

Burden of Illness

NAFLD/NASH

September 2019

NAFLD & NASH Overview¹



As a consequence of the spread of obesity, NAFLD is one of the most important causes of liver disease worldwide in adults and children



Global prevalence of NAFLD is estimated at **24%**, with the highest rates reported from South America and the Middle East, followed by Asia, the U.S, and Europe



The major focus of clinical care is discerning those at highest risk of progressive liver disease



Being overweight in childhood and adolescence is associated with increased risk of NAFLD later in life

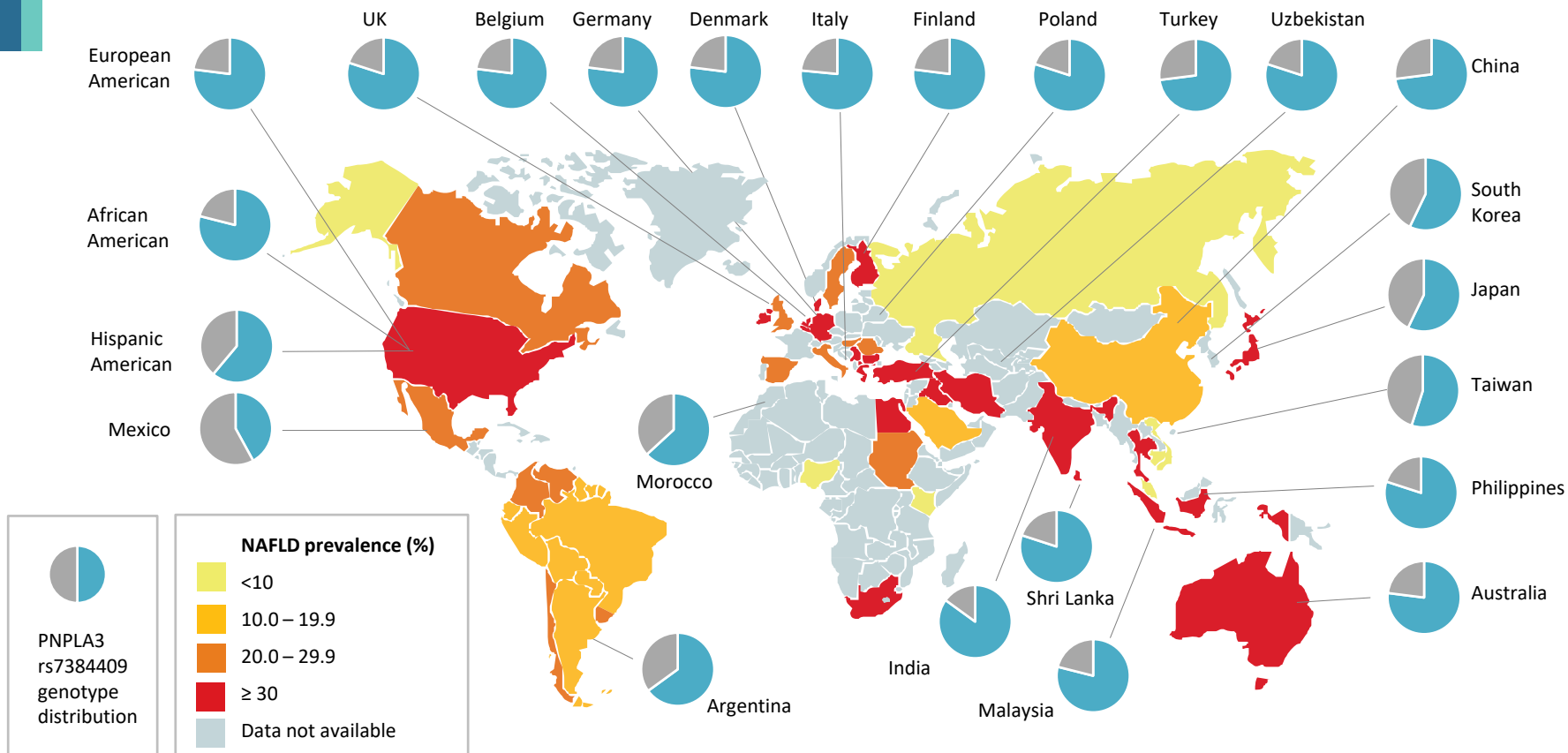


Patients with NAFLD have a high risk of liver-related morbidity and mortality along with metabolic comorbidities



