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Real-World Medication Adherence and Persistence to Resmetirom in Patients with MASH

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Real World Evidence of Resmetirom Advancing Outcomes, Natural History, Assessment, and Clinical Effectiveness

INTRODUCTION

- MASH is a progressive liver disease with limited treatment options.
- Resmetirom is a thyroid hormone receptor-beta agonist indicated for adults with MASH and moderate to advanced liver fibrosis.[1,2]
- In March 2024, the FDA approved resmetirom as the first medication for MASH with fibrosis stages F2 and F3.[3]
- Real-world evidence on patients initiating resmetirom and their adherence and persistence patterns is needed to inform clinical practice.

AIM

- Assess real-world adherence to resmetirom among U.S. patients with MASH.
- Evaluate persistence and discontinuation patterns following resmetirom initiation.
- Characterize concomitant medication use among patients treated with resmetirom.

METHOD

- Retrospective cohort study used large U.S. specialty and retail pharmacies databases (**Figure 1**).
- Index date: the first resmetirom prescription filled for MASH or after March 14, 2024 (FDA approval date).
- Included adults (≥18 years) with ≥ 2 resmetirom fills.
- Adherence assessed using PDC at 6 and 12 months, good adherence defined as PDC ≥ 80%.
- Persistence defined as active resmetirom use at 6- and 12-months post initiation, allowing a 60/90-day refill grace period.
- Discontinuation evaluated based on gaps exceeding the permissible grace period.
- Multivariable logistic regression was used to identify factors associated with high PDC.

RESULTS

Baseline Characteristics

- 11,469 patients were evaluated after 6 months of follow-up.
- Mean age was 57.5 (SD: 12.9) years, and 56.1% were female.
- 74.6% of patients had commercial health insurance.
- Patients were distributed across the South (39.8%), West (21.5%), Northeast (20.4%), and Midwest (17.5%).
- 44.2% lived in rural areas, 32.6% in urban areas, and 23.1% in suburban areas.
- Mean household income was $60,44 6 (SD: 22,354).
- Mean Social Vulnerability Index (SVI) score was 0.48 (SD, 0.23).[4]
- Mean Rx-Risk Index score was 2.3 (SD: 4.0).[5]
- Common concomitant medications included treatments for
  - Cardiovascular conditions (52.4%)
  - Dyslipidemia (42.6%)
  - Statins (36.9%)
  - Diabetes (32.8%)
  - GLP-1 receptor agonists (24.4%).

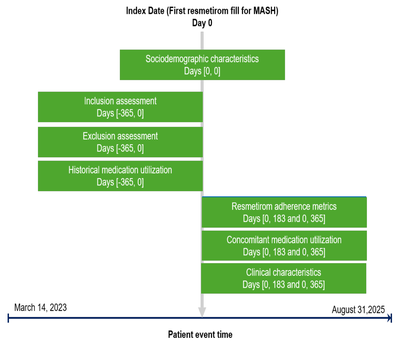


Figure 1. Study design diagram

Prescriber Characteristics

- 54.5% of resmetirom prescriptions were written by hepatologists and gastroenterologists; 45.5% were prescribed by other specialties.
- 70.5% of prescribing physicians were affiliated with academic hospitals.
- Practice locations were urban (50.3%), suburban (28.3%), and rural (21.4%).
- Prescribers were geographically distributed across the South (39.3%), West (21.3%), Northeast (20.8%), and Midwest (17.9%).

Adherence and Persistence

- Mean PDC decreased from 85.7% (SD: 20.5%) at 6 months to 76.4% (SD: 27.5%) at 12 months (**Figure 2**).
- Good adherence (PDC ≥80%) was observed in 75.9% of patients at 6 months and 61.7% at 12 months **(Figure 2**).
- Persistence (60-day grace period) was 89.4% at 6 months and 72.4% at 12 months (**Figure 2**).
- Discontinuation (≥45-day gap) occurred in 18.7% of patients at 6 months and 38.4% at 12 months.
- Treatment restart following a ≥45-day gap occurred in 24.8% of patients at 6 months and 29.3% at 12 months.

