

# Putting the Patient First: Learnings from the Real World of HCM

REPORT FROM MEETING IN MARCH 2023



Hypertrophic  
Cardiomyopathy  
Association®



PARTNERSHIP TO ADVANCE  
Cardiovascular  
Health

# Introduction



The Hypertrophic Cardiomyopathy Association and Partnership to Advance Cardiovascular Health convened clinicians who specialize in treating hypertrophic cardiomyopathy on March 3, 2023 in New Orleans, Louisiana to identify methods to improve patient access.

## Clinicians included:

- Kia Afshar, MD, Intermountain Medical
- Bipul Baibhav, MD, Rochester Regional
- Lubna Choudhury, MD, Northwestern
- Milind Desai, MD, Cleveland Clinic
- Matt Martinez, MD, Atlantic Health
- Alanna Morris, MD, Emory
- Srihari S. Naidu, MD, Westchester
- Anjali Owens, MD, UPenn
- Dharmesh Patel, MD, Stern Cardiovascular
- Timothy Wong, MD, UPMC

## ABOUT THE MODERATORS



**Matthew Martinez, MD**, is the director of Atlantic Health System Hypertrophic Cardiomyopathy and Sports Cardiology programs at Morristown Medical Center and a nationally recognized expert in hypertrophic cardiomyopathy, or HCM. He specializes in identifying and treating athletes who have underlying heart issues such as arrhythmia or HCM.



**Srihari S. Naidu, MD**, is director of the Hypertrophic Cardiomyopathy Program and Cardiac Catheterization Laboratories at the Westchester Heart and Vascular Institute and is nationally recognized for his expertise in the procedural treatment of patients with HCM. Dr. Naidu is triple board certified in internal medicine, cardiology and interventional cardiology.



## About HCM & Treatment



Hypertrophic cardiomyopathy is a cardiovascular disease that affects the heart muscle. It causes thickening of the left ventricle, the chamber responsible for pumping blood to the body. Hypertrophic cardiomyopathy is the most common inherited cardiovascular disorder, affecting about one in every 250 people.<sup>1</sup>

In 2019, the health care cost of hypertrophic cardiomyopathy was an estimated \$43,000 per patient in the United States, with 38% of patients experiencing at least one hospitalization within the first year of diagnosis.<sup>2</sup> Hypertrophic cardiomyopathy is a progressive disease with complications including arrhythmias, stroke and heart failure, which can each be costly to diagnose and treat.

The condition can cause a range of symptoms, including chest pain, shortness of breath, palpitations and fainting. These can vary from day to day. Some people with hypertrophic cardiomyopathy may have no symptoms

at all. Hypertrophic cardiomyopathy can also increase the risk of sudden cardiac death.

Historically, treatment options have aimed to manage symptoms, prevent complications and reduce the risk of sudden cardiac death. Medications, such as beta-blockers, calcium channel blockers and disopyramide, have helped to control symptoms by reducing the heart's workload and improving its ability to relax. Surgical interventions, such as septal myectomy or alcohol septal ablation, have also been performed to reduce the thickness of the heart muscle and improve blood flow. Approximately 5% of patients will be referred for heart transplants.

# Access to Mavacamten



Meeting participants discussed patient access to mavacamten, a novel medication used to treat obstructive hypertrophic cardiomyopathy. Approved by the FDA in 2022, mavacamten is a targeted treatment that addresses underlying causes of hypertrophic cardiomyopathy. Prior to mavacamten's approval, pharmacotherapeutic options were limited to medications that simply manage symptoms.

Providers have identified helpful practices to manage a limited number of patients, but as more patients gain access to mavacamten, treatment barriers will become a bottleneck. The existing workflow for managing patients needs to be scalable.

## SPECIALTY PHARMACIES



Specialty pharmacies dispense medications that are often expensive and require special handling, storage and administration. Specialty pharmacies play an important role in ensuring that patients have access to the medications they need for complex medical conditions.

