

CONSEQUENCES OF HEPATITIS C VIRUS (HCV) COSTS OF A BABY BOOMER EPIDEMIC OF LIVER DISEASE

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A BABY BOOMER EPIDEMIC OF LIVER DISEASE

- **Annual medical costs for patients with HCV infection are expected to more than double, from \$30 billion to over \$85 billion over the next 15 years.**
- Baby boomers account for two out of every three cases of chronic HCV infection in the United States.
- As baby-boomers infected with hepatitis C virus (HCV) age, their disease may progress from asymptomatic infection to advanced liver disease.
- While new HCV infections have declined dramatically over the last two decades, at least 3 million Americans are chronically infected with HCV.

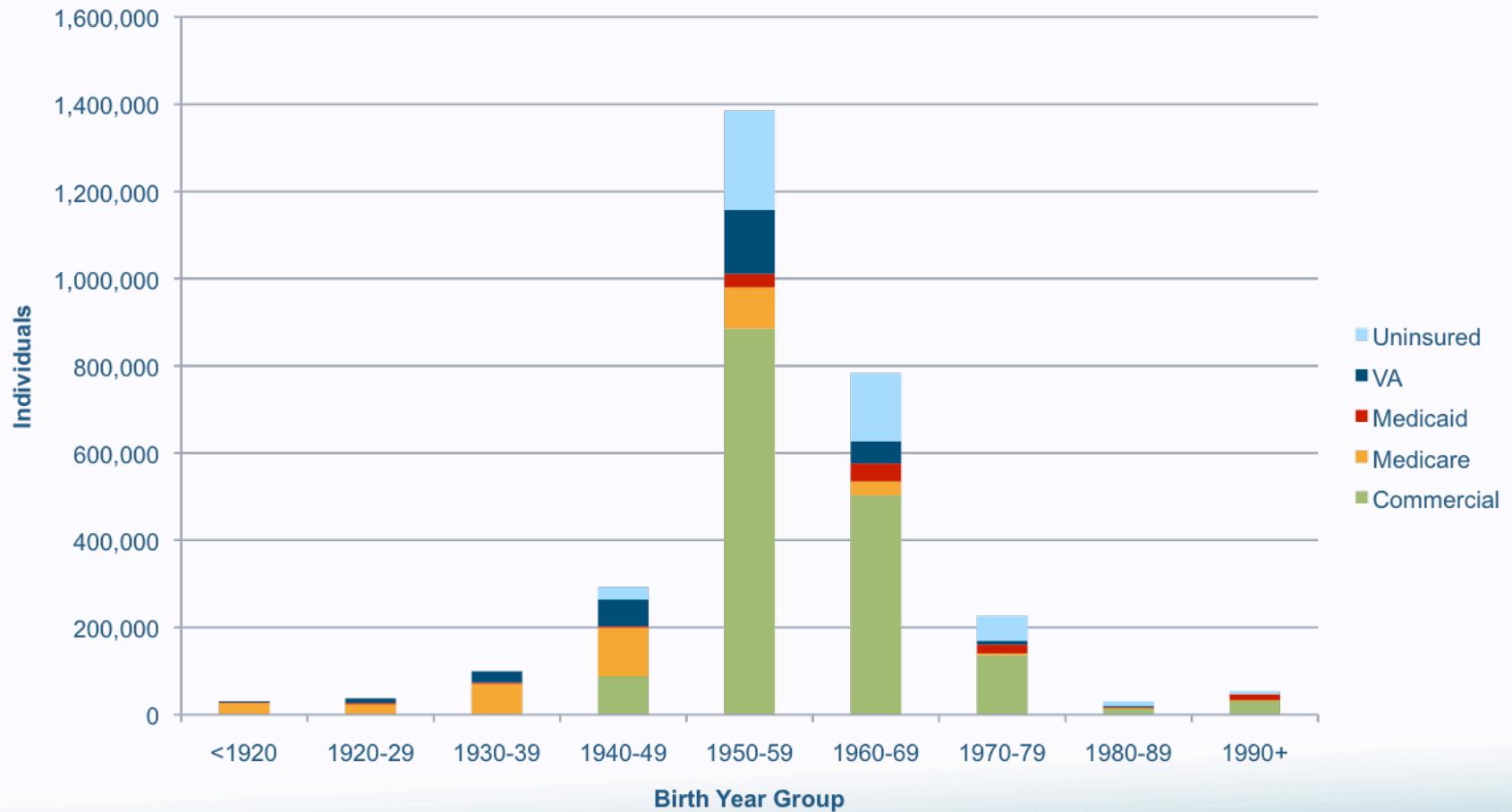
This presentation contains the summary findings of research by the authors. Please refer to the full report for details.

