pricing of adding **inlisiran** to usual care versus **usual care alone**?
 - a. Low long-term value for money
 - b. Intermediate long-term value for money
 - c. High long-term value for money