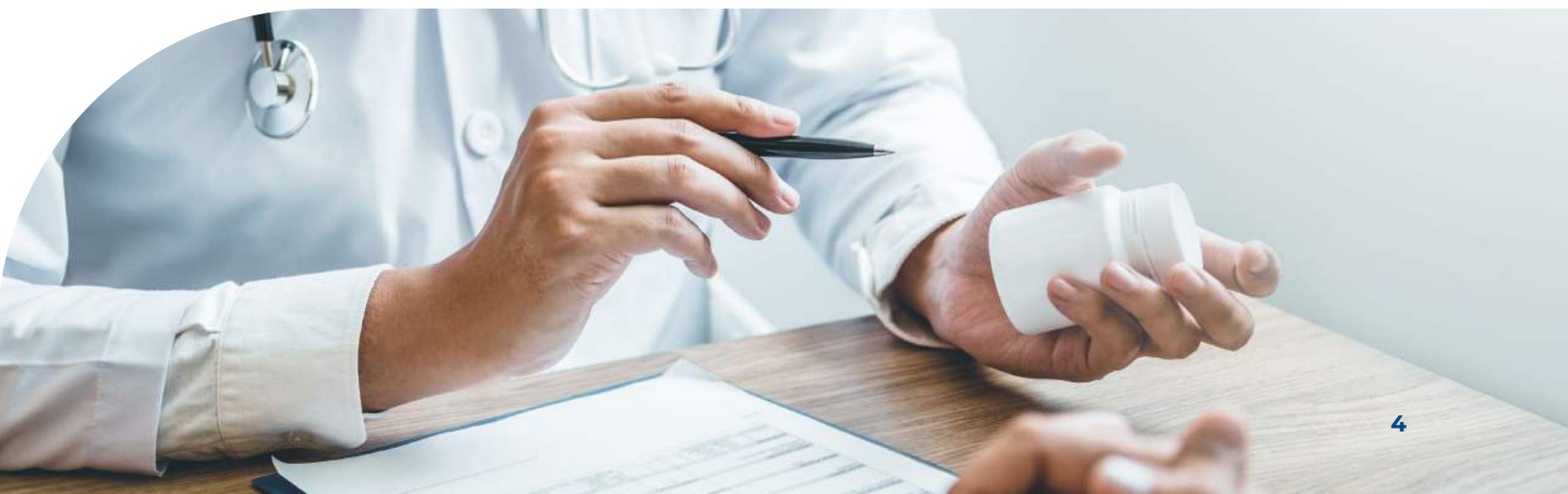
Specialty pharmacies are largely unknown to the general patient population. Patients might lack an understanding of how specialty pharmacies work and require education about how to engage with them. They may also experience additional stress with the processing of dealing with a third access point for their medication.

## PRIOR AUTHORIZATION



Prior authorization can also impact patient access. Prior authorization is a practice that insurers use to evaluate a patient's coverage eligibility for physician-prescribed medications. Insurers claim prior authorization stops unnecessary use of novel or expensive treatments, but it can cause treatment delays or inappropriate denials.

For patients with hypertrophic cardiomyopathy, prior authorization can be risky. Hypertrophic cardiomyopathy is a serious and potentially life-threatening condition. Delays or denials of coverage could lead to worsening of symptoms and increased risk of complications, including sudden cardiac death.





## RISK EVALUATION AND MITIGATION STRATEGIES



Risk Evaluation and Mitigation Strategies, or REMS, is a regulatory tool used by the Food and Drug Administration to manage known or potential risks associated with medications. These are typically reserved for medications that require medical interventions or other actions by health care professionals prior to prescribing or dispensing the drug. Overall, REMS are designed to ensure patient safety. To help providers assess the benefit-risk balance of a therapy, the FDA's Division of Drug Information provides tools such as notices of safety-related label changes and risk alerts.

Mavacamten is currently assigned to a Risk Evaluation and Mitigation Strategies program to mitigate the risk of heart failure due to systolic dysfunction. A major requirement of mavacamten's program is monthly echocardiograms for patients the first several months. Echocardiograms create logistical issues for patients and health systems trying to manage mavacamten. Financial barriers, like high out-of-pocket costs for un- and under-insured patients, and transportation barriers can prevent patients from receiving this test. Another objective of mavacamten's program is to screen for drug interaction prior to each dispense of therapy.



# Provider Pain Points & Best Practices



Meeting participants discussed challenges and best practices associated with onboarding patients onto mavacamten, scheduling echocardiograms and filling prescriptions.

## ECHOCARDIOGRAM SCHEDULING



Another challenge is scheduling required echocardiograms. In line with REMS requirements, patients must have regular echocardiograms to monitor their condition while taking mavacamten. It is critical that scheduling take into account echocardiogram quality and patient convenience. These can be difficult for providers, particularly in the context of sonographer shortages.

To address this, providers can designate schedulers specifically for hypertrophic cardiomyopathy patients and empower nurse practitioners to develop best practices. Providers can also develop protocols for advanced scheduling, such as scheduling a series of echocardiograms for the first three months every four weeks and designating specific days for hypertrophic cardiomyopathy patients to come in.

