Cardiovascular Disease Working Group

HCM Initiative

2025 MEETING SUMMARY

The Alliance for Patient Access hosted its second annual meeting for the Hypertrophic Cardiomyopathy Initiative of its Cardiovascular Disease Working Group. Clinicians and stakeholders convened June 6-7, 2025, in Washington, DC to discuss policies impacting HCM patients and ways to advocate for them.

DELAYS IN DIAGNOSIS

Awareness of HCM

An ongoing issue in the HCM community is awareness, as agreed upon by meeting participants. Although the disease affects hundreds of thousands of people across the country, it is still widely unfamiliar to many patients and even some clinicians. Awareness is a vital component of early diagnosis and treatment of HCM.

Systemic Approach to Diagnosing

Clinicians across various specialties agree that the present guidelines for diagnosing HCM make it difficult to identify the disease early. Currently, diagnostic practices consist of echocardiograms, genetic testing and counseling, a review of family history, and cardiological work ups. Meeting attendees expressed the need for more extensive diagnostic practices, and for imaging to be reviewed by the appropriate clinician.

A genetic counselor said, “negative genetic results don’t necessarily rule out HCM,” which highlights the need for more comprehensive testing.

Communication Among Clinicians

Meeting participants identified the need to communicate across specialties sooner rather than later in the course of a patient’s care. Primary care clinicians, general cardiologists and HCM specialists should be in frequent communication— especially as patients are first experiencing symptoms. A primary care clinician said, “Patients come to me with symptoms. It’s my job to then help connect the pieces that are their symptoms.” These symptoms can often be misdiagnosed as other cardiac conditions.

Participants echoed the sentiment that HCM is and should be treated as a part of preventive cardiology. Clinicians could take it upon themselves to ask more questions and prescribe more exams.

BARRIERS TO ACCESS AND TREATMENT

Coverage for Genetic Counseling

Genetic counseling is an important part of the HCM diagnostic journey. However, these services are typically not covered by health plans. For genetic counselors, this means that they are often not reimbursed for their time spent in and out of patient visits. This burden is compounded by health plans like Medicare that don't recognize genetic counselors as providers, impacting reimbursement.

This roadblock highlights the need for insurance plans to have a comprehensive understanding of HCM and the role of genetic counseling in cardiovascular health.

Risk Evaluation and Mitigation Strategies

Risk Evaluation and Mitigation Strategies, or REMS, are regulatory tools used by the FDA's Division of Drug Information intended to manage risks associated with medications. While REMS can be an important tool, it creates an extra hurdle for patients and clinicians. These include administrative requirements and enrollment processes.

Patients on mavacamten have historically been required to undergo drug interaction screenings and echocardiograms every 12 weeks before receiving their medication. But in positive news, the FDA recently scaled back these requirements to every 6 months, doubling the time between visits.

Utilization Management Practices

REMS gives way to utilization management practices like prior authorization. Clinicians expressed frustration with a mandated prior authorization protocol for an echocardiogram—the most common diagnostic and monitoring tool for HCM. These prior authorizations can often delay mandated testing for patients and increase hurdles for clinicians. One clinician said, "Insurance companies are using prior authorization to delay paying for treatment."

Insurance barriers place additional burden on the patient to keep up with protocols, on top of managing appointments and costs. One cardiologist said, "They make patients jump through hoops that are not based on literature."

PBMs and Formulary Exclusions

A rising barrier to treatment of HCM as discussed in the meeting was the role of pharmacy benefit managers, or PBMs. Studies show that there is an increase in medication exclusions for cardiovascular patients. These exclusions contribute to treatment delays, reduce the quality of care and increase out-of-pocket costs for patients.

One cardiologist explained, "PBMs should not be involved in patient care. They don't look at commonly prescribed medications before deciding to exclude them from the formulary."

NEXT STEPS

Meeting participants were enthusiastic about the opportunity to increase awareness about HCM and lend their voice to patient advocacy. Participants offered ideas for new educational resources and expressed interest in legislative engagement.

GET INVOLVED

To learn more about AfPA's Hypertrophic Cardiomyopathy Initiative, contact Payton Marvin at **pmarvin@allianceforpatientaccess.org** and visit our website at **AllianceForPatientAccess.Org**