Definitions

- **Adherence:** Adherence was measured using the proportion of days covered (PDC), defined as the proportion of days during the 6- and 12-month follow-up periods for which patients had resmetirom available based on pharmacy dispensing records. Good adherence was defined as a PDC ≥80%.
- **Persistence:** Persistence was defined as active resmetirom use at 6 and 12 months after treatment initiation, allowing a 60- or 90-day refill grace period. Patients with a gap exceeding the grace period were considered non-persistent.
- **Discontinuation:** Discontinuation was defined as a gap in resmetirom therapy exceeding 45, 60, or 90 days after exhaustion of medication supply, depending on the grace-period definition used.

Table 1. Multivariable Logistic Regression. Data represented as Adjusted Odds Ratios (95%CI)

Characteristics	PDC ≥80% (12 months follow-up)	Persistence (12 months follow-up)	Discontinuation (12 months follow-up)
Age ≤ 44 vs ≥ 65 years	0.66 (0.55-0.78)	0.70 (0.58-0.94)	1.45 (1.20-1.76)
Age 44-64 vs ≥ 65 years	0.83 (0.73-0.94)	0.90 (0.75-1.08)	1.20 (1.04-1.38)
Male vs Female	1.27 (1.13-1.44)	1.48 (1.25-1.76)	0.75 (0.66-0.85)
Urban vs Rural Area	0.79 (0.69-0.90)	0.89 (0.74-1.08)	1.27 (1.10-1.47)
SVI Quartile Q4 vs Q1	0.55 (0.44-0.69)	0.63 (0.47-0.86)	1.76 (1.38-2.24)
Rx Risk Index > 4 vs ≤ 1	0.70 (0.59-0.82)	0.54 (0.43-0.68)	1.58 (1.32-1.90)

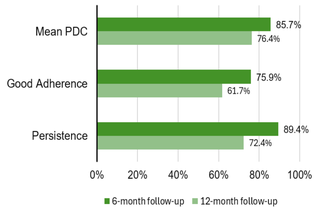


Figure 2. Resmetirom adherence, persistence during the 12-month follow-up period

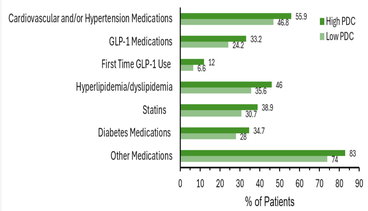


Figure 4. Concomitant medication use during the 12-month follow-up period

- Age, sex, urban-rural residence, SVI, and Rx-Risk Index score were significantly associated with adherence and persistence (**Table 1, Figure 3**).

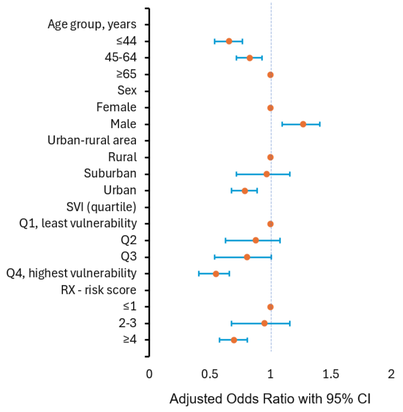


Figure 3. Forest plot of adjusted odds ratios (AOR) of sociodemographic and clinical characteristics for good resmetirom adherence

CONCLUSIONS

- Resmetirom demonstrated high real-world adherence and persistence among patients with MASH at 6 and 12 months.
- At 6 months, 75.9% of patients achieved good adherence (PDC ≥80%), with persistence exceeding 89%.
- Although adherence and persistence was lower at 12 months, most patients remained adherent (61.7%) and persistent (72.4%).
- Continued monitoring and targeted interventions may help sustain long-term treatment use.
- Further research is needed to understand drivers of persistence and the relationship between adherence and clinical outcomes.

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