NAFLD warrants the coordination and collaboration of primary-care physicians, specialists, payers, and health policy makers

Global Prevalence of NAFLD & NASH¹



- Approximately one-quarter of the European population and 1 in 3 of the USA population is affected by NAFLD
- The average prevalence of NAFLD is **23.71%** in Europe, varying from **5 - 44%** in different countries

- The pooled NASH prevalence in Europe among patients with NAFLD, with an indication for biopsy, was **69.25%**

U.S. Prevalence of NAFLD & NASH¹



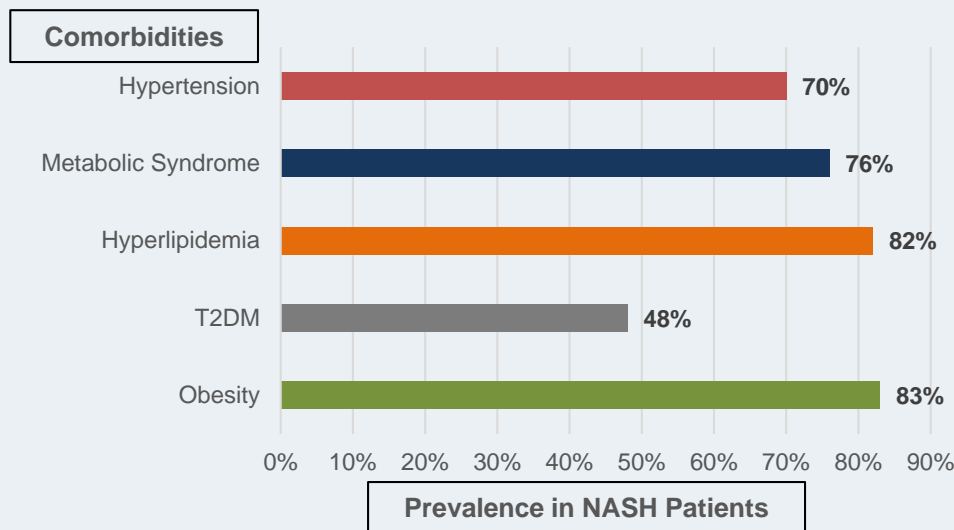
An estimated **64 million** individuals in the U.S are affected by NAFLD with a reported 21% of NAFLD patients having NASH



NASH is therefore estimated to be prevalent in **12%** of the population²



Patients with NASH are likely to have other comorbidities, such as:



1. Younossi, Z., Anstee, Q., Marietti, M., Hardy, T., Henry, L., Eslam, M., George, J. and Bugianesi, E. (2017). Global burden of NAFLD and NASH: trends, predictions, risk factors and prevention. *Nature Reviews Gastroenterology & Hepatology*, 15(1), pp.11-20.
 2. Kim, D. et al., Association between noninvasive fibrosis markers and mortality among adults with nonalcoholic fatty liver disease in the United States. *Hepatology*, 2013. 57(4): p. 1357-65.

U.S. Incidence and Economic Burden of NAFLD and NASH¹

NAFLD¹

The annual burden associated with NAFLD is **\$103 billion**



NAFLD costs **\$1,613 per patient**



The mean yearly inflation-adjusted charges of Medicare patients with NAFLD from the outpatient setting increased from **\$2,624 ± 3,308** in 2005 to **\$3,608 ± 5,132** in 2010



The expected 10-year burden of NAFLD could increase to an estimated **\$1.005 trillion** in the U.S



NASH²

8.6 million individuals in the U.S are estimated to be affected by NASH

The lifetime cost burden of all NASH is estimated to be **\$859.3 billion**

The projections of cost for each age-specific NASH cohort suggests an estimated **350%** increase in the next five years

