SHIELDS
HEALTH SOLUTIONS

Development and Implementation of an Innovative Pulmonary Arterial Hypertension Clinical Management Model

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SCAN ME

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Background

- Pulmonary arterial hypertension (PAH) is a rare and progressive condition, characterized by elevated blood pressure in the vessels of the lungs. With no known cure, PAH affects fewer than 50,000 people in the US, and about 500-1000 new cases are diagnosed each year.[1]

- PAH treatments include ambrisentan, a specialty drug that requires a Risk Evaluation Mitigation Strategy (REMS) protocol and close management for dispensing by a specialty pharmacy.[2]

- The objective was to describe the process of developing and implementing an innovative clinical management model for PAH patients receiving ambrisentan from integrated health system specialty pharmacies (HSSPs) to support accreditation, payer, REMS, and clinical outcomes requirements.

Methods

Gap Analysis: Ambrisentan REMS requirements and PAH clinical literature were reviewed to create the care model. A standardized, validated assessment tool was selected to measure patient QOL and to assess disease severity.[3,4]

Workflow Development: Workflows for patient onboarding, REMS counseling, clinical assessment and adverse event screening were created for the dedicated PAH care team.

Training: A training curriculum was developed, including ambrisentan REMS and adverse event reporting requirements, policy and procedures, and knowledge assessment.

Implementation and Evaluation:. PAH clinical care model implemented at four HSSPs Program was evaluated for REMS compliance.

Results

Figure 1. Description of the ten core elements identified for ambrisentan REMS desktop audit. **Figure 2.** Illustration of the ambrisentan REMS workflow at the health system specialty pharmacy as supported by the dedicated PAH care team of pharmacists, nurses and in-clinic pharmacy liaisons. **Figure 3.** Depiction of program outcomes.

Figure 1

10 CORE AMBRISENTAN REMS AUDIT ELEMENTS:

- 01 EMPLOYEE TRAINING CURRICULUM
- 02 EMPLOYEE TRAINING RECORDS
- 03 PHARMACY DISPENSE REPORTS
- 04 POLICY & PROCEDURE
- 05 REMS COMPLIANCE
- 06 DATA REPORTING CAPABILITIES
- 07 REMS PORTAL ACCESS / AUTHORIZATION HISTORY
- 08 QUALITY MANAGEMENT PROCESSES
- 09 PHARMACY ORGANIZATIONAL STRUCTURE
- 10 ADVERSE EVENT REPORTING

Figure 2

CORE STEPS FOR THE AMBRISENTAN PROCESS

Unique steps for this program | Standard for Shields model

- Liaison verifies plan benefits / completes PA/FA
- Clinician verifies prescriber and patient REMS enrollment
- Clinician performs REMS counsel for FRP patients (Females of Reproductive Potential)
- Clinician obtains REMS authorization code
- Clinician completes PAH clinical assessments
- Delivery coordination with patient and pharmacy
- Pharmacy dispenses ambrisentan with medication guide
- Pharmacy ships ambrisentan within 7 days of authorization code

Figure 3

AMBRISENTAN REMS PROGRAM OUTCOMES

- **4** Ambrisentan certified health system specialty pharmacies
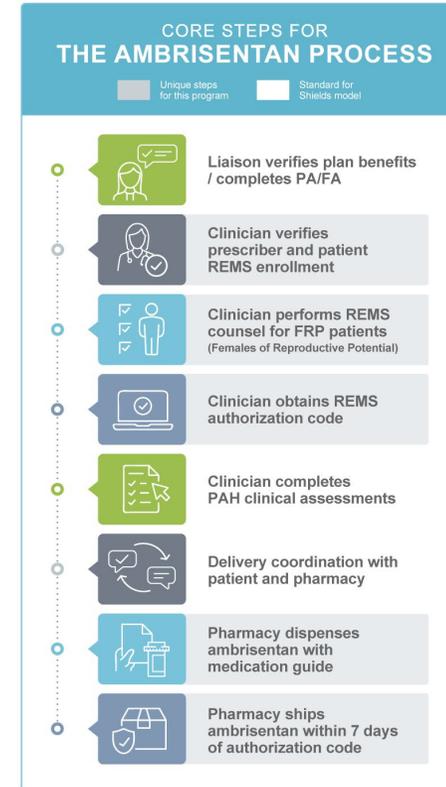- **9** Ambrisentan desktop audits since 2020
- **0** Identified REMS deviations

Conclusions

- An innovative clinical management model was developed and implemented at four health system specialty pharmacies, allowing dispensing of ambrisentan, a specialty medication with a required REMS protocol.
- Pharmacy audit readiness can be achieved through annual and post-dispense mock audit utilizing the identified audit elements.
- Future analysis of QOL scores for patients can be used to measure the program's impact on clinical outcomes.

REFERENCES
1. Pulmonary Arterial Hypertension. https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertensions/ [accessed 3.27.23]
2. Ambrisentan REMS. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=396 [accessed 3.27.23]
3. Yorke J, et al. emphasis-10: development of a health-related quality of life measure in pulmonary hypertension. Eur Respir J 2014;43:1106-1113
4. Galie N, Olschewski H, Oudiz R, et al. Abrisentan for the Treatment of Pulmonary Arterial Hypertension: Results of the Ambrisentan in PAH, Randomized, Double-blind, Placebo-controlled, multicenter, Efficacy (ARIES) Study 1 and 2. Circulation 2008;117:3010-3019.