

# Projected Prevalence of Cirrhosis and Overt Hepatic Encephalopathy in the United States, 2021–2030

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9:00 – 9:15 AM

PRESENTER

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**DDW2024**

Digestive Disease Week<sup>®</sup>

**MAY 18-21, 2024 | WASHINGTON, D.C.**

EXHIBIT DATES: MAY 19-21, 2024

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# Projected Prevalence of Cirrhosis and Overt Hepatic Encephalopathy in the United States, 2021–2030

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<sup>4</sup>Salix Pharmaceuticals

<sup>5</sup>Bausch Health

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## COI

Dr. Wong consults for Salix Pharmaceuticals & Bausch Health (without compensation)

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## SPONSORSHIP OF STUDY

Bausch Health

# BACKGROUND



- | **Overt hepatic encephalopathy (OHE)** is a serious complication of **liver cirrhosis**, associated with recurrent and expensive hospitalizations and a median survival time of 1 year<sup>1,2</sup>
- | The **prevalence of cirrhosis and OHE has increased** over time among commercially-insured<sup>3</sup> and Medicare-insured adults<sup>4</sup> in the United States (US)
- | These trends in prevalence may be influenced by factors including **changes in coding practices**, **shifting etiologies** of liver disease<sup>5</sup>, increasing **disease awareness**, and an **aging US population**<sup>6</sup>
- | Understanding the future prevalence of cirrhosis and OHE may help to identify high-risk populations, guide intervention, and inform policy to mitigate the potential disease burden

<sup>1</sup>Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735. doi:10.1002/hep.27210

<sup>2</sup>Tapper EB, et al. *JAMA*. 2023;329(18):1589-1602. doi:10.1001/jama.2023.5997

<sup>3</sup>Wong R, et al. *Gastroenterology*. 2023;164(6):S-1325-S-1326 (Su1546). doi:10.1016/S0016-5085(23)04085-4

<sup>4</sup>Wong R, et al. *Hepatology*. 2023;78(S1):p S1-S2154 (3076-A). doi:10.1097/HEP.0000000000000580

<sup>5</sup>Huang DQ, et al. *Gastroenterology & hepatology*. 2023;20(6):388-398. doi:10.1038/s41575-023-00759-2

<sup>6</sup>Stahl EC, et al. *Frontiers in immunology*. 2018;9:2795. doi:10.3389/fimmu.2018.02795

# OBJECTIVE

To estimate the **projected prevalence** of

**cirrhosis** and **OHE** in **2030**

by **extrapolating observed trends** from 2007-2020, among

**commercially-insured** and **Medicare-insured** adults in the US

# METHODS

## DATA SOURCE

### Data sources (analyzed separately)

#### MarketScan Commercial Claims Database

2007-2020

- Claims for beneficiaries covered by employer-sponsored private health insurance
- Medical (e.g., inpatient, outpatient) and pharmacy claims, eligibility data
- Diagnosis/procedure and economic information available

#### 100% Medicare Research Identifiable Files

2007-2020

- Health care system encounters for Medicare fee-for-service beneficiaries
- Institutional (Part A; e.g., inpatient), non-institutional (Part B), and drug prescription events (Part D)
- Diagnosis/procedure and economic information available

# METHODS

## PREVALENCE OF CIRRHOSIS

### Prevalence of cirrhosis in year

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{Adults with cirrhosis in current or prior years}^1}{\text{Adults insured for current year}}$$

<sup>1</sup>Adults identified with cirrhosis were carried forward in subsequent years as prevalent cases, so long as they met the denominator criteria for that year.

#### Numerator (calculated per year):

Adults from the denominator with **cirrhosis** in current or prior years based on ICD-9/10 codes<sup>1</sup>

#### Denominator (calculated per year):

Adults aged **18-64 years (commercial)** or **≥ 65 years (Medicare)**:

- With continuous health plan enrollment for the entire calendar year, and;
- Without a liver transplant in a prior year

# METHODS

## PREVALENCE OF CIRRHOSIS

### Prevalence of OHE in year

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{Adults with OHE in current or prior years}^1}{\text{Adults with cirrhosis in current or prior years}}$$

#### **Numerator** (calculated per year):

Adults from the denominator with **OHE** in current or prior years based on ICD-9/10 codes<sup>1</sup>

#### **Denominator** (calculated per year):

Adults with **cirrhosis** in current or prior years

<sup>1</sup>Adults identified with OHE were carried forward in subsequent years as prevalent cases, so long as they met the denominator criteria for that year.

