Mavacamten for Hypertrophic Cardiomyopathy: Policy Recommendations

November 16, 2021

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the policy roundtable discussion at the October 22, 2021 California Technology Assessment Forum (CTAF) public meeting on the use of mavacamten for the treatment of hypertrophic cardiomyopathy (HCM). At the meeting, ICER presented the findings of its revised report on this treatment and the CTAF voting panel deliberated on key questions related to the treatment's comparative clinical effectiveness and potential other benefits and contextual considerations. Following the votes, ICER convened a policy roundtable of two patients, two clinical experts, and two payers to discuss how best to apply the evidence and votes to real-world practice and policy. The manufacturer declined to send a representative to participate in the policy roundtable. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on policy roundtable participants, including conflict of interest (COI) disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Dr. Steven Pearson, MD, MSc, President of ICER. The themes and recommendations from the discussion are organized by audience and summarized below.

All Stakeholders

All stakeholders have a responsibility to facilitate meaningful patient access to multidisciplinary centers of excellence for HCM in ways that do not exacerbate disparities.

The most recent clinical guidelines developed by the American Heart Association/American College of Cardiology in 2020 for management of HCM explicitly recommend (class 2a) "consultation with or referral to" experienced multidisciplinary centers to aid in complex management decisions. Furthermore, for patients with hypertrophic obstructive cardiomyopathy (HOCM), the guidelines strongly recommend that septal reduction procedures are performed in such centers (class 1).

Access to the expertise offered by these experienced multidisciplinary centers is critically important for several reasons. Although HCM is not a rare condition, many general cardiologists do not have deep expertise in diagnosis or management of HCM. HCM can mimic other disease conditions such as infiltrative cardiomyopathies and hypertensive heart disease, and even variants of normal (such

as normal athlete's heart). Electrocardiograms for patients with HCM often mimic electrocardiograms for acute myocardial infarction (heart attack). As such, patients report unnecessary care escalations. In part because of these issues, patients report frustration interacting with care teams that do not have expertise in HCM. Furthermore, the diagnosis, monitoring, and management of patients with HCM often require specialized expertise in cardiac imaging and the interpretation of genetic data available only at specific centers. Lack of access to specialized centers can lead to health care disparities with respect to wealth, income, location, and race.

However, community-based physicians, including general cardiologists, also have an important role in the management of patients with HCM. Ideal care pathways could include regular care from an accessible local cardiologist with intermittent input from experts at centers of excellence. These ideal care pathways, however, are complicated by lack of access to telemedicine, restrictions on the practice of medicine between states, and payment policies limiting reimbursement for interprofessional (community physician to specialist physician) consultation.

To address these concerns:

<u>Payers should take the following actions:</u>

- Provide adequate reimbursement for telemedicine and interprofessional consultation between centers of excellence and community cardiologists to facilitate both access to care and appropriate subspecialist expertise when needed. Adequate reimbursement for telemedicine is also important both for initial consultation and ongoing monitoring for patients taking mavacamten.

- If payers restrict access to mavacamten to providers at specialized centers of excellence, they should work with the patient community as well as clinical experts to select these centers. Designations of centers of excellence should be meaningful. For example, provider self-attestation of expertise is unlikely to be meaningful and accurate. The HCM patient community has spent many years developing an understanding of which centers reflect the full spectrum of expertise and experience needed for excellent care of patients with HCM, and payers should collaborate with the patient community to leverage this work.

- Ensure that in the setting of promising short-term efficacy but long-term unresolved questions about safety, mavacamten is prescribed in centers with appropriate expertise and monitoring protocols. In the policy roundtable, both patients and clinical experts expressed safety concerns about the prospect of widespread use of mavacamten shortly after approval prior to the generation of longer-term data. If longer-term concerns about safety are resolved with time, however, any restrictions could be loosened to allow mavacamten to be prescribed in broader settings by a greater range of cardiologists.

Clinical specialty societies should take the following actions:

- Work with patient organizations to develop and validate standards for centers of excellence for HCM. For example, the Hypertrophic Cardiomyopathy Association has identified centers of excellence available on their website (www.4hcm.org/center-of-excellence). Aligning this type of list with input from professional societies could inform payer policy in a patient- and clinician-informed way.