BACKGROUND

CHRONIC HCV INFECTION: AN EPIDEMIC AMONG BABY BOOMERS

- Approximately 3 million Americans are currently infected with hepatitis C virus (HCV).
- Baby boomers account for two out of every three cases of chronic HCV infection in the United States.
- This report provides 20-year cost projections for the population infected with HCV in the U.S.

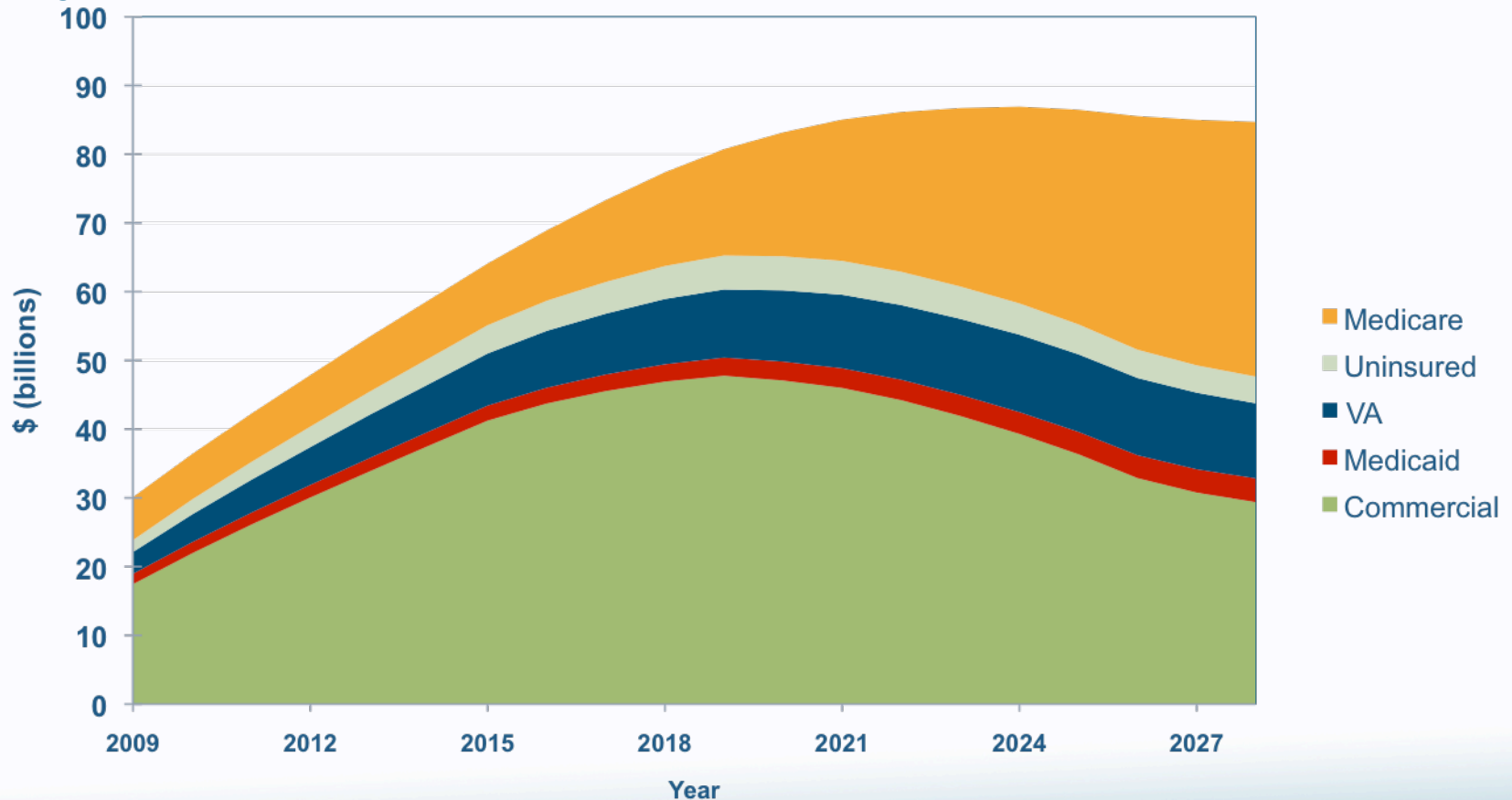
The Peak Prevalence for HCV is in People Born in the 1950s