# METHODS

## STATISTICAL ANALYSES

1

Trends in prevalence from 2007 – 2020 extrapolated to 2030 using **linear regression models**

2

Average **year-over-year (YOY) growth rates** were estimated for 2007 – 2020 and 2020 – 2030, separately

3

**Population counts in 2030 were estimated** using population projections from the US Census Bureau<sup>1</sup>

Results were reported for the **commercial** and **Medicare** populations, separately, and were stratified by sex (male and female) and the following age groups:


- **Commercial:** 18-44 years; 45-64 years
- **Medicare:** 65-74 years; ≥75 years



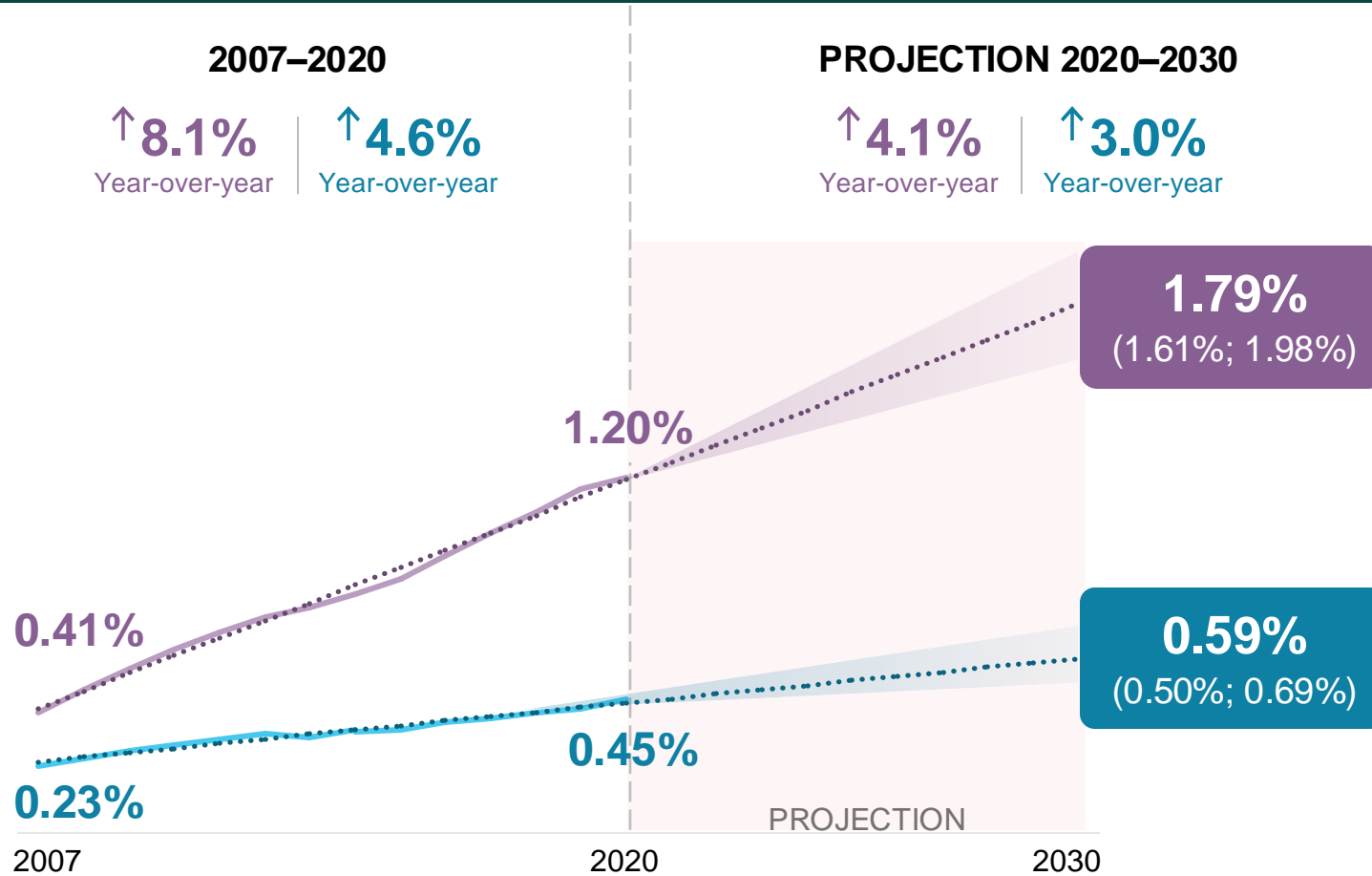
# RESULTS

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# PREVALENCE OF CIRRHOSIS



**Commercial** | **Medicare**

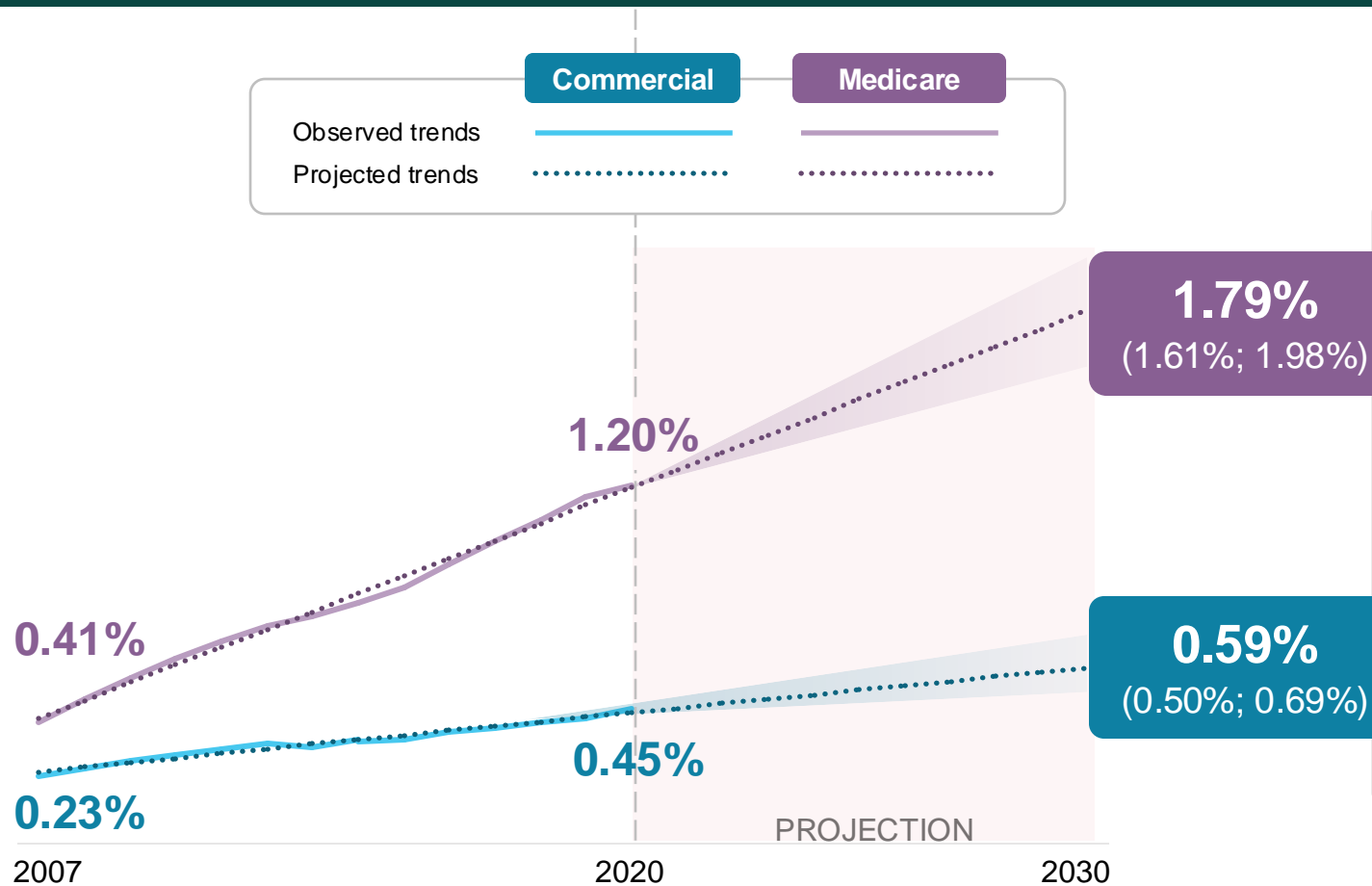
Observed trends: — (solid line)  
 Projected trends: ..... (dotted line)