- Work with payers, regulators, and patients to develop educational tools to improve knowledge about the management of HCM among community providers, including situations in which referral to a center of excellence is important.

- Continue to educate cardiologists about the critical importance of shared decision-making for all treatment options for HCM, including therapies to reduce left ventricular outflow tract (LVOT) gradient in patients with symptomatic HOCM. The 2020 guidelines recommend shared decision-making in HCM (class 1).

Organizations that provide health care should take the following actions:

- Develop and use platforms to share primary imaging data between community providers and centers of excellence to improve accuracy of diagnosis and appropriate utilization of treatments for HCM, including symptomatic HOCM. Both diagnosis and ongoing management for patients with HCM require relevant imaging and genetic counseling expertise.

- Restrict the performance of surgical myectomy and alcohol septal ablation to high-volume procedural centers with appropriate supportive services including cardiac critical care.

- Centers and providers with less expertise should establish referral pathways to and relationships with high-volume centers to ensure equity in access to patients (despite the restriction of the procedures to higher-volume centers). Since patients with HCM often seek emergency care in different settings, for example when traveling, emergency providers should have pathways to communicate with subspecialty experts in HCM when needed even when they are not physically available.

Manufacturers

The manufacturer of mavacamten should:

Commit to sponsoring research that will address the lack of evidence on the comparative effectiveness of mavacamten versus disopyramide and septal reduction procedures.

When patients with symptomatic HOCM have inadequate relief or intolerable side effects with beta blockers and calcium channel blockers, clinical guidelines support the use of disopyramide and or septal reduction procedures. After mavacamten is available, it will also become an important treatment option. Disopyramide has been approved for clinical use for many decades. The evidence evaluating the effectiveness of disopyramide is limited, but there are fewer concerns about long-term adverse effects because of more experience. As a practical matter, the short-acting form is difficult to use for patients because of a short half-life and four times per day daily dosing. However, the long-acting form, which can be given twice per day, is difficult to obtain because of drug shortages. If access to the long-acting form of disopyramide improves, it could provide a treatment option that works for many patients. Many of the patients with NYHA class III symptoms in the EXPLORER trial may also have been potential candidates for septal reduction therapies. Although VALOR-HCM will likely provide some important information for these patients, VALOR-HCM does not compare mavacamten to septal reduction procedures directly and as such, will not resolve the question of comparative effectiveness of mavacamten versus these procedures.

In that context, data are inadequate to inform important clinical choices such as:

1) Disopyramide versus mavacamten
2) Mavacamten versus alcohol septal ablation
3) Mavacamten versus surgical myectomy
4) Surgical myectomy versus alcohol septal ablation.

Although prospective, randomized trials with at least one to two years follow up would be ideal to establish evidence for these comparisons, some comparisons such as surgical myectomy versus alcohol septal ablation are likely never to occur. In that context, observational analyses with proper statistical methods to account for confounding and selection bias may be able to provide some information on the comparative effectiveness of these options.

Align the price of mavacamten with the explicit and transparent estimates of its treatment benefits for patients and families. Pricing should also be moderated to reflect the uncertainty about longer-term safety until such time as further outcomes data are generated.

- There is no available price for mavacamten. However, an analyst estimate suggests that the price of mavacamten could far exceed a price aligned with its value. Our analysis suggests a health-benefit price benchmark (HBPB) of $12,000-$15,000 per year. However, our estimate does not account for legitimate concerns about longer-term safety. In that context, an appropriate price after initial approval could be even lower.

- In 2020, Bristol Myers Squibb purchased MyoKardia. The purchase price for the smaller company should not be a basis of a price that is higher than a value-based price.

- A lower price would have several benefits for patients. First, it would likely expand access to mavacamten for patients who wish to try the medication early. Second, by expanding the proportion of patients who have access to the drug, it would allow a more rapid assessment of longer-term safety through post-approval monitoring with real-world evidence. Although there are known limitations to this type of observational data, a larger number of patients creates more statistical power to detect rarer side effects.

- If this type of longer-term evidence provides reassurance about longer-term safety, it would be appropriate to raise the price of mavacamten to the HBPB established in our analysis or to an even higher level should the effectiveness of the drug exceed early estimates.

