Characterizing patients prescribed resmetirom for noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in a real-world setting: A United States cohort study using electronic medical records

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Introduction

- 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 FDA 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 cohort study sourced electronic medical records from the **Latica** real-world gastroenterology data repository, a major gastroenterology community-based health center, to identify adults prescribed resmetirom by **January 2025**
- Where available, both **structured** and **unstructured** EMR data were included to maximize clinical information

The **proportion of patients** with **at least one encounter** documented in the baseline year prior to index was used as a **proxy** to indicate active coverage within the health system(s) covered within these EMR data

Index date was defined as the first prescription date

Patient demographics, **disease characteristics**, and **comorbidities**, were descriptively summarized within the **baseline year prior to the index date**

Characteristics of real-world resmetirom users were comparable to that of the baseline characteristics of participants from the MAESTRO-NASH study

→ Real-word resmetirom initiation is in line with patient characteristics and NIT thresholds consistent with published recommendations.[1-4]

→ Ongoing follow-up is needed to better understand prescribing patterns and long-term outcomes.

Abbreviations: BMI, body mass index; CT, computed tomography; DSCI, disease severity classification index; EMR, electronic medical records; ICD, International Classification of Diseases; IQR, interquartile range; kg, kilogram; MASLD, metabolic dysfunction-associated steatotic liver disease; MASH, metabolic dysfunction-associated steatohepatitis; mg, milligram; MRI, magnetic resonance imaging; MRE, magnetic resonance elastography; SD, standard deviation; SNOMED, Systematized Nomenclature of Medicine.
* Fibrosis staging was informed by FibroScan, abdominal ultrasounds, CTs, MRI/MRE and liver biopsy results, where available for each patient

Results

- A total of **561 patients** were included and **96.8%** of these had **at least one encounter** during the baseline year.

At index

- **57.2%** were **female**, had a mean (SD) age of **58.8 (12.8) years**, and **38.3%** were self-reported as **White**, with **30.8%** having **unreported race/ethnicity** information, and **62.2%** were **Florida residents** ***(Table 1)***
- The majority of these patients were prescribed the **80 mg dose** of resmetirom (**58.8%**), **37.6%** were prescribed the **100 mg dose**, and **2.7%** were prescribed the **60 mg dose** ***(Figures 1-3)***
- A small percentage (**<1%**) of patients were prescribed **more than one dose** and/or had **missing dose information**

At baseline

- The majority of patients were **<100kg** (**59.5%**), and **67.7%** had a body mass index of **≥30 kg/m2** ***(Table 3)***
- **Type 2 diabetes mellitus** was observed among **46.2%, hypertension** among **29.2%,** and **hyperlipidemia** among **22.5%;** with **25.7%** of patients having any baseline use of incretins and **51.3%** having use of statins ***(Table 2,6)***
- **Diagnosis of MASH** based on ICD or SNOMED codes was observed during the baseline period among **51.7%** of the cohort ***(Table 4)***
- Similarly, diagnosis coding for **MASLD** was also commonly observed among **74.2%** of the cohort
- At baseline, the average liver stiffness measured via FibroScan was 11.6 ± 7.8 kPa (n=266), which is **in line with published guidances**[1-4] ***(Table 5)***

Table 1: Population characteristics at index (n=561)

Active coverage during baseline	
At least one encounter during baseline, n (%)	543 (96.8)
Number of encounters during baseline, Mean ± SD	8.3 ± 5.2
Age at index, years	
Mean ± SD	58.8 ± 12.8
Categorical age at index, years, n (%)	
≤30	13 (2.3)
31-44	75 (13.4)
45-64	268 (47.8)
≥65	205 (36.5)
Sex/gender, n(%)	
Females, n (%)	321 (57.2)
Race/ethnicity, n (%)	
White	215 (38.3)
Multiple	89 (15.9)
Hispanic	40 (7.1)
Black	20 (3.6)
Asian	13 (2.3)
Other	11 (2.0)
Unknown	173 (30.8)
State*, n (%)	
Florida	349 (62.2)
Ohio	89 (15.9)
Virginia	35 (6.2)
Alabama	33 (5.9)
Massachusetts	26 (4.6)
Maryland	23 (4.1)
Insurance coverage	
Medicare	225 (40.1)
Medicaid	9 (1.6)
Commercial	559 (99.6)