**The prevalence of cirrhosis is projected to continue to increase** in both commercial and Medicare populations

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In 2030, the **prevalence of cirrhosis is projected to be 3x higher** in the Medicare vs commercial population

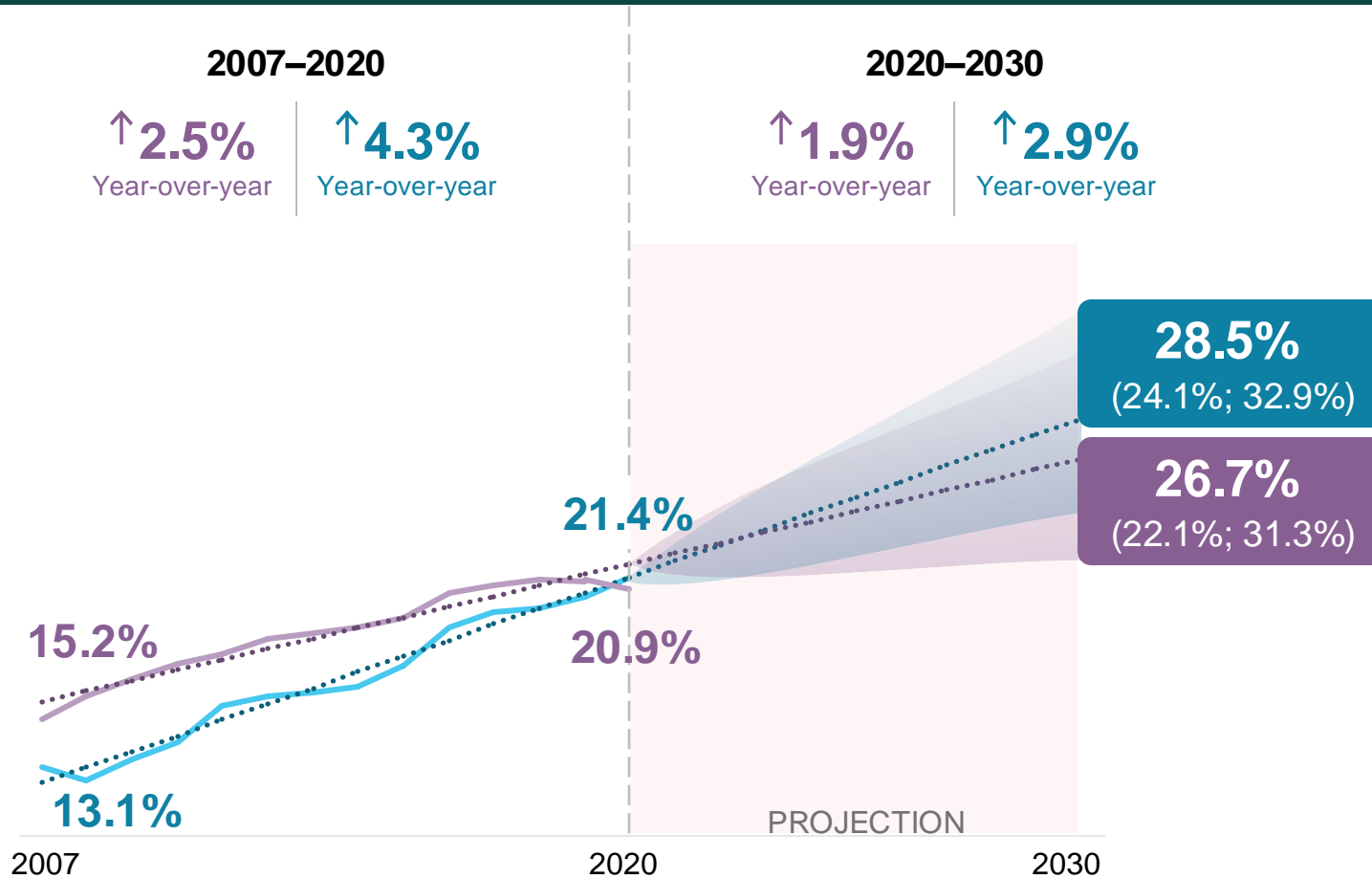
# PREVALENCE OF CIRRHOSIS



## 2030 predicted prevalence by group

GENDER		AGE	
Male	2.06%	65-74	<b>Higher prevalence among males and those aged 65-74</b>
Female	1.59%	≥75	
Male	0.81%	18-44	<b>Higher prevalence among males and those aged 45-64</b>
Female	0.46%	45-64	