Until rigorous evidence is available, avoid speculative suggestions about potential therapeutic benefits of novel treatment options.

The clinical evidence is inadequate to suggest that mavacamten may confer a survival benefit, irrespective of improvement in cardiac structure as measured by cardiac magnetic-resonance imaging (cMRI) as well as improvements in cardiac biomarkers. Particularly given the discordance between cMRI and patient-reported outcomes after mavacamten is stopped, there is substantial uncertainty about longer-term effects of the medication on cardiac structure and longer-term outcomes. Any suggestion that mavacamten reduces mortality at this point is speculative and carries the risk of creating false hope for this patient community.

Engage fully with patient groups, clinical experts, and independent entities seeking to produce transparent evaluations of the effectiveness and value of mavacamten.

Access to novel therapies for patients who will benefit at a price aligned with the benefits of that therapy is an important societal goal. This type of access can result from open communication between manufacturers, payers, and patients and their advocates. A representative of Bristol Myers Squibb delivered public comments at the public meeting on mavacamten but declined to participate in the policy roundtable. Avoiding this type of transparent public discussion does a disservice to the patient community and ultimately harms patient access to mavacamten.

All manufacturers of treatments for patients with HCM should be encouraged to assess patient-reported outcomes in clinical trials.

One of the important strengths of the EXPLORER study was that patient-reported outcomes were collected and a new patient-reported outcome specific to HCM was developed. These data complemented physiologic endpoints as well as clinician assessed measures of health status. Future trials should be encouraged to follow this example of including patient-reported outcomes, in particular when therapies are intended to improve subjective health status as opposed to “hard” event outcomes such as mortality.

Payers

Payers should use the Food and Drug Administration (FDA) label as the guide to coverage policy and engage clinical experts and diverse patient representatives in considering how to address coverage issues for which there is limited or no evidence at the current time.

Given the significant uncertainty that will remain about the relative benefits and longer-term risks of mavacamten for different patients, it will be reasonable for payers to use prior authorization as a component of coverage policy. Prior authorization criteria should be based on the FDA label, clinical evidence and patient eligibility criteria from pivotal trials, specialty society guidelines, and input from clinical experts and patient groups. The process for authorization should be clear and efficient for providers and patients. Options for specific elements of coverage criteria within insurance coverage policy are discussed below.

Coverage Criteria

Age: Mavacamten is likely to be covered for adult patients (18 years or greater), in line with the inclusion criteria of the EXPLORER trial. There is greater uncertainty about both treatment effects and risks in younger patients, since the mean age in the trial was 58.5 years. However, younger adults were eligible for and included in the key trial.

Clinical Eligibility: Current evidence pertains to patients with symptomatic, obstructive HCM with LVOT gradients greater than or equal to 50 mmHg at rest after Valsalva maneuver or exercise.

Inclusion Criteria: When mavacamten is prescribed with the intent of improving symptoms in symptomatic HOCM, key clinical issues include establishing the presence of a LVOT gradient and excluding non-cardiac sources of exertional symptoms (such as pulmonary symptoms). Conditions that mimic HCM are common but are very unlikely to result in the subtype of HCM that causes obstruction. We are aware that therapeutic concepts are in development that eventually may lead to the use of mavacamten for HCM without obstruction. In that case, depending on the evidence available at the time, it may become reasonable to establish specific anatomic cutoffs for ventricular wall thickness. Overall, the distinction between HCM generally and conditions that mimic HCM are subtle and require interdisciplinary discussion among experts in cardiac imaging, genetics, and clinical cardiology. That integrative expertise is more helpful than specific anatomic cutoffs. For these reasons, it seems unreasonable for payers to establish specific cutoffs for left ventricular dimensions prior to approving mavacamten for symptomatic HOCM.

Although the diagnosis of HCM is subtle and often requires specialist expertise and, in some cases, confirmation through genetic testing, there are multiple important limitations to genetic testing. For example, some genetic variants that cause HCM are unknown. Secondly, of all the pathologic conditions (like hypertension and infiltrative cardiomyopathies) and non-pathologic conditions (athlete's heart) that can mimic HCM, they are unlikely to cause a hemodynamic gradient in the

outflow tract. Since mavacamten is likely to be used in patients with symptomatic HOCM, rigorous establishment and confirmation of a hemodynamic outflow tract gradient is important. Conversely, in this situation, genetic testing will not be useful for establishing candidacy for mavacamten. For these reasons, it is unreasonable for payers to require genetic testing to confirm diagnosis prior to approval of mavacamten for symptomatic HOCM.

