Characterizing patients prescribed resmetirom for noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in a real world setting: A United States cohort study of the Forian database

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Background

- Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive liver disease, characterized by fat accumulation and inflammation of the liver.
- Prolonged inflammation and liver damage resulting from MASH can lead to liver fibrosis, cirrhosis, and increased risk of liver failure and cardiovascular diseases.
- Resmetirom, an oral thyroid hormone receptor β-selective agonist, was conditionally approved (based on Phase 3 MAESTRO-NASH trial) on 03/14/2024 for the treatment of patients with noncirrhotic NASH with moderate to advanced fibrosis (consistent with stages F2/F3) in the US.

This study aims to characterize the initial patient population prescribed resmetirom in a real-world setting

Methods

This **open-cohort study** used the Forian open-claims database to identify **adults prescribed resmetirom** through 10/10/2024 in the US.

*Forian's database is one of the **largest integrated**, **longitudinal** repositories of **de-identified** patient-level health data in the U.S., representing 300M+ patients annually.*

Index date was defined as the first prescription date.

Due to the open-claims nature of this study, **active insurance claims status** was assessed via the presence of **any health encounter** in the 1-year prior to the index date.

Population characteristics, **comorbidities**, **diagnoses, procedures**, and **provider characteristics** at index were descriptively summarized for a **1-year pre-index baseline period**.

Results

- A total of **2,350 patients** were included, with **92%** having **≥1 active claim** (for any health encounter) during baseline.
- At index, **58%** of patients were **female**, with a **mean age** of **58.1 years**, and **44.7%** resided in the **south** ***(Table 1)***
- Over the baseline period leading up to resmetirom initiation:
  - The most prevalent metabolic comorbidity was **type 2 diabetes mellitus** at **42.6%** and **overweight/obese/severe obese** at **32.3%** ***(Table 2)***.
  - Only **21.5%** had ≥1 observed diagnosis for **MASH (K75.81)** and **42.7%** for **MASLD (K76.0)** ***(Table 3)***.
  - The most frequently documented imaging procedures were abdominal ultrasound (21.8%), FibroScan® (10.4%), and CT (9.1%), with liver biopsy only documented among 3.3% of these patients (***Table 3***).
- Among the **1,385 prescribers** (each prescribing to a mean of 1.7 patients), **over half prescribers were physicians** who had a specialty of gastroenterology, hepatology, or transplant hepatology; while over a third were advanced practice practitioners (APPs), such as nurse practitioners and physician assistants‡ (***Table 4***).
- At resmetirom initiation, **54.4%** received **80 mg**, **41.3%** received **100 mg**, and 4.6% received 60 mg. A small proportion (0.3%) had multiple doses at index dispensation.

Table 1: Population characteristics at index

Population characteristics (n=2,350)	
Age at index, years	
Mean (SD)	58.1 (13.1)
Sex, n(%)	
Female	1,360 (57.9%)
Male	990 (42.1%)
Race, n(%)[a]	
Other	532 (22.6%)
White	125 (5.3%)
Hispanic	190 (8.1%)
Black	48 (2.0%)
Asian	30 (1.3%)
Missing	1,424 (60.6%)
Region, n(%)	
South	1,050 (44.7%)
Midwest	381 (16.2%)
Northeast	312 (13.3%)
West	280 (11.9%)
Missing	327 (13.9%)
Treatment patterns, n(%)	
GLP-1 RA use, any	377 (16.0%)
Statins use, any	491 (20.9%)