Milliman estimates based on analysis of NHANES databases

THE COSTS OF HCV WILL GROW AND SHIFT TO MEDICARE

Annual Medical Costs for People with Chronic HCV infection from 2009 to 2028 by Source of Insurance



Milliman estimates. VA = Veterans Administration

Cost Projections

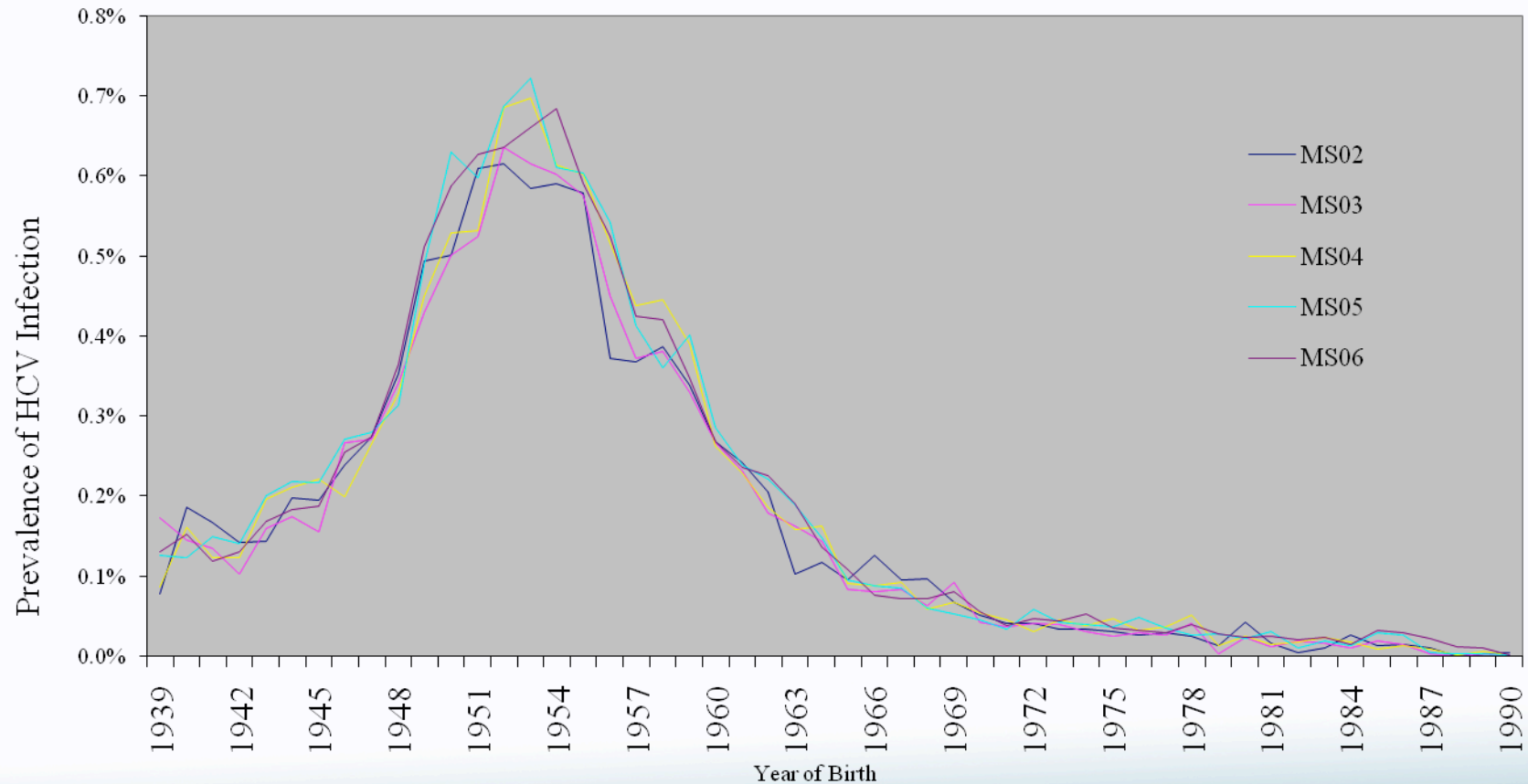
- Overall healthcare costs will more than double over 20 years.
- The per-patient cost of caring for people with chronic HCV infection will increase 3.5 times in 20 years.
- In 10 years, commercial and Medicare costs will more than double.
- In 20 years, Medicare costs will increase 5-fold.