# PREVALENCE OF OHE



**Commercial** **Medicare**

Observed trends: — (solid line)  
 Projected trends: ..... (dotted line)

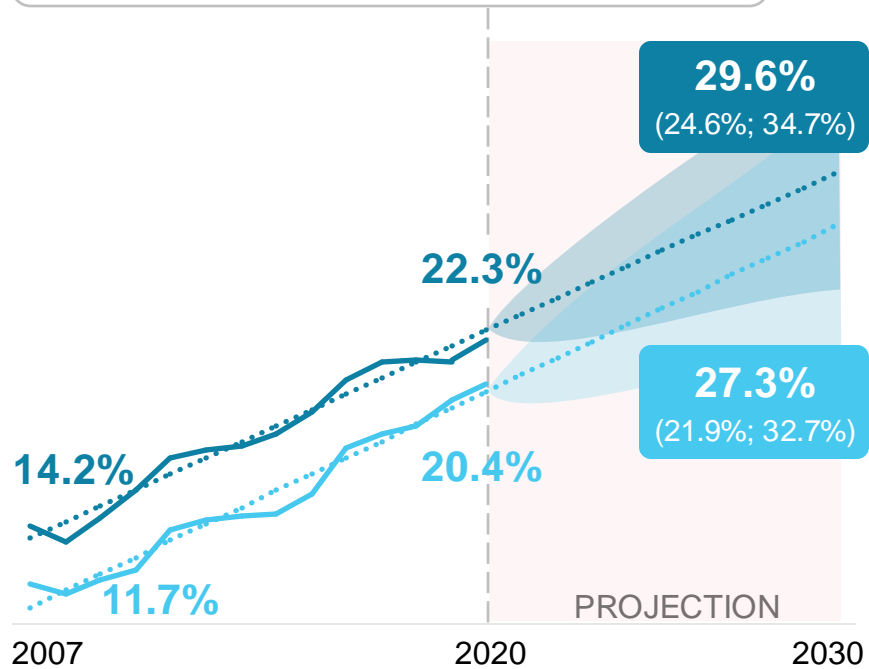
The **prevalence of OHE** among patients with cirrhosis is projected to be **similar in commercial and Medicare populations** in 2030

May be influenced by **shifting etiologies** of liver disease with increased alcohol use and **alcohol-related liver diseases** particularly among younger adults<sup>1,2</sup>

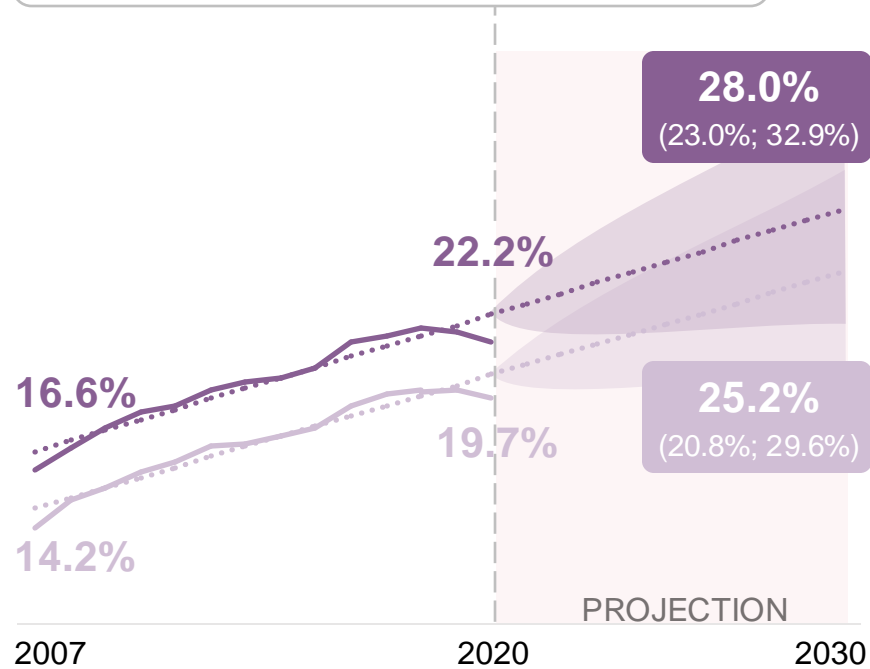
<sup>1</sup>Huang DQ, et al. *Gastroenterology & hepatology*. 2023;20(6):388–398. doi:10.1038/s41575-023-00759-2  
<sup>2</sup>Tapper EB, et al. *BMJ*. 2018;362:k2817. doi:10.1136/bmj.k2817