Exclusion Criteria: There are no specific medical comorbidities that would serve as exclusion criteria for mavacamten. Patients with permanent atrial fibrillation who are either not on anticoagulation for more than four weeks or not adequately rate controlled for more than six months, or any patients with paroxysmal atrial fibrillation were not included in the EXPLORER trial (see section on atrial fibrillation below). However, there is no specific contraindication to using mavacamten in patients with atrial fibrillation. Since atrial fibrillation is a common source of symptoms in patients with all types of HCM, distinguishing between symptoms related to outflow tract obstruction and symptoms related to atrial fibrillation is important before attempting to reduce outflow tract obstruction with mavacamten.

Duration of Coverage and Renewal Criteria: Experts advised that patients initiated on mavacamten generally should have documented benefits within three months. Accordingly, patients generally should be reevaluated by clinicians within that timeframe (either in person or via telemedicine). Patients who remain on mavacamten should then again be reevaluated within one year.

Provider Restrictions: Both clinical experts and patients expressed concern about the safety of early widespread use of mavacamten in community-based settings outside of centers of excellence. As such, it seems reasonable to keep use of mavacamten very narrow within two to five years after FDA approval. As more safety data are available and clinicians gain more experience, it seems reasonable to widen provider access. This reflects a difficult balance between potentially concerning safety signals and patient access. Particularly given this balance, we encourage payers to collaborate with patient organizations to establish lists of preferred providers at centers of excellence. The Hypertrophic Cardiomyopathy Association has identified centers of excellence available on their website (www.4hcm.org/center-of-excellence).

Step Therapy

It is reasonable for payers to require an attempt to manage symptomatic HOCM with beta blockers and calcium channel blockers before approving mavacamten.

Patients in both the placebo and mavacamten arms of the EXPLORER trial could take beta blockers and calcium channel blockers. Very few patients enrolled in the trial were taking neither medication. As such, it is reasonable to require an attempt at managing symptoms with beta blockers and calcium channel blockers alone before approving mavacamten. Many patients report intolerable side effects with these medications. As such, intolerable side effects or

contraindications are reasonable justifications for defining treatment failure of beta blockers and/or calcium channel blockers.

It is unreasonable for insurers to require either myectomy or septal ablation prior to approval of mavacamten.

Given that surgical myectomy and alcohol septal ablation involve very different trade-offs and risks for patients relative to an oral medication, it is unreasonable for insurers to require either myectomy or septal ablation prior to access to mavacamten. The comparative effectiveness of these treatment options is obscured by the absence of relevant trials. Even if more definitive evidence is established, the decision of an oral medication versus a procedure or surgery seems very dependent on the preferences and circumstances of an individual patient. Shared decision-making is appropriate in these situations.

Despite this recommendation, if insurers ever do require either surgical myectomy or septal ablation prior to coverage of mavacamten, they should recognize that patients lose considerable time from work while recuperating from these procedures and full consideration should be given to compensating patients for this lost time in some way.

Unless patients have better access to disopyramide, it seems unreasonable to consider requiring a trial of disopyramide prior to coverage of mavacamten. Further clinical evidence on the clinical benefits of disopyramide is also required to strengthen any consideration of this step therapy option.

Clinical experts disagreed about whether requiring a trial of disopyramide prior to approval of mavacamten would be reasonable. If the initial price of mavacamten is high, there would be more justification of the importance of a trial of disopyramide before mavacamten. Despite that, short-acting disopyramide requires onerous dosing every six hours. Long-acting disopyramide is a more reasonable option but is currently in a drug shortage, limiting access.

Clinical Investigators and Grant Funding Organizations

Researchers and funding agencies should ensure that future research assesses the potential benefits of treatment related to improved productivity and reductions in caregiver burden.