5.5 million prevalent adult cases of NASH and **4.5 million** new incident adult cases are predicted in the U.S



Genetic Factors

- Evidence from familial aggregation and twin studies have shown a heritable component to NAFLD



Environmental Factors

- The most relevant environmental factors are dietary habits:
 - Alcohol consumption and the presence of obesity act together to increase the risk of liver disease morbidity and mortality
 - Eating processed foods and/or foods with a high content of fat, salt, and sugar or corn syrup

NASH Care Delivery Gaps

Disease Education

- Strong awareness and education of NASH in Hepatology
- Limited disease knowledge in Endocrinology and minimal in Primary Care

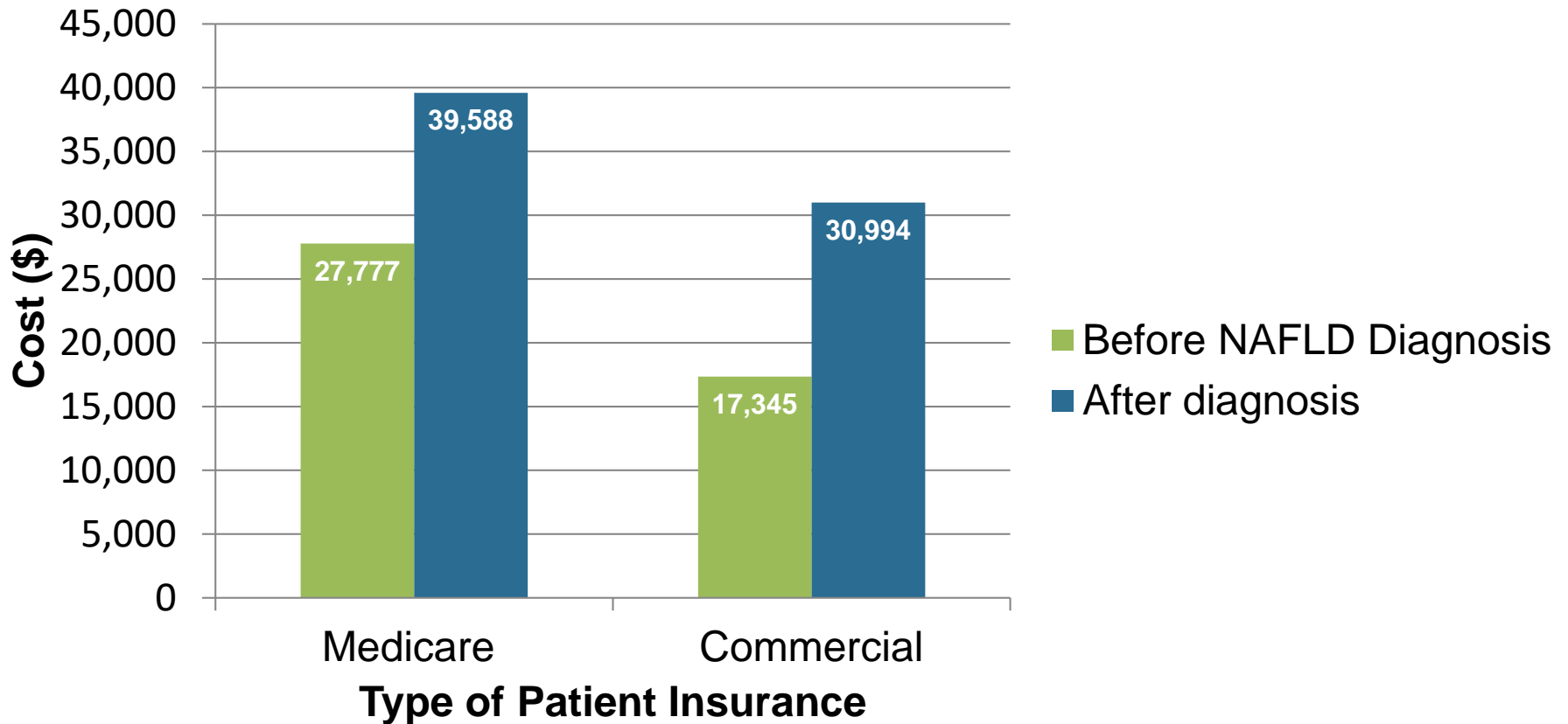
Care Coordination

- Relatively few patients are currently identified by lab values and referred to hepatology
- Early patient identification via Primary Care, Endocrinology, and Bariatric departments is essential to improve NASH care delivery