# PREVALENCE OF OHE BY GENDER

## Commercial

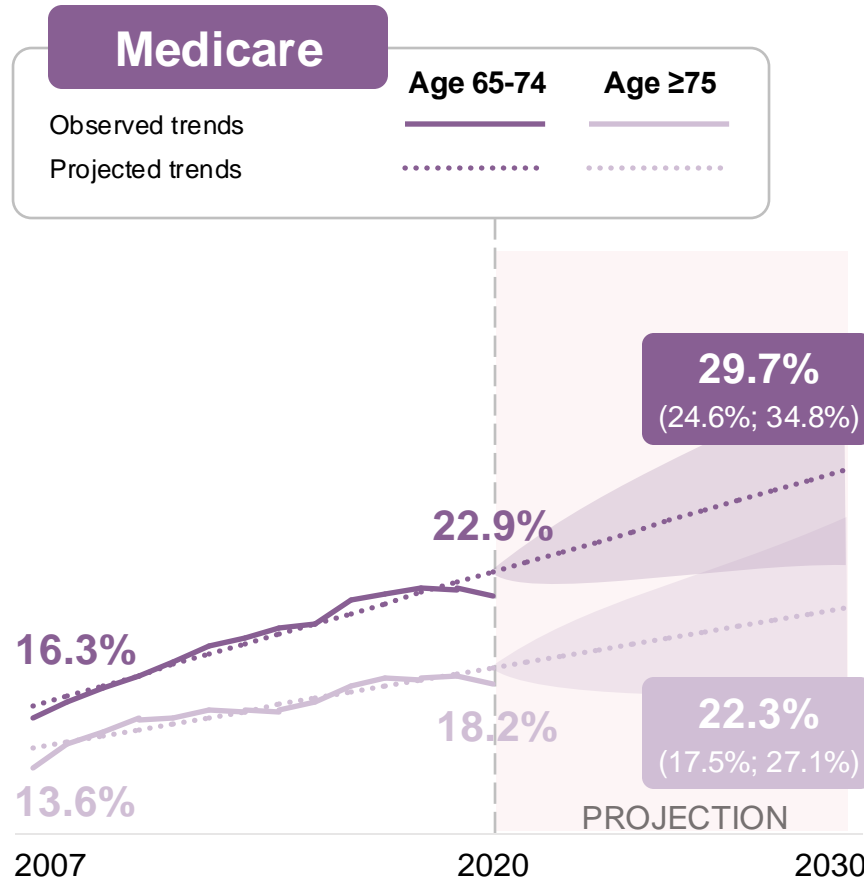
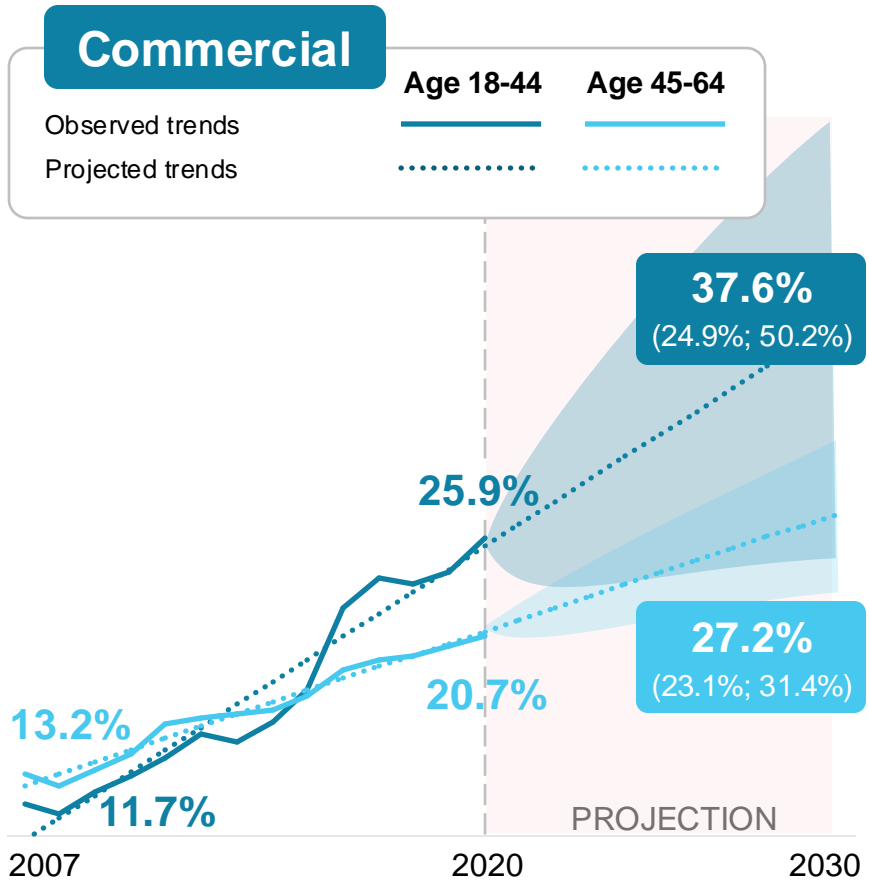