In determining a value-based price for a novel therapy, standard methods account for both increases in life expectancy and improvement in health status for patients. However, it is also reasonable to account for potential other benefits. Novel clinical innovations can provide additional benefits by easing caregiver burden and improving patient workforce productivity, but these benefits are often not measured. Unfortunately, these potential other benefits have not been well-captured in prior research. Patient-centered research that aims to quantify these potential other benefits would allow inclusion in decision-analytic models. Inclusion of this information in decision-

analytic models would more fully capture the benefits of a novel therapy but also could potentially increase a value-based price estimate.

Further research should be targeted at evaluating the safety and benefits of mavacamten for patients with HOCM and atrial fibrillation.

Patients with permanent atrial fibrillation not on anticoagulation who are either not on anticoagulation for more than four weeks or not adequately rate controlled for more than six months, or any patients with paroxysmal atrial fibrillation were not included in the EXPLORER trial. In the setting of these exclusion criteria, only 12 patients (10%) in mavacamten arm of EXPLORER had even a history of atrial fibrillation. Atrial fibrillation is common in patients with HOCM, thromboembolic risk off anticoagulation is high, and because atrial fibrillation can exacerbate the hemodynamic gradient in the LVOT, atrial fibrillation often causes intolerable symptoms. In a patient with symptomatic HOCM and atrial fibrillation, it is often difficult to distinguish between symptoms caused by atrial fibrillation and symptoms caused by the outflow tract gradient.

The comparative effectiveness and safety of mavacamten in many patients with atrial fibrillation is therefore unclear. More work is required to establish the efficacy and safety of mavacamten for patients with atrial fibrillation including paroxysmal atrial fibrillation.

Post-approval clinical registries should be established to detect rare side effects as well as assess the efficacy of mavacamten in more diverse populations.

Since the MAVA-LTE study uses the same population as the EXPLORER population, there is very limited representation among patients of color. Furthermore, this cohort that includes 224 patients will be underpowered to detect rarer side effects among all patients. Especially because there is a substantial concern about longer-term safety, clinical registries will be essential for detecting rarer adverse events and for assessing if the results of EXPLORER are extrapolatable to more diverse populations.

Patient Groups

Patient groups should continue to demonstrate leadership in defining clinical excellence and appropriate pricing.

- The Hypertrophic Cardiomyopathy Association has played a longstanding leadership role in advocacy for this patient community, including work generating educational information for patients and families, supporting research efforts, and identifying centers of excellence for HCM. Their actions serve as a model for other patient communities seeking to advance the best interests of patients today and in the future. Given the critical importance of centers for excellence for HCM generally, the Hypertrophic Cardiomyopathy Association should

continue this involvement and seek to work with payers to find the right balance between breadth of access and quality of the care provided at diverse provider organizations.

- Hypertrophic Cardiomyopathy Association representatives and others have expressed concerns about the potential that the manufacturer will set a high price of mavacamten. The Hypertrophic Cardiomyopathy Association has established its credibility within its own community and with clinical experts. It has a powerful voice that will be used to advocate for appropriate access for patients to mavacamten and other new treatments. This group, and others, should fully exercise that voice and that power in support of responsible pricing that will advance the best interests of patients while sending a strong signal to innovators that they should develop robust evidence of benefits to patients to support their pricing. We hope that government, manufacturers, private payers, and other advocates will work with the Hypertrophic Cardiomyopathy Association to facilitate their advocacy, which is critically important for patients with HCM.

Appendix

Appendix Tables 1 through 3 contain COI disclosures for all participants at the October 22, 2021, public meeting of CTAF.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants	
Molly Beinfeld, MPH, Senior Research Lead, Evidence Synthesis, ICER*	**David Rind, MD, MSc**, Chief Medical Officer, ICER*
Laura Cianciolo, Program Manager, ICER*	**Jyotirmoy Sarker, MPharm, MBA, MBiotech**, Graduate Student, Pharmacy Systems, Outcomes, and Policy, University of Illinois at Chicago*
Maggie Houle, Program and Event Coordinator, ICER*	**Surrey M. Walton, PhD, MA**, Professor, Pharmacy Systems, Outcomes, and Policy; Assistant Director, Center for Pharmacoepidemiology and Pharmacoeconomic Research, University of Illinois at Chicago*
Emily Nhan, Research Assistant, ICER*	**Jason H. Wasfy, MD, MPhil**, Associate Professor, Harvard Medical School; Medical Director, Massachusetts General Hospital Physicians Organization; Director of Outcomes Research, Massachusetts General Hospital Heart Center*
Rasheed Mohammed, PharmD, MPH, Health Technology Assessment Fellow, ICER*	**Melanie Whittington, PhD**, Associate Director of Health Economics, ICER*
Steven D. Pearson, MD, MSc, President, ICER	

*None of the above authors disclosed any conflicts of interest defined as more than $10,000 in health care company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.

