Estimation of the treatment-eligible patients with compensated MASH cirrhosis in the United States

POSTER 146

Yestle Kim,[1] Nipun Atreja,[1] Latashree Goswami,[2] Atish De,[2] Nandini Hadker,[2] Christina M. Parrinello,[1] John O'Donnell[1]

[1]Madrigal Pharmaceuticals, Inc., West Conshohocken, PA; [2]Trinity Life Sciences, LLC, Waltham, MA

INTRODUCTION

- Metabolic dysfunction–associated steatohepatitis (MASH) is associated with substantial clinical and economic burden, which increases incrementally with increasing fibrosis stage[1-3]
- Patients with compensated cirrhosis due to MASH are at particularly high risk of liver-related events, including hepatic decompensation and greater healthcare resource utilization[1-3]
- As multiple investigational treatments for patients with compensated cirrhosis due to MASH are being evaluated in clinical trials, reliable estimates of the treatment-eligible population are needed to inform healthcare planning, resource allocation, and future access considerations

AIM

- To estimate the potential size of the treatment-eligible population with compensated cirrhosis due to MASH in the US using published epidemiologic data

METHODS

Systematic literature review

- A systematic literature review (SLR) was conducted in accordance with PRISMA 2020 guidelines to identify published epidemiologic estimates relevant to the US population with MASH and compensated cirrhosis due to MASH
  - English-language peer-reviewed publications from January 2017 through January 2026 and conference abstracts from January 2021 through January 2026 were evaluated
  - Searches of PubMed Central and MEDLINE (via PubMed.gov) and Embase and MEDLINE (via embase.com) combined controlled vocabulary (medical subject headings [MeSH] and Emtree) and free-text terms related to metabolic dysfunction–associated steatotic liver disease (MASLD)/MASH, advanced fibrosis, cirrhosis, liver transplantation, and outcomes of interest
  - Supplementary sources included ClinicalTrials.gov, reference list screening, and targeted journal searches

METHODS (CONT'D)

Systematic literature review (cont'd)

- The SLR was used to identify the following epidemiologic parameters:
  - Prevalence of MASH (fibrosis stages F0-F4, consistent with no fibrosis to cirrhosis)
  - Proportion of patients with MASH who have compensated cirrhosis due to MASH
  - Proportion of patients with compensated cirrhosis due to MASH

Population calculator

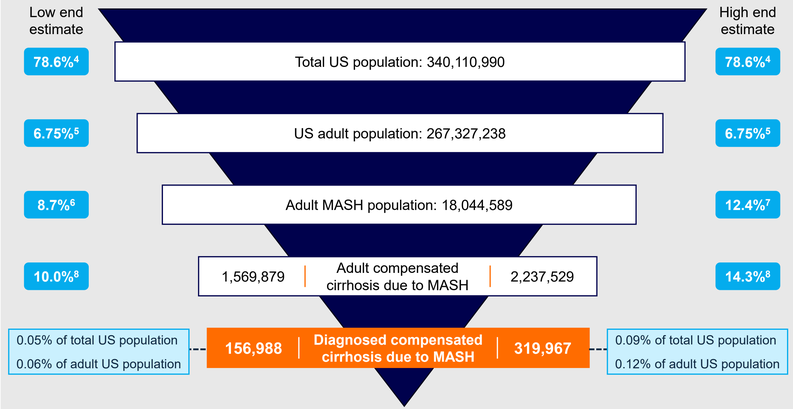
- A dynamic population calculator was developed using selected epidemiologic estimates identified through the SLR
- The calculator was used to estimate the potential number of US adults with diagnosed compensated cirrhosis due to MASH who may be eligible for treatment within the first year following approval of a given therapy, based on the assumption that the diagnosed population represents the population potentially eligible for treatment during this period
- The calculator sequentially applied SLR-derived epidemiologic estimates to the 2024 US Census population from the American Community Survey,[4] to estimate the treatment-eligible population, with the output from each step serving as the input for the subsequent step
- Calculations were performed as follows:
  - **Step 1:** Estimate the US adult population (≥18 years)
    - The US adult population was estimated to be 78.6% of the total US population[4]
  - **Step 2:** Estimate the number of adults living with MASH
    - A prevalence of 6.75% was selected based on literature[5]
  - **Step 3:** Estimate the number of patients with MASH who have compensated cirrhosis due to MASH
    - Proportions of 8.7%-12.4% were used as low-end and high-end estimates, respectively[6,7]
  - **Step 4:** Estimate the number of patients with compensated cirrhosis due to MASH who are diagnosed
    - Proportions of 10.0%-14.3% were used as low-end and high-end estimates, respectively[8]
- Future analyses will apply alternative epidemiologic inputs and assumptions

RESULTS

Estimated treatment-eligible population

- Using epidemiologic estimates identified through the SLR, the population calculator estimated 156,988-319,967 US adults with diagnosed compensated cirrhosis due to MASH who may be treatment-eligible within the first year following approval of a given therapy (**FIGURE 1**)
- This estimate corresponded to an overall US prevalence of 0.05%-0.09% for diagnosed compensated cirrhosis due to MASH; equivalent to 0.06%-0.12% of the US adult population

FIGURE 1. Population funnel: estimated treatment-eligible population with diagnosed compensated cirrhosis due to MASH in the US



MASH, metabolic dysfunction–associated steatohepatitis.

CONCLUSION

- **A population calculator informed by SLR-derived epidemiologic estimates projected ~157,000–320,000 US adults with diagnosed compensated cirrhosis due to MASH could be treatment-eligible within the first year of drug approval**
- **These findings address a critical knowledge gap in quantifying this underdiagnosed population, for which no approved therapies were available at the time of analysis**

REFERENCES

1. Boursier J et al. *EClinicalMedicine*. 2020;25:100445.
2. Taylor RS et al. *Gastroenterology*. 2020;158:1611–1625.e12.
3. Dulai PS et al. *Hepatology*. 2017;65:1557-1565.
4. U.S. Census Bureau. Population by age and sex: United States. Accessed April 15, 2026. https://data.census.gov.
5. Younossi ZM et al. *Clin Gastroenterol Hepatol*. 2026;24:1016–1034.
6. Sartini C et al. BMC *Gastroenterology*. 2026;26:213.
7. Ruiz-Casas L et al. *Medicine (Baltimore)*. 2021;100:e28165.
8. Fishman J et al. *Adv Ther*. 2024;41:4172–4190.

DISCLOSURES

YK, NA, CMP, and **JO** are employees and shareholders of Madrigal Pharmaceuticals, Inc. **LG, AD,** and **NH** are employees of Trinity Life Sciences, LLC, and have provided consulting services to Madrigal Pharmaceuticals, Inc., through their employment with Trinity. Trinity received funding from Madrigal Pharmaceuticals, Inc., for this study.

CONTACT INFORMATION
Yestle Kim
ykim@madrigalpharma.com

ACKNOWLEDGMENTS
Medical writing and/or editorial assistance was provided by ApotheCom (San Francisco, CA, USA). This assistance was funded by Madrigal Pharmaceuticals, Inc., West Conshohocken, PA, USA.
Funding for this research was provided by Madrigal Pharmaceuticals, Inc., West Conshohocken, PA, USA.

COPIES OF THIS POSTER OBTAINED THROUGH QR (QUICK RESPONSE) CODES ARE FOR PERSONAL USE ONLY AND MAY NOT BE REPRODUCED WITHOUT PERMISSION FROM THE AUTHORS.

Madrigal

Copyright © 2026 Madrigal Pharmaceuticals, Inc. All rights reserved. Presented at AMCP Nexus; October 26-29, 2026; San Diego, CA