Thank you for the opportunity to provide comments. I speak on behalf of the National Forum for Heart Disease & Stroke Prevention, a nonprofit convener for public-private collaboration to improve cardiorenal metabolic health, and the members of the Value & Access Collaborative, who represent patients, providers, public health, payers, purchasers, and pharmaceutical and biotechnology companies. The Collaborative provides consensus input to ICER on a variety of reviews.

Hypertension remains one of the most significant drivers of cardiovascular morbidity and mortality in the United States. Fewer than half of people with hypertension have their blood pressure under control, demonstrating that the current treatment arsenal is insufficient. Resistant hypertension contributes to persistent gaps in blood pressure control and disproportionately affects communities already facing structural barriers to health and well-being. Given the burden of disease and the limitations of existing therapies, the evaluation of new aldosterone synthase inhibitors (ASIs), including baxdrostat and lorundrostat, is both timely and important.

Today, I would like to highlight several recommendations from our Collaborative.

First, patient perspectives should be more fully incorporated into the economic model dataset.

While we appreciate ICER's inclusion of patient perspectives in the narrative report, patient-reported experience, including pill burden, side effects, adherence challenges, and barriers to access, directly affects real-world outcomes and should be reflected in the economic model. Adherence and tolerability materially influence blood pressure control and long-term cardiovascular risk, and critical patient-important outcomes may otherwise be overlooked.

Second, we encourage ICER to revisit key model assumptions related to uptake, tolerability, and discontinuation.

The draft report assumes that 20 percent of eligible patients will receive baxdrostat in its first year. However, studies show that uptake of novel cardiometabolic therapies typically remains in the low single digits during year one due to payer controls, step therapy, prior authorization, and slow clinician adoption. Overestimating uptake inflates budget impact and may lead to inappropriate conclusions about affordability.

We also encourage ICER to account for tolerability-related discontinuation. Older mineralocorticoid receptor antagonists (MRAs) are often discontinued because of side effects

that limit real-world effectiveness and contribute to persistent uncontrolled hypertension. Because ASIs may reduce these barriers due to their nonsteroidal mechanism, ICER's model should incorporate discontinuation rates and tolerability-related adherence patterns.

Third, fair access considerations should be incorporated into the revised model.

Resistant hypertension disproportionately affects Black adults and individuals with lower socioeconomic status, and access to specialized care and newer therapies is uneven across geographic and demographic groups. We recommend incorporating differential access, geographic variation, and disparities in tolerability and adherence into the revised model.

Fourth, we urge caution in interpreting the current clinical evidence.

Long-term outcomes data for ASIs are not yet available. However, short-term blood pressure reduction remains a useful surrogate for long-term cardiovascular risk reduction, and early hypertension trials rarely include long-term outcomes. We recommend that ICER avoid prematurely assigning "comparable or inferior" ratings based solely on short-term data. Additionally, longer-term data presented at the European Society of Cardiology Congress showed that baxdrostat achieved significantly lower systolic blood pressure than standard of care plus placebo, with benefits that were durable and greater at 52 weeks.

Finally, we encourage caution in interpreting early cost-effectiveness and budget impact estimates.

Cost-effectiveness for new therapies is inherently uncertain. We recommend that ICER emphasize this uncertainty, avoid conclusions that may inadvertently create access barriers, clearly distinguish cost-effectiveness findings from budget impact projections, and avoid linking budget impact to recommended price ranges.

In closing, we appreciate ICER's thorough review and commitment to transparency and stakeholder engagement. ASIs may offer an important alternative for patients who cannot tolerate MRAs, who face adherence barriers, or who lack access to specialized care. We respectfully urge ICER to incorporate additional patient perspectives, contemporary real-world evidence, fair access considerations, and realistic uptake assumptions into the revised evidence report.

Thank you for your consideration.