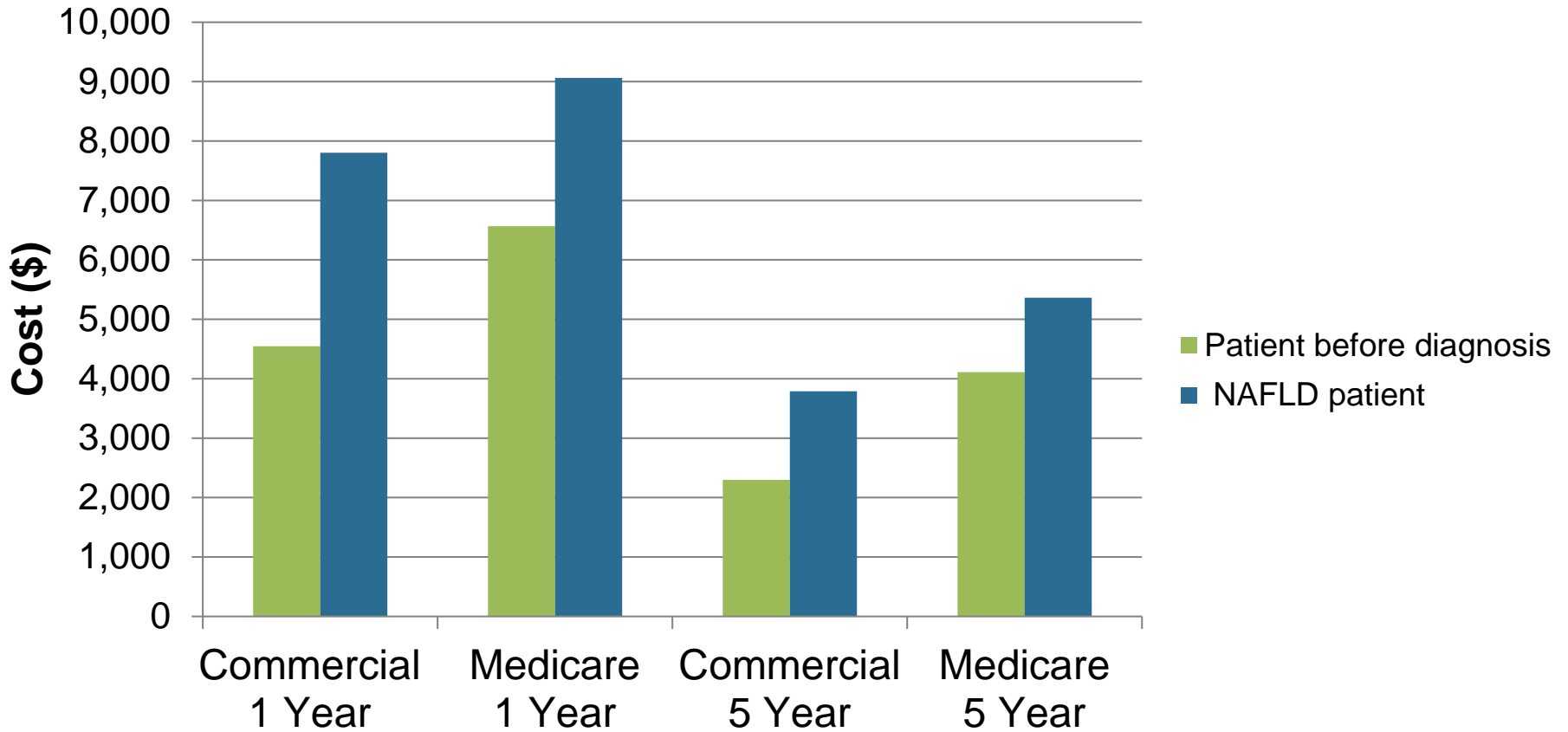
Best Practice Care Delivery Model

- Awareness/education
- Lack of model that aligns all stakeholders including Hepatology, Primary Care, Endocrinology, and Payers
- Minimal best practice sharing, utilizing a RWE foundation