## PATIENT ONBOARDING



Some patients may be underinformed about the signup and paperwork process for mavacamten treatment. Patients with Medicare, in particular, may have difficulty with the affordability of mavacamten and may be unaware of grant availability. Providers say unnecessary time is spent during office visits covering information that could be handled as a pre-read.

Nurses and advanced practice providers play a crucial role in educating patients and managing onboarding. Designating these individuals to oversee paperwork and explain the process can help patients, but the paperwork load can be substantial. Provider burnout, therefore, is a significant concern.

There is a need for a standardized drug interaction form and prior authorization form, templates for appeals, and a documentation checklist for prior authorization. Another useful tool for providers would be a comprehensive checklist of best practices to move patients through a timeline of activities.



---

Nurses and advanced practice providers play a crucial role in educating patients.



## SPECIALTY PHARMACY FULFILLMENT



There is substantial confusion and a need to streamline the process for filling prescriptions of mavacamten through specialty pharmacies. Some providers use EPIC ordering, while others have their own process for identifying patients, filling out prior authorization paperwork and sending the prescription to the nursing team, which then sends it to the pharmacy.

Dedicating one professional to prescribing and one to handling the rest of the process has utility. Better communication and collaboration between providers and specialty pharmacies can also streamline the process.

## PEER AND PROVIDER ENGAGEMENT



Providers can be trusted voices in making aware and sharing materials helpful to their peers treating hypertrophic cardiomyopathy patients. Patient advocacy organizations, medical societies, key opinion leaders and center of excellence partners are identified as potential avenues for sharing best practices and lessons learned.

---

**Providers can be trusted voices  
in making aware and sharing  
materials helpful to their  
peers treating hypertrophic  
cardiomyopathy patients.**



# Needed Education Materials for Patients

## ACCESSIBLE, ENGAGING EDUCATION MATERIALS



Participants emphasized the need for hypertrophic cardiomyopathy patients to have access to simplified educational materials as a time-saving and adherence measure.

The group suggested:

- **Creating education materials** such as:
  - What to expect in your first visit
  - Principles of good patient adherence
  - What is a specialty pharmacy
  - What is REMS
  - What is prior authorization
  - A patient perspective of what to expect when starting mavacamten
- **Developing decision-tree infographics**
- **Educating patients on how hypertrophic cardiomyopathy medications are made affordable** and concerns regarding out-of-pocket costs for Medicare patients.

## COMMUNITY OUTREACH AND ENGAGEMENT



Participants also highlighted the need for increased patient education and outreach in traditionally underserved communities. A hypertrophic cardiomyopathy ambassador program could bolster efforts, participants noted.

HCMA will play a critical role in helping distribute education materials to patients to streamline care and treatment. HCMA will help advocate for access to myosin inhibitors and all scientifically based therapies.

---

HCMA will play a critical role in helping distribute education materials to patients to streamline care and treatment.

## Conclusion

**As the number of patients on hypertrophic cardiomyopathy medications grows, clinics will face significant challenges, and solutions need to be found now.** Collaboration between providers and patient advocates can raise awareness for hypertrophic cardiomyopathy patients' challenges and needs and lay the groundwork for meaningful change.



## REFERENCES

1. Hypertrophic Cardiomyopathy. UC San Diego Health. <https://health.ucsd.edu/care/heart-vascular/hypertrophic-cardiomyopathy/>
2. Owens AT, Sutton MB, Gao W, et al. Treatment changes, healthcare resource utilization, and costs among patients with symptomatic obstructive hypertrophic cardiomyopathy: A claims database study - cardiology and therapy. SpringerLink. <https://link.springer.com/article/10.1007/s40119-022-00257-7#:~:text=A%20large%20US%20claims%20study,year%20of%20diagnosis%20%5B17%5D>. Published March 1, 2022. Accessed March 16, 2023.



**Hypertrophic  
Cardiomyopathy  
Association®**

The Hypertrophic Cardiomyopathy Association is committed to providing support, education, advocacy and advancing research, understanding and care to those with HCM.

**4hcm.org**



@4hcm



4HCM.org



**PARTNERSHIP TO ADVANCE  
Cardiovascular  
Health**

The Partnership to Advance Cardiovascular Health works to advance public policies and practices that result in more treatment options and improved cardiovascular health for heart patients around the world.

**AdvanceCardioHealth.org**



@advcardiohealth



Partnership to Advance  
Cardiovascular Health