TODAY'S HCV INFECTED POPULATION

Identifying Cases in U.S. Payer Data

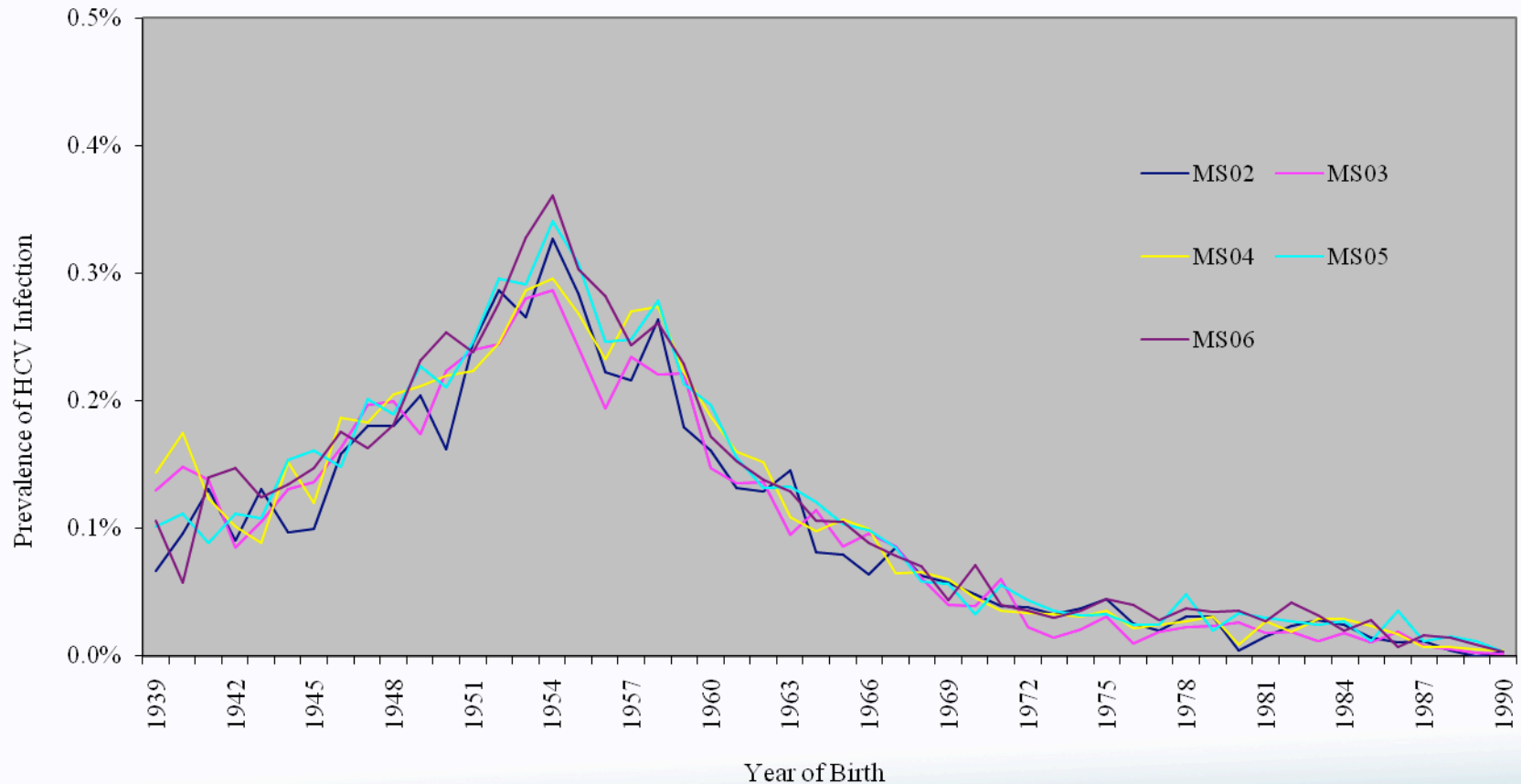
- Based on NHANES, we estimate that about 1.0% of Americans have chronic HCV infection.
- Comparing NHANES prevalence with our examination of medical claims data, we estimate that 78% of people with HCV infection have not been diagnosed.
- The peak birth year for both men and women is about 1953, with men having higher prevalence than women.

