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Submitted Electronically: [mogrady@icer-review.org](mailto:mogrady@icer-review.org), [publiccomments@icer-review.org](mailto:publiccomments@icer-review.org)

Dear Ms. O’Grady,

Thank you for the opportunity to provide feedback to ICER on its draft scoping document for assessing the comparative clinical effectiveness and value of inclisiran (Novartis) and bempedoic acid (Nexletol™, Esperion Therapeutics, Inc.) for treatment of high cholesterol in the setting of heterozygous familial hypercholesterolemia or secondary prevention of ASCVD. We appreciate your willingness to review comments and recommendations from the National Forum’s Value & Access Steering Committee and partners working on these issues.

The Value & Access Steering Committee and partners reviewed the draft scoping document and jointly offer the following feedback for ICER’s consideration.

**Positives:**

The Steering Committee and partners affirm the inclusion of the following key points in the draft scoping document:

- Consideration of the HeFH and ASCVD populations separately
- Inclusion of people with statin intolerance
- Review of both bempedoic acid alone and in combination with ezetimibe
- Inclusion of health-related quality of life among Patient-Important Outcomes

**Opportunities:**

The Steering Committee and partners identified the following opportunities for the review.

- As mentioned in the section above, we appreciate the examination of data related to patients with HeFH with and without established ASCVD (secondary and primary prevention).
  - High ASCVD event rates suggest that adults with FH warrant designation as having an ASCVD risk equivalent even though they have not had an event. Earlier and more aggressive therapy of FH is needed to prevent ASCVD events.<sup>1</sup> Importantly, evidence suggests that health disparities

contribute to undertreatment of FH patients in the US.<sup>2</sup> Increased efforts are warranted to raise awareness and treatment of these patients.

- Health system utilization was not included among outcomes. Based on the increased healthcare resource utilization by people with ASCVD, including these costs is important to gain a complete understanding of the cost-effectiveness of the treatments being reviewed.
- We recommend that future reviews focus on cost and clinical effectiveness in which ICER has demonstrated strength, and not include budget impact analysis. However, if this review includes a budget impact analysis, we recommend using realistic estimates of the actual use of medications and the cost of non-utilization and non-adherence. Data show that the overall non-utilization /non-adherence rate can be up to 50%.<sup>3</sup> In patients with hyperlipidemia, data show between 44.4% and 52.7% non-adherence.<sup>4</sup> Leaving out the non-utilization rate would distort the overall budget impact.
- We appreciate your inclusion of information on wasteful or lower-value services and recommend that you interview Dr. Mark Fendrick, Director of the University of Michigan's Center for Value-Based Insurance Design whose work centers around these issues. Dr. Fendrick is a member of the Value & Access Steering Committee. We would be happy to introduce you to him.

Again, thank you for your consideration. We would like to have the opportunity for representatives from the Steering Committee to meet with your team to further the conversation.

Sincerely,

Members of the Value & Access Steering Committee and Partners representing the following organizations:

*National Forum for Heart Disease & Stroke Prevention (convener)*  
*American Association of Heart Failure Nurses*  
*American Heart Association*  
*American Pharmacists Association Foundation*  
*Association of Black Cardiologists*  
*Association of State and Territorial Health Officials*  
*BallengeRx Consulting*  
*The FH Foundation*  
*Global Healthy Living Foundation*  
*Independent Health*  
*Institute for Patient Access*  
*Mended Hearts*  
*National Alliance of Healthcare Purchaser Coalitions*

*National Lipid Association  
Partnership to Advance Cardiovascular Health  
Partnership to Improve Patient Care  
Preventive Cardiovascular Nurses Association  
University of Michigan Center for Value-Based Insurance Design  
WomenHeart*

## **References**

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- <sup>1</sup> Duell PB, Gidding SS, Andersen RL, et. al. Longitudinal low density lipoprotein cholesterol goal achievement and cardiovascular outcomes among adult patients with familial hypercholesterolemia: The CASCADE FH registry. *Atherosclerosis*. 2019;289:85-93. DOI:<https://doi.org/10.1016/j.atherosclerosis.2019.08.007>
- <sup>2</sup> Amrock SM, Duell PB, Knickelbine T, et al. Health disparities among adult patients with a phenotypic diagnosis of familial hypercholesterolemia in the CASCADE-FH™ patient registry. *Atherosclerosis*. 2017;267:19-26. doi:10.1016/j.atherosclerosis.2017.10.006
- <sup>3</sup> Osterberg L, Blaschke T, Adherence to medication. *N Engl J Med*. 2005; 353: 487- 97. <https://doi.org/10.1056/NEJMra050100>
- <sup>4</sup> Gillespie CW, Morin PE, Tucker JM, et. al. Medication Adherence, Health Care Utilization, and Spending Among Privately Insured Adults With Chronic Conditions in the United States, 2010-2016. *Am J Med*. 2020;133:690-704. DOI:<https://doi.org/10.1016/j.amjmed.2019.12.021>