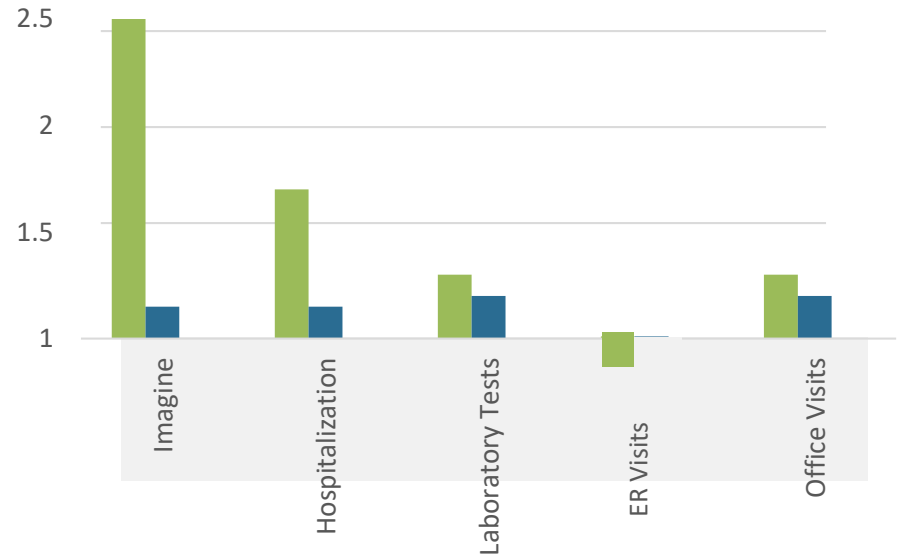
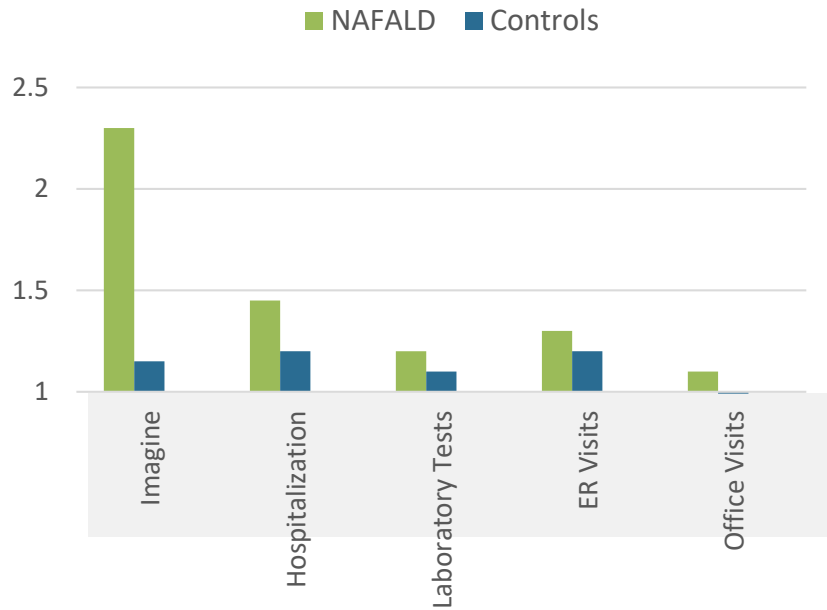
Median Cumulative Healthcare Costs 5 Years After Diagnosis



Median Annual Healthcare Costs After Diagnosis (1 and 5 year)