Born in Early 1950s -- The Peak Prevalence of Diagnosed HCV Infection for Males in the Commercial Population



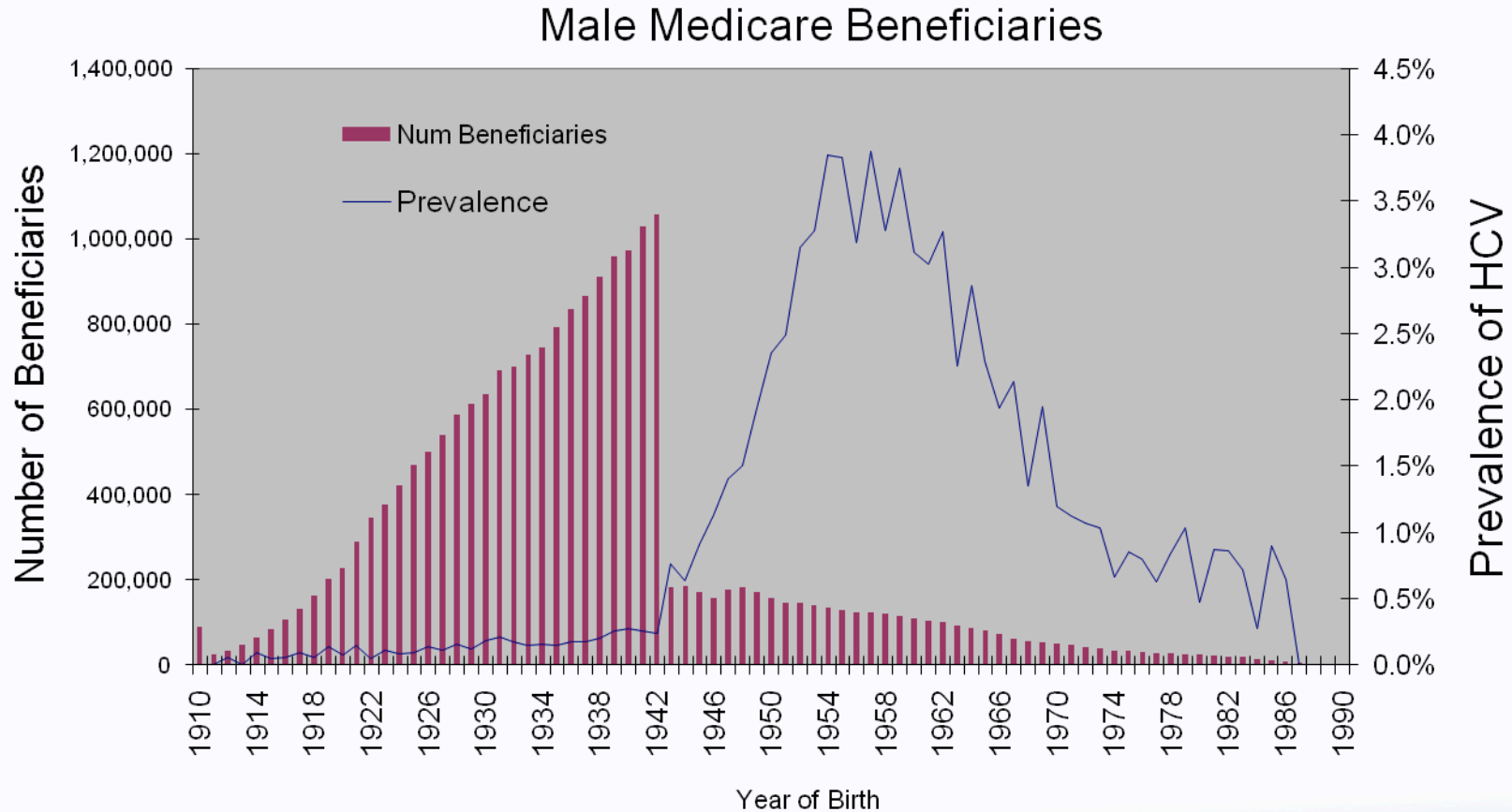
Milliman analysis of Thompson Medstat MarketScan data. "MS02" refers to the source data – MedStat 2002. Each annual MedStat database contains the medical claims for millions of lives.