Appendix Table 2. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	COI
Milind Desai, MD, MBA, Director of Clinical Operations, Hypertrophic Cardiomyopathy Center, Cleveland Clinic	Dr. Desai served as an investigator for the VALOR study of mavacamten sponsored by Bristol Myers Squibb/MyoKardia.
Martin Maron, MD, Director, Hypertrophic Cardiomyopathy Center and Research Institute, Tufts Medical Center	Dr. Maron served as a site investigator for a Phase I study of mavacamten and currently serves as a steering committee member for a Phase II study of a second-generation myosin inhibitor sponsored by Cytokinetics.
Gwendolyn Mayes, JD, MMSc, Founder and Chief Concept Officer, GwenCo Health	Gwendolyn Mayes serves as a consultant to the Hypertrophic Cardiomyopathy Association, which receives 20% of its sponsorship for educational programming from Bristol Myers Squibb/MyoKardia. She also consults for Edwards Lifesciences, Paragonix, and Natural Cycles.
Carla McSpadden, RPh, BCGP, MBA, Director, Clinical Formulary Strategies, Humana	Carla McSpadden is a full-time employee of Humana.
Lisa Salberg, Founder and CEO, Hypertrophic Cardiomyopathy Association	The Hypertrophic Cardiomyopathy Association receives 20% of its sponsorship for educational programming from Bristol Myers Squibb/MyoKardia.
John Watkins, PharmD, MPH, BCPS, Residency Program Director, Premera Blue Cross	John Watkins is a full-time employee of Premera Blue Cross.

Appendix Table 3. CTAF Member Participants and COI Disclosures

Participating Members of CTAF	
Ralph G. Brindis, MD, MPH, MACC, FSCAI, FAHA, Clinical Professor of Medicine, UCSF*	**Elizabeth J. Murphy, MD, DPhil**, Professor of Clinical Medicine, UCSF; Chief, Division of Endocrinology and Metabolism, Zuckerberg San Francisco General Hospital*
Felicia Cohn, PhD, Bioethics Director, Kaiser Permanente, Orange County; Clinical Professor of Bioethics, Department of Medicine, University of California, Irvine School of Medicine*	**Kathryn A. Phillips, PhD**, Professor of Health Economics and Health Services Research; Director and Founder, UCSF Center for Translational and Policy Research on Personalized Medicine; Department of Clinical Pharmacy/School of Pharmacy, UCSF Institute for Health Policy Studies, and UCSF Comprehensive Cancer Center*
Robert Collyar, Patient Advocate in Research*	**Rita F. Redberg, MD, MSc, FACC**, Cardiologist and Professor of Medicine and Women's Cardiovascular Services at UCSF*
Kimberly Gregory, MD, MPH, Vice Chair, Women's Healthcare Quality & Performance Improvement, Cedars-Sinai Medical Center*	**Richard Seiden, JD**, Patient Advocate, Retired Partner, Foley & Lardner LLP*
Paul Heidenreich, MD, MS, Professor of Medicine, Stanford University School of Medicine*	**Alexander Smith, MD, MPH**, Professor of Medicine, UCSF
Jeffrey Hoch, PhD, Associate Director, Center for Healthcare Policy and Research, UC Davis*	**Joanna Smith, LCSW, MPH, CHA**, Chief Executive Officer, Healthcare Liaison, Inc.*
Sei Lee, MD, Associate Professor of Medicine, Division of Geriatrics, UCSF*	**Anthony Sowry,** Patient Advocate and Lead Volunteer, California, National Patient Advocate Foundation; Senior Vice President, Maritime Container Shipping (Retired)*
Joy Melnikow, MD, Director of the Center for Healthcare Policy and Research and Professor of Family and Community Medicine at UCD*	

*No COIs to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.