AASLD The Liver Meeting®

PATIENT CHARACTERISTICS, TREATMENT PATTERNS AND OUTCOMES AMONG PATIENTS USING RESMETIROM IN THE REAL-WORLD SETTING

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INTRODUCTION

- Metabolic dysfunction-associated steatohepatitis (MASH) involves hepatic steatosis with inflammation and hepatocellular injury that often progresses to fibrosis.
- In March 2024, the US FDA approved resmetirom as the first therapy for MASH patients with moderate to advanced liver fibrosis.[1]
- Given its recent approval, real-world evidence on resmetirom use remains limited.

AIM

- To describe US patients prescribed resmetirom and their treatment patterns.

METHODS

Study design and data source

- This was a descriptive, retrospective study of adults treated with resmetirom in the Optum® de-identified Market Clarity data from March 14, 2023 through March 31, 2025 (study period).
- The Optum® de-identified Market Clarity Dataset deterministically links medical and pharmacy claims with electronic health record (EHR) data from providers across the continuum of care.
- Data used in this study include pharmacy claims linked to EHR data.

Study population

- Patients with ≥ 1 paid prescription claim for resmetirom on or after March 14, 2024 (first paid claim = index date), aged ≥ 18 years, and with continuous medical and pharmacy enrollment in the 12-month pre-index period were included.
- Patients with ≥ 1 claim for cirrhosis-related complications, non-MASH liver conditions, or heavy metal exposure in the 12-month pre-index period were excluded.
- All patients who met the selection criteria were included in the resmetirom cohort.

Study outcomes

- Baseline demographics, clinical characteristics, and cardiometabolic risk factors were reported, including body mass index (BMI), obesity, type 2 diabetes mellitus (T2DM), and hypertension.
- Treatment patterns in the follow-up, including duration, persistence (≤ 45-day gap), discontinuation (> 45-day gap), restart, and adherence (proportion of days covered [PDC]) were described.
- Overall glucagon-like peptide-1 receptor agonists (GLP-1 RAs) use in the study period and concomitant MASH treatments (ie, GLP-1 RAs, statins) in the follow-up were reported.

Statistical methods

- Continuous variables were reported as mean (SD), and categorical variables as frequency (%).
- Concomitant use with GLP-1 RAs or statins was standardized per 100 person-years.
- Persistency was summarized as the proportion of patients remaining on resmetirom treatment at each follow-up time point.

RESULTS

Patient attrition

- In total, 540 patients were included in the study.

Table 1. Baseline demographics and clinical characteristics

	Resmetirom cohort N = 540
Age, years	
Mean (SD)	60.3 (12.5)
Sex, n (%)	
Female	328 (61%)
Payor, n (%)	
Commercial	239 (44%)
Medicare	243 (45%)
Medicaid	53 (10%)
Unknown	5 (1%)
BMI, continuous, kg/m²	
Mean (SD)	33.5 (6.5)
BMI, categorical, n (%)	
Normal/underweight, BMI < 25.0 kg/m²	17 (4%)
Overweight, 25.0 ≤ BMI < 30.0 kg/m²	63 (16%)
Obese, BMI ≥ 30.0 kg/m²	310 (80%)
Comorbidities[a], n (%)	
Obesity	313 (58%)
T2DM	283 (52%)
Hypertension	381 (71%)
Baseline MASH treatments[b], n (%)	
GLP-1 RAs	
Any GLP-1 RA	226 (42%)
Semaglutide (Wegovy®)[c]	16 (3%)
Semaglutide (Ozempic®)[c]	122 (23%)
Statins	335 (62%)
Cardiometabolic risk factors	
0	34 (6%)
1	63 (12%)
2	137 (25%)
3+	306 (57%)

BMI, body mass index; GLP-1 RA, glucagon-like peptide-1 receptor agonist; MASH, metabolic dysfunction-associated steatohepatitis; SD, standard deviation; T2DM, type 2 diabetes mellitus.

[a]Patients may have > 1 comorbidity.
[b]Patients may have received > 1 MASH treatments.
[c]All available dose ranges included.

Baseline characteristics (Table 1)

- The mean patient age was 60.3 years (SD, 12.5 years).
- Over half of the patients (61%) were female.
- Most patients had Medicare (45%) or commercial insurance (44%), with few Medicaid beneficiaries (10%).
- Based on the BMI, 4% of patients were normal/underweight, 16% were overweight, and 80% were obese. The mean continuous BMI among patients was 33.5 kg/m² (SD, 6.5 kg/m²).
- A little over half of patients (52%) had T2DM.
- Statin and GLP-1 RAs use were common during the baseline period: 62% and 42%, respectively.
- Over half of the resmetirom cohort (57%) had ≥ 3 cardiometabolic risk factors, 25% had two, 12% had one, and 6% had no cardiometabolic risk factors.

Treatment patterns (Table 2)

- 63% of the resmetirom cohort (n = 340) had ≥ 3 months of follow-up and 34% (n = 185) had ≥ 6 months of follow-up.
- Among those with sufficient follow-up at each time point, 94% of the resmetirom cohort were persistent after 3 months of follow-up and 91% after 6 months (Figure).