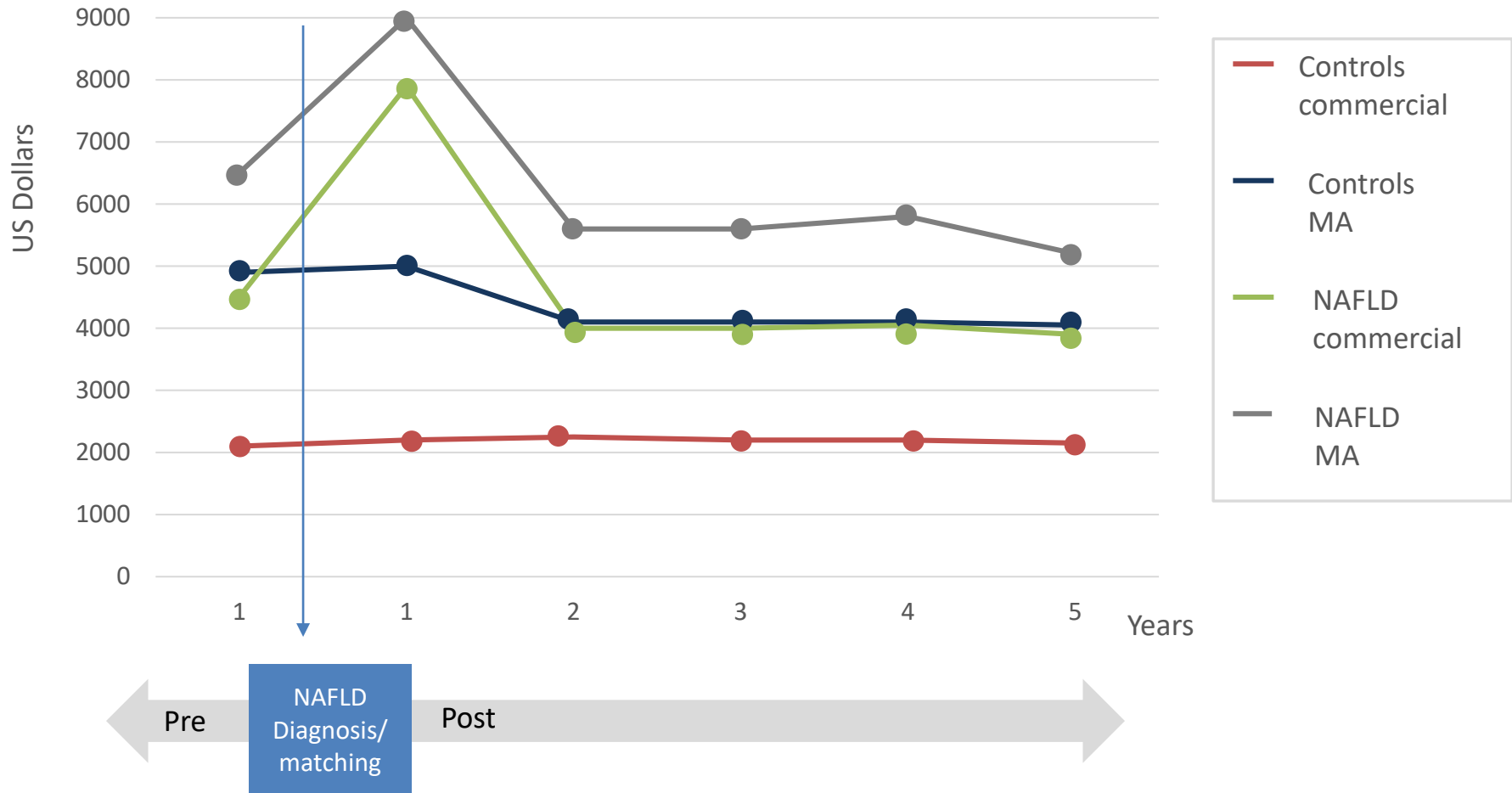
NAFLD Utilization Rates



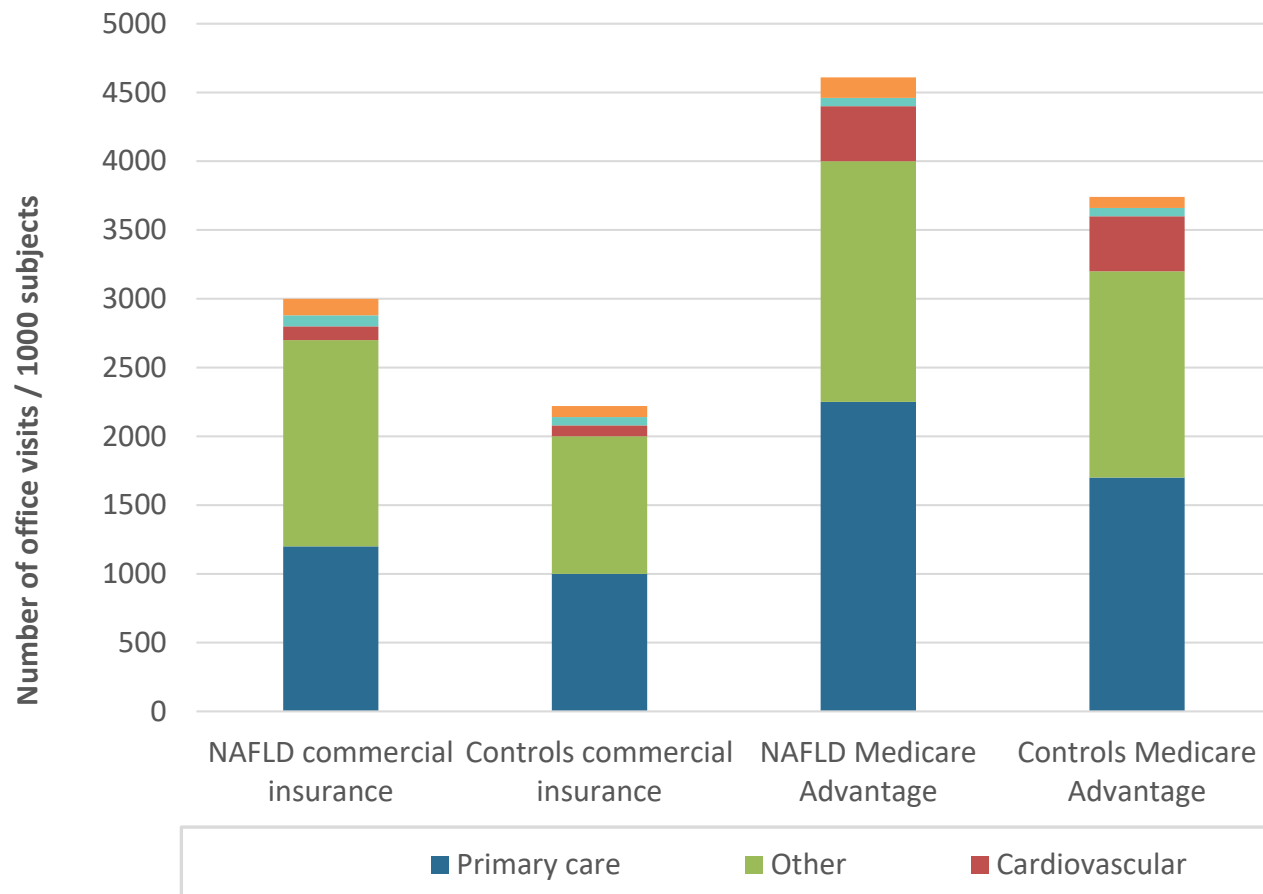
Utilization Information

Patients with NAFLD visit the doctor more often than control, with the highest usage increase associated with imaging tests, followed by hospitalizations

NAFLD Costs



NASH Patient Flow Volume



Type of doctor

For NAFLD commercial insurance patients

1. Primary Care
2. Other
3. Gastroenterology
4. Cardiovascular
5. Endocrinology

For control commercial insurance patients

1. Primary Care
2. Other
3. Cardiovascular
4. Gastroenterology
5. Endocrinology

On average, the NAFLD Medicare Advantage patient visits 4.5 times per year and the NAFLD commercial insurance individual visits 3 times

NAFLD/NASH Pipeline Drugs