Figure 1: Distribution of resmetirom dosing at initiation

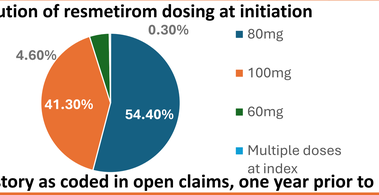

Table 2: Comorbidities within the one year prior to resmetirom use

Comorbidities (n=2,350)	
Elixhauser comorbidity index (unweighted)	
Mean (SD)	2.5 (2.6)
Cardiovascular disease[b]	
Other cardiovascular and circulatory diseases	976 (41.5%)
Hypertension	863 (36.7%)
Hyperlipidemia	782 (33.3%)
Ischemic heart disease	211 (9.0%)
Cerebrovascular disease	92 (3.9%)
Heart failure	73 (3.1%)
Metabolic conditions	
Type 2 diabetes mellitus	1,001 (42.6%)
Overweight/obese/severe obese	770 (32.3%)
Type 1 diabetes mellitus	127 (5.4%)
Specific comorbidities[b]	
Gastroesophageal reflux disease	553 (23.5%)
Abdominal/pelvic pain	465 (19.8%)
Sleep apnea	425 (18.1%)
Vitamin D deficiency	268 (11.4%)
Thyroid disease	224 (9.5%)
Fatigue	202 (8.6%)
Smoking	195 (8.3%)
Renal impairment	148 (6.3%)
Unspecified anemia	96 (4.1%)
Iron deficiency anemia	91 (3.9%)

Table 3: Disease history as coded in open claims, one year prior to resmetirom use

Disease history (n=2,350)	
Diagnosis[c,d]	n(%)
MASLD (K76.0)	1,004 (42.7%)
MASH (K75.81)	506 (21.5%)
Fibrosis (K74.0)	367 (15.6%)
F1/F2 (K74.01)	74 (3.1%)
F3 (K74.02)	91 (3.9%)
Other diseases of the liver (K76.x excluding K76.0)	152 (6.5%)
Fibrosis staging related procedures[c]	
Abdominal ultrasound	512 (21.8%)
FibroScan®[e]	244 (10.4%)
CT	215 (9.1%)
MRI/MRE/LiverMultiScan™	145 (6.1%)
Liver biopsy	78 (3.3%)
Documented advanced stages of fibrosis[a,f,g]	
Any (cirrhosis, decompensated cirrhosis, LT, HCC)	62 (2.6%)
Cirrhosis	54 (2.3%)

*Both cirrhosis and decompensated cirrhosis patients were identified in this subgroup, however, the majority of patients in this subgroup were cirrhosis patients.

Table 4: Provider information among those who prescribed resmetirom to ≥1 patient

Provider taxonomy (n=1,385 total prescribers of resmetirom during the study period)[b]	
Physicians (Gastroenterology/ Hepatology/ Transplant Hepatology)	722 (52.1%)
Nurse Practitioner	350 (25.2%)
Physician Assistant	165 (12.0%)
Other 'Internal Medicine'	76 (5.4%)

Conclusion

Overall, patient demographics were comparable to those of MAESTRO-NASH, with fewer coded comorbidities at baseline.

- While it cannot be ascertained whether results reflect coding or actual practice differences in real-world settings, these findings help establish **population characteristics** at **resmetirom initiation** and provide insight into **prescribing behaviors**.
- Continued **follow-up** and **additional patients** are needed to better understand characteristics and outcomes of patients using resmetirom **over time**.

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Notes

‡In this study, using the data available, it was not possible to ascertain whether APPs had prescribed resmetirom in consultation with liver specialists.
aCategories with n≤5 are suppressed: race='Indian American'; advanced liver disease events of liver transplant and hepatocellular carcinoma.
bAdditional categories were reviewed but are not included in the table as each accounted for <3%. cPatients may have had more than one of these codes (non-mutually exclusive). dCategories with <5% of patients are not included in the table: alcoholic liver disease (K70.x), toxic liver disease (K71.x), hepatic failure not elsewhere classified (K72.x), chronic hepatitis (K73.x), other inflammatory liver diseases (K75.x excluding K75.81), liver disorders in diseases classified elsewhere (K77.x). eFibroscans are infrequently 'coded' due to low reimbursement. fFurther research is needed to better ascertain the timing of these documented events and whether the decompensation event may have resolved, in addition to understanding potential miscoding in the data. gPatients with advanced liver disease were identified using the validated algorithm proposed by Khalifa et al. (*Dig Dis Sci. 2023 June* ; 68(6): 2360–2369)

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