Table 2. Follow-up treatment patterns

	Resmetirom cohort N = 540
Duration of follow-up, continuous, days	
Mean (SD)	138.5 (90.8)
Min (Max)	1.0 (363.0)
Duration of follow-up, categorical, n (%)	
≥ 1 month	472 (87%)
≥ 3 months	340 (63%)
≥ 6 months	185 (34%)
Duration of resmetirom treatment, days PPPM	
Mean (SD)	24.6 (8.7)
Resmetirom discontinuation, n (%)	
1 month	12 (3%)
3 months	19 (6%)
6 months	17 (9%)
Resmetirom restart, n (%)	
1 month	12 (100%)
3 months	19 (100%)
6 months	17 (100%)
PDC, mean (SD)	
1 month	1.00 (0.00)
3 months	0.83 (0.25)
6 months	0.73 (0.32)

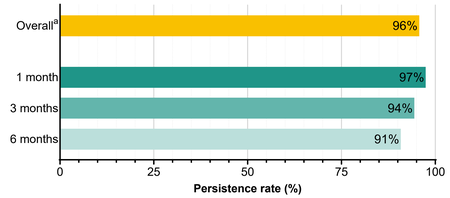
PDC, proportion of days covered; PPPM, per patient per month; SD, standard deviation.

- All patients who discontinued resmetirom later restarted.
  - For the 19 patients who discontinued in the first 3 months of follow-up, mean time to restart was 141.6 days (SD, 48.3 days).
  - For the 17 patients who discontinued in the first 6 months of follow-up, mean time to restart was 166.8 days (SD, 46.0 days).
- Mean PDC was 0.83 (SD, 0.25) at 3 months, and 0.73 (SD, 0.32) at 6 months.

Concomitant MASH treatment use (Table 3)

- In the resmetirom cohort, the GLP-1 RA use rate during the overall study period was 55.5 per 100 person-years.
- During the follow-up period, the concomitant GLP-1 RA and statin use rates were 158.3 per 100 person-years and 304.1 per 100 person-years, respectively.

Figure. Follow-up resmetirom persistence



[a]Does not account for the variable follow-up time. The 1-, 3-, 6-month persistent figures are more appropriate.

Table 3. Overall and concomitant[a] MASH treatments

	Resmetirom cohort N = 540
Overall GLP-1 RA use	
Events	91
P-T (years)	163.8
Rate per 100 P-T (years)	55.5
Follow-up concomitant treatment with GLP-1 RAs	
Events	204
P-T (years)	128.9
Rate per 100 P-T (years)	158.3
Follow-up concomitant treatment with statins	
Events	285
P-T (years)	93.7
Rate per 100 P-T (years)	304.1

GLP-1 RA, glucagon-like peptide-1 receptor agonist; MASH, metabolic dysfunction-associated steatohepatitis; P-T, person-time.

[a]Concomitant treatment required a 14-day overlap with resmetirom.

LIMITATIONS

- The study population is more representative of commercially-insured and Medicare patients; findings may be less generalizable to other payer populations (eg, Medicaid) or uninsured populations.
- Retrospective analyses of administrative claims data depend on correct diagnosis, procedure, and drug codes; coding inaccuracies may lead to case misidentification.
- Missing data is a common issue in administrative claim databases, potentially leading to misclassification bias.
- Selection bias may arise in this study due to the exclusion of patients who lacked continuous medical and pharmacy insurance coverage for ≥ 12 months prior to the index date.

CONCLUSIONS

- This study provides an early look at real-world resmetirom use in the US.
- In the resmetirom cohort, over half of the patients treated had obesity and over half had T2DM.
- Resmetirom adherence was high, with most patients remaining persistent for ≥ 3 months.
- All patients who discontinued resmetirom restarted during the study period.
- Future studies with longer follow-up are needed to evaluate longitudinal clinical outcomes in real-world resmetirom users.

ABBREVIATIONS

BMI, body mass index; EHR, electronic health record; FDA, Food and Drug Administration; GLP-1 RA, glucagon-like peptide-1 receptor agonist; MASH, metabolic dysfunction-associated steatohepatitis; PDC, proportion of days covered; PPPM, per patient per month; P-T, person-time; SD, standard deviation; T2DM, type 2 diabetes mellitus; US, United States.

REFERENCES

1. **US Food & Drug Administration**. FDA approves first treatment for patients with liver scarring due to fatty liver disease. *2024*. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-liver-scarring-due-fatty-liver-disease.

ACKNOWLEDGEMENTS

Madrigal funded this study and was involved in its design, conduct, and reporting. The authors thank Justine Mailliot, PhD of Genesis Research Group, London, UK for medical writing and editorial support.

DISCLOSURES

MB serves on advisory boards or steering committees for Boehringer Ingelheim, Boston Pharma, CurveBio, Fibronostics, GSK, Madrigal, Merck, Novo Nordisk, Surrozen, and Theratechnologies Medical, and received research funding from Histoindex, Pfizer, and Siemens. AR is an employee of Sun Pharma. CG, HS, DVV, and JPM are employees of Genesis Research Group, which received consulting fees from Madrigal. BT, NA, FL, and JO are employees of Madrigal.