Born in Early 1950s -- The Peak Prevalence of Diagnosed HCV Infection for Females in the Commercial Population



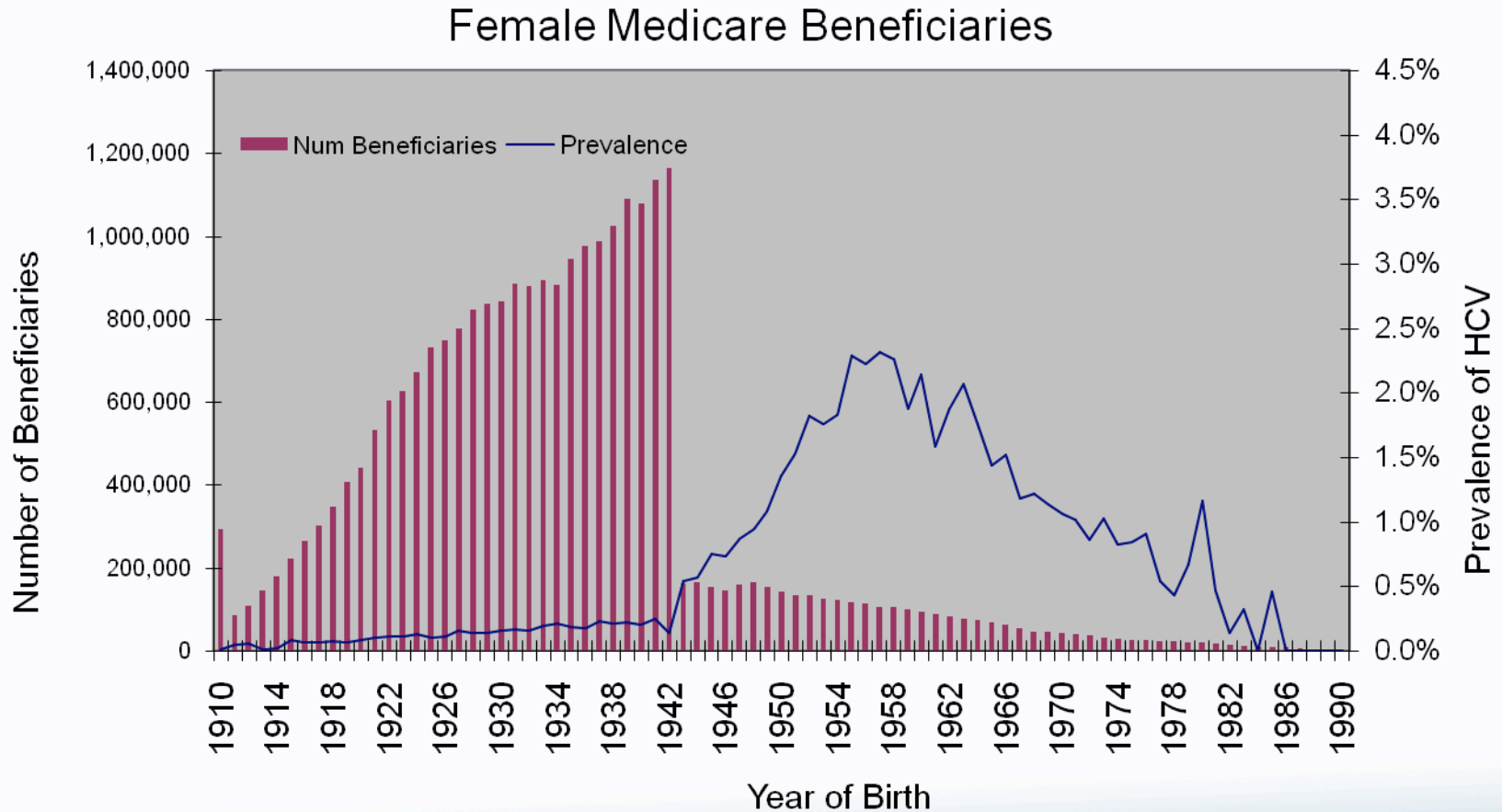
Milliman analysis of Thompson Medstat MarketScan data. "MS02" refers to the source data – MedStat 2002. Each annual MedStat database contains the medical claims for millions of lives.