## Medicare



The prevalence of OHE is higher among males in both populations

# PREVALENCE OF OHE BY AGE



The prevalence of **OHE** among younger age groups is increasing at a higher rate than older age groups

**Alcohol use is increasing in younger adults, and increases risks of decompensation<sup>1-4</sup>**

<sup>1</sup>Louvet A, et al. *Journal of hepatology*. 2023;78(3):501–512. doi:10.1016/j.jhep.2022.11.013; <sup>2</sup>Pearson MM, et al. *Hepatol Commun*. 2021 Dec;5(12):2080–2095. doi: 10.1002/hep4.1776; <sup>3</sup>National Survey on Drug Use and Health. SAMHSA. 2021;p 560. Available from: <https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTab2021/NSDUHDetailedTab2021.pdf>; <sup>4</sup>Kanny D, et al. *MMWR Morb Mortal Wkly Rep* 2020;69:30–34. doi:10.15585/mmwr.mm6902a2

# PROJECTED 2030 POPULATION

	Commercial	Medicare
Prevalence of cirrhosis (2030), %	0.59%	1.79%
Extrapolated US adults with cirrhosis (2030), N	1,217,235	1,309,170
Prevalence of OHE among adults with cirrhosis (2030), %	28.5%	26.7%
Extrapolated US adults with OHE (2030), N	347,034	349,548

**2,526,405**  
Total US adults with  
**cirrhosis (2030)**

**696,582**  
Total US adults  
with **OHE (2030)**

# CONCLUSIONS

1

If current trends hold, the prevalence of **cirrhosis** and **OHE** are projected to continue to increase, impacting up to **2.5 million** and **700 thousand** adults in 2030, respectively

2

Findings highlight the need for **increased disease awareness and policy strategies** to help reduce the rates of high-risk behaviors, such as alcohol consumption, and aid in **early detection and prevention** of cirrhosis and OHE

3

Strategies for **disease management**, such as **new therapies** for reducing the risk of OHE and **improved access** to treatments targeting OHE recurrence, may help to reduce the overall disease burden



# LIMITATIONS

A simple modeling approach was selected given observed trends; however, other models were attempted and yielded similar results

Projections are based on observed data from 2007 – 2020, which assumes status quo is maintained through 2030 and does not account for future shifts in etiologies, continued advancements in treatment, or new policy initiatives

Prevalent cases of cirrhosis and OHE were carried forward under the assumption that both conditions are chronic in nature; however, this does not account for potential re-compensation of cirrhosis

Other common limitations in healthcare claims databases such as misclassification due to erroneous or missing data

# Q&A

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# APPENDIX

- **Definition of cirrhosis**

- 2 diagnoses of cirrhosis or its complications on distinct dates within the same calendar year
  - Complications of cirrhosis were defined as varices, spontaneous bacterial peritonitis, OHE, and/or hepatorenal syndrome
    - Presence of ascites was not considered to identify patients with cirrhosis given that ascites is transient and can occur in conditions unrelated to liver disease<sup>1</sup>
  - Based on International Classification of Diseases, Ninth & Tenth Editions (ICD-9/10) codes

- **Definition of OHE**

- 1 diagnosis of OHE (among patients identified with cirrhosis)
  - Based on ICD-9/10 codes
    - ICD-10 codes were obtained from the Centers for Medicare & Medicaid Services (CMS) General Equivalence Mappings (GEM)