Table 2: Comorbidities, within the one year prior to resmetirom use (n=561)

Elixhauser comorbidity (unweighted)	
Mean ± SD	9.3 ± 4.1
Diabetes complications severity index	
Mean ± SD	0.0 ± 0.2
Comorbidities, n(%)	
Type 2 diabetes mellitus	259 (46.2)
Obesity	380 (67.7)
Hypertension	164 (29.2)
Hyperlipidemia	126 (22.5)
Smoking	71 (12.7)
Unspecified anemia	34 (6.1)

Table 3: Weight characteristics at baseline (n=561)

Categorical weight at index, years, n(%)	
<100kg	334 (59.5)
≥100kg	223 (39.8)
Unknown	4 (0.7)
BMI, n(%)	557 (99.3)
Mean ± SD, kg/m²	33.7 ± 6.9
Median (IQR), kg/m²	33.1 (28.7, 38.1)
Categorical BMI, n(%)	
Normal weight, <25	39 (7.0)
Overweight, 25 to <30	138 (24.6)
Obese, ≥30	380 (67.7)

Table 4: Disease history based on ICD or SNOMED codes, one year prior to resmetirom use (n=561)

Diagnosis (ICD/SNOMED codes), n (%)	
MASH (K75.81)	290 (51.7)
MASLD (K76.0)	416 (74.2)
Fibrosis (K74.0)	256 (45.6)
F1/F2 (K74.01)	106 (18.9)
F3 (K74.02)	95 (16.9)

Table 5: Mean NIT values, at baseline

Diagnostic procedure	Patients (n)	Mean ± SD
FibroScan (kPa)	266	11.6 ± 7.8
Enhanced Liver Fibrosis Score (ELF) score	29	10.2 ± 1.1

Table 6: Treatment patterns, at baseline

Diagnostic procedure	N (%)
Statin use, any	288 (51.3)
Incretin use, any	144 (25.7)

Figure 1: Distribution of resmetirom dosing at initiation for the total sample (n=561)

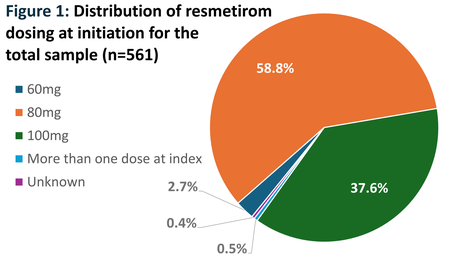


Figure 2: Distribution of resmetirom dosing at initiation among those <100 kg (n=334)

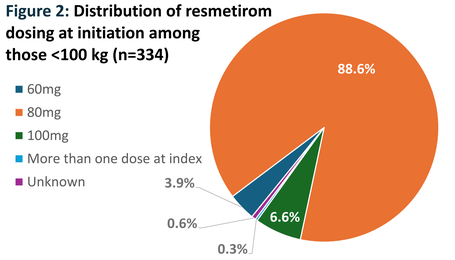
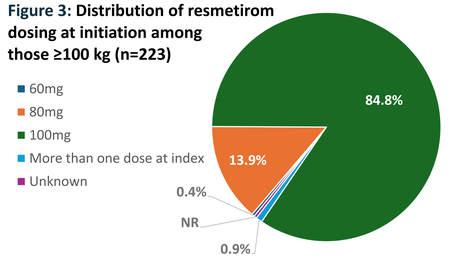


Figure 3: Distribution of resmetirom dosing at initiation among those ≥100 kg (n=223)



References: 1. Lam BP, et al. Focused Recommendations for the Management of Metabolic Dysfunction-Associated Steatohepatitis (MASH) by Advanced Practice Providers in the United States. J Clin Gastroenterol. 2025 Apr 1;59(4):298-309. 2. Noureddin M, et al. Expert Panel Recommendations: Practical Clinical Applications for Initiating and Monitoring Resmetirom in Patients With MASH/NASH and Moderate to Noncirrhotic Advanced Fibrosis. Clin Gastroenterol Hepatol. 2024 Dec;22(12):2367-2377. 3. Chen VL, et al. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. Hepatology. 2025 Jan 1;81(1):312-320. 4. European Association for the Study of the Liver (EASL); European Association for the Study of Diabetes (EASD); European Association for the Study of Obesity (EASO). EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD). J Hepatol. 2024 Sep;81(3):492-542.

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