High Prevalence of Diagnosed HCV Infection among Under 65 Medicare Beneficiaries -- Males



Milliman analysis of Medicare 5% Sample 2006 database

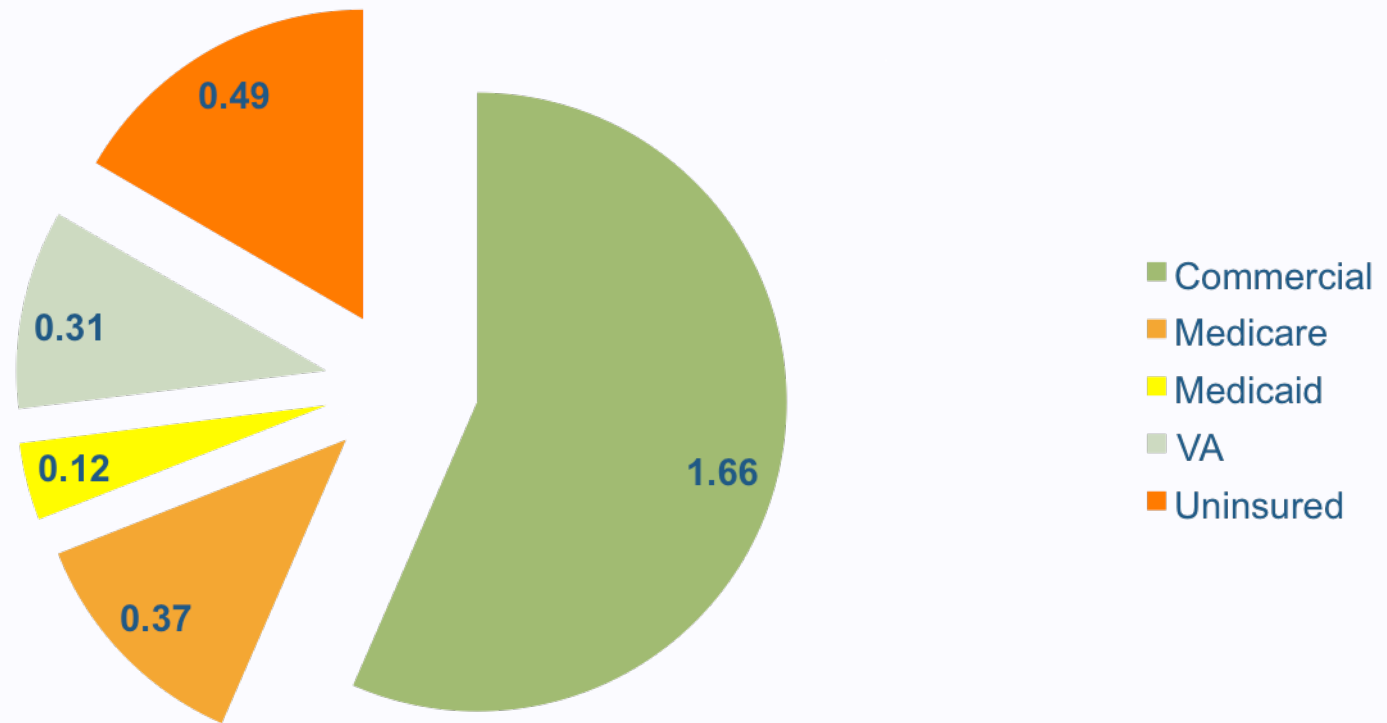
High Prevalence of Diagnosed HCV Infection among Under 65 Medicare Beneficiaries -- Females



Milliman analysis of Medicare 5% Sample 2006 database

In 2008, Most People with Chronic HCV Infection are Covered by Commercial Insurance

Infected Population in Millions by Primary Coverage

