# Fifteen-year Trends in the Prevalence of Decompensated Cirrhosis and Overt Hepatic Encephalopathy **Among Medicare Beneficiaries in the United States (2007-2020)**

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# Background

- Development of cirrhosis and its complications, including overt hepatic encephalopathy (OHE), is associated with significant morbidity, especially in inpatient care<sup>1</sup>
- Understanding the trends in epidemiology, treatment, and burden of cirrhosis and OHE can help guide healthcare policy and resource allocation

# Objectives

This study aimed to describe the trends in cirrhosis among Medicare beneficiaries in the United States (US), with a focus on the prevalence of OHE, related hospitalizations, and medication use

### Methods

- Data source: Medicare 100% Research Identifiable Files (2006-2020)
- Medicare beneficiaries aged  $\geq$ 65 with cirrhosis were identified, defined as the presence of  $\geq 2$  diagnoses of cirrhosis<sup>a</sup> or its complications<sup>b</sup>
- For each year from 2007 to 2020, prevalence of cirrhosis was calculated based on patients who had continuous Medicare enrollment for the entire calendar year
- The prevalence of decompensated cirrhosis<sup>c</sup> (defined as ascites, variceal bleeding, hepatorenal syndrome, OHE, or spontaneous bacterial peritonitis) and OHE were estimated among cirrhosis patients
- Sensitivity analyses were performed on various definitions<sup>d</sup> of indicators of OHE including OHE-related medications (lactulose or rifaximin 550mg twice daily (BID) for ≥30 days)
- Trends in cirrhosis and OHE were stratified by sex and age (65-74 and  $\geq$ 75 years)
- Annual prevalence of OHE medication utilization (lactulose and/or rifaximin 550mg) among patients with cirrhosis and OHE hospitalizations defined as  $\geq 1$  inpatient stay with OHE as a primary diagnosis among patients with OHE were estimated from 2007-2020
- Cirrhosis and OHE prevalence in 2020 were applied to American Community Survey (ACS) 2021 population estimates<sup>2</sup> to estimate the population of Medicare-insured adults with cirrhosis and OHE in the US in 2020<sup>e</sup>

Notes: a Cirrhosis was defined as ICD-9 571.2, 571.5, 571.6 or ICD-10 K70.3, K71.7, K74.3, K74.4, K74.5, K74.6; <sup>b</sup> Varices was defined as ICD-9 456.0, 456.1, 456.2 or ICD-10 I85, I86.4; hepatorenal syndrome was defined as ICD-9 572.4 or ICD-10 K76.7, K91.83; OHE was defined using CMS GEM codes as ICD-9 572.2 or ICD-10 K72.01, K72.11, K72.90, K72.91, K70.41, K71.11; spontaneous bacterial peritonitis was defined as ICD-9 567.23 or ICD-10 K65.2; <sup>c</sup>Ascites was defined as ICD-9 789.5 or ICD-10 K70.11, K70.31, K71.51, R18; variceal bleeding was defined as ICD-9 456.0 or ICD-10 185.07 185.11. 186.4: d OHE definitions for sensitivity analyses include unspecified OHE for years 2015 - 2020, defined as ICD-10 G93.40, G93.41, G93.49; e 2021 ACS estimates were used with 2020 prevalence estimates given that the ACS did not release estimates for 2020 due to significant disruptions to data collection brought on by the coronavirus pandemic

### Results

## 1.40% 1.20% 1.00% 0.80% 0.60% 0.40% 0.20% **0.41%** 0.00% 2007 2009 Decompensated Cirrhosis 45% 40% **\_39.0%** 35% 30% 25% <sup>20%</sup> **15.2%** 15% 2007 2009 2011 **OHE in the US over time** 26.2% Rifaximin 550mg BID FDA 25% approval for reduction in risk of OHE recurrence 20% 18.1% 15% 2007 2009 2010 2008



# Conclusions

- Over 15 years, the prevalence of decompensated cirrhosis and OHE notably increased among Medicare beneficiaries to over 40% and 20%, respectively
- Over the same period, OHE hospitalizations declined from 26.2% to 9.5%, which may reflect improvements in management of OHE
- Among patients with cirrhosis, rifaximin 550mg utilization was observed to increase from 1.2% at its approval in 2010 to 4.1% in 2014, then decline to 3.1% in 2020
- Based on observed trends, the extrapolated US populations of Medicare-insured adults with cirrhosis and OHE in 2020 were 628,515 and 132,706, respectively

### Limitations

- This claim-based study is subject to common limitations including billing inaccuracies and missing
- Definition of OHE was based on literature and clinical input, but no unanimous consensus on ICD code exists from 2015 through the analysis period
- This study focuses on a publicly-insured population and findings may not be generalizable to a general population

### References

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### Disclosures

RW is consulting on this project (without compensation). PGS, JM, RB, and AG are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Bausch Health Companies Inc., which funded the development and conduct of this study. ZH is an employee of Salix Pharmaceuticals. AAD and BB are employees of Bausch Health Companies, Inc, and GJ was an employee of Bausch Health Companies, Inc at the time of study conduct. OO is a postdoctora fellow with Rutgers Pharmaceutical Industry Fellowship Program, and DB was a postdoctoral fellow with Rutgers Pharmaceutical Industry Fellowship Program at time of study conduct.