Optimizing Mavacamten Clinical and Dispensing Practices at an Integrated Specialty Pharmacy

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Background

- Mavacamten, a first-in-class specialty medication for the treatment of hypertrophic obstructive cardiomyopathy, is subject to a stringent Risk Evaluation and Mitigation Strategy (REMS).
- Coordination of medication delivery hinges on patients possessing less than a week's medication supply, reviewing echocardiogram results, and completion of a drug interaction and counseling checklist via the REMS portal.
- Specialty pharmacies play a crucial role in the management of patients initiating mavacamten and ensuring compliance with REMS requirements. However, navigating the complex REMS requirements can pose challenges for specialty pharmacies. Optimizing dispensing practices is essential in ensuring medication access and maintaining patient safety.

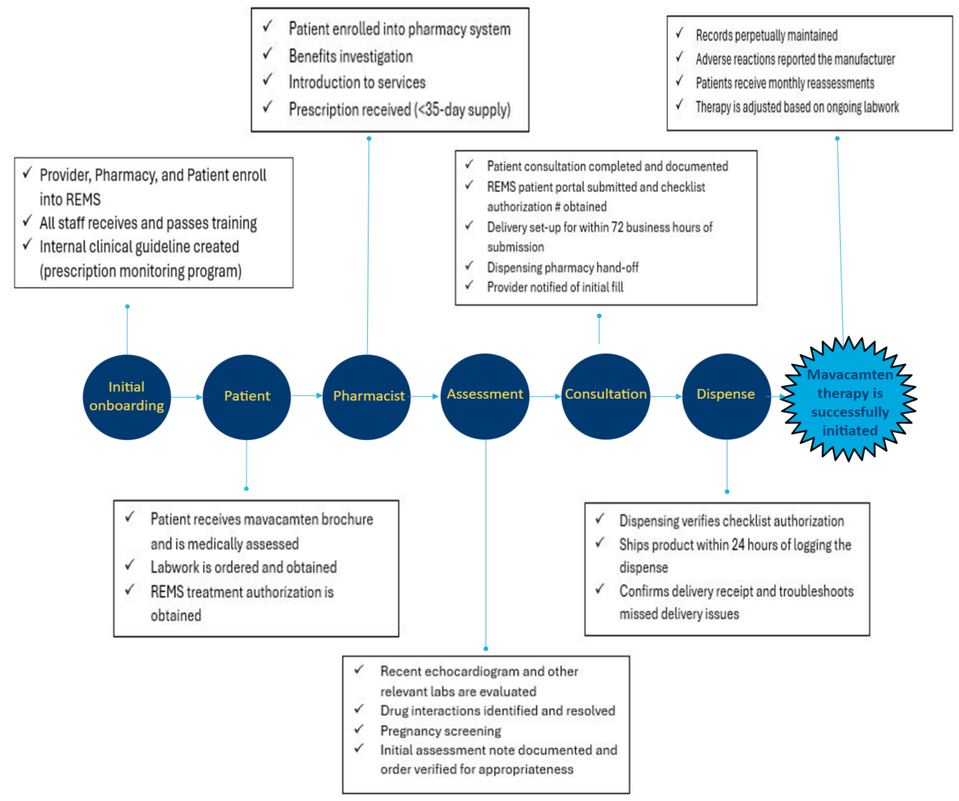
Objectives

- To optimize and implement a dispensing process for mavacamten that complies with the strict REMS requirements.

Methods

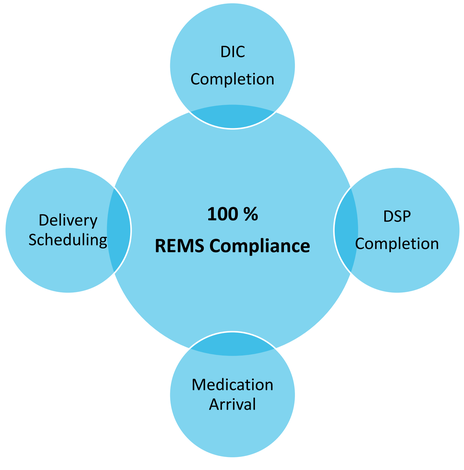
- Pharmacists clinically reviewed mavacamten prescriptions and exclusively managed patient outreach and delivery scheduling to ensure REMS compliance.
- A comprehensive report was integrated into the software, allowing clinical pharmacists to view all patients due for a mavacamten refill.
- In the electronic dispensing system, flags were embedded in all mavacamten prescriptions, serving as mandatory checkpoints for process completion.
- A dedicated electronic messaging channel was created to facilitate communication for mavacamten-related deliveries.
- Following verification, the dispensing pharmacist logged dispenses within the REMS portal and removed hard stop flags.

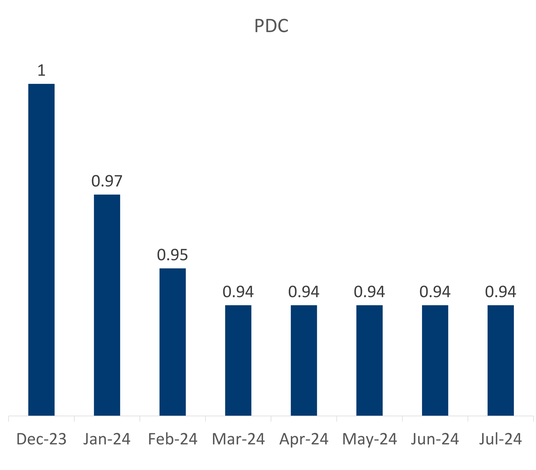
Process Implemented



Results

The primary outcome was 100% compliance with the completion of the drug interaction, counseling checklist and log dispense checklist. The secondary outcome included proportion of days covered (PDC) with a goal of 0.85 and a stretch goal of 0.9.





Discussion

- The implementation of an optimized dispensing process for mavacamten led to 100% compliance with REMS requirements. This demonstrated the success of integrated workflow checks and a dedicated communication channel.
- This approach ensured that patients maintained consistent access to mavacamten, as evidenced by exceeding the PDC goal (0.85) and stretch goal (0.9).
- Collaboration between clinical and dispensing pharmacists was instrumental in navigating the complex REMS requirements, reducing the risk of non-compliance, and enhancing patient safety.
- The integration of comprehensive reporting tools and mandatory checkpoints within the electronic dispensing system streamlined the process, minimizing the likelihood of non-compliance.
- This model of dispensing ensured adherence to the stringent REMS requirements, ultimately improving patient outcomes and ensuring adherence to safety protocols.

Conclusion

- An efficient and safe dispensing process was developed by adding extra checks within workflows, instituting a collaborative approach to ensure a dispensing process in compliance with the REMS requirements.

Future Directions

- Integration of ambulatory care pharmacists to assist with coordination of care and prescribing under collaborative practice agreements.
- Collaborate with external providers outside of the health system to allow access for more patients
- Assess prior authorization and copay assistance time studies to maximize PDC for patients transitioning from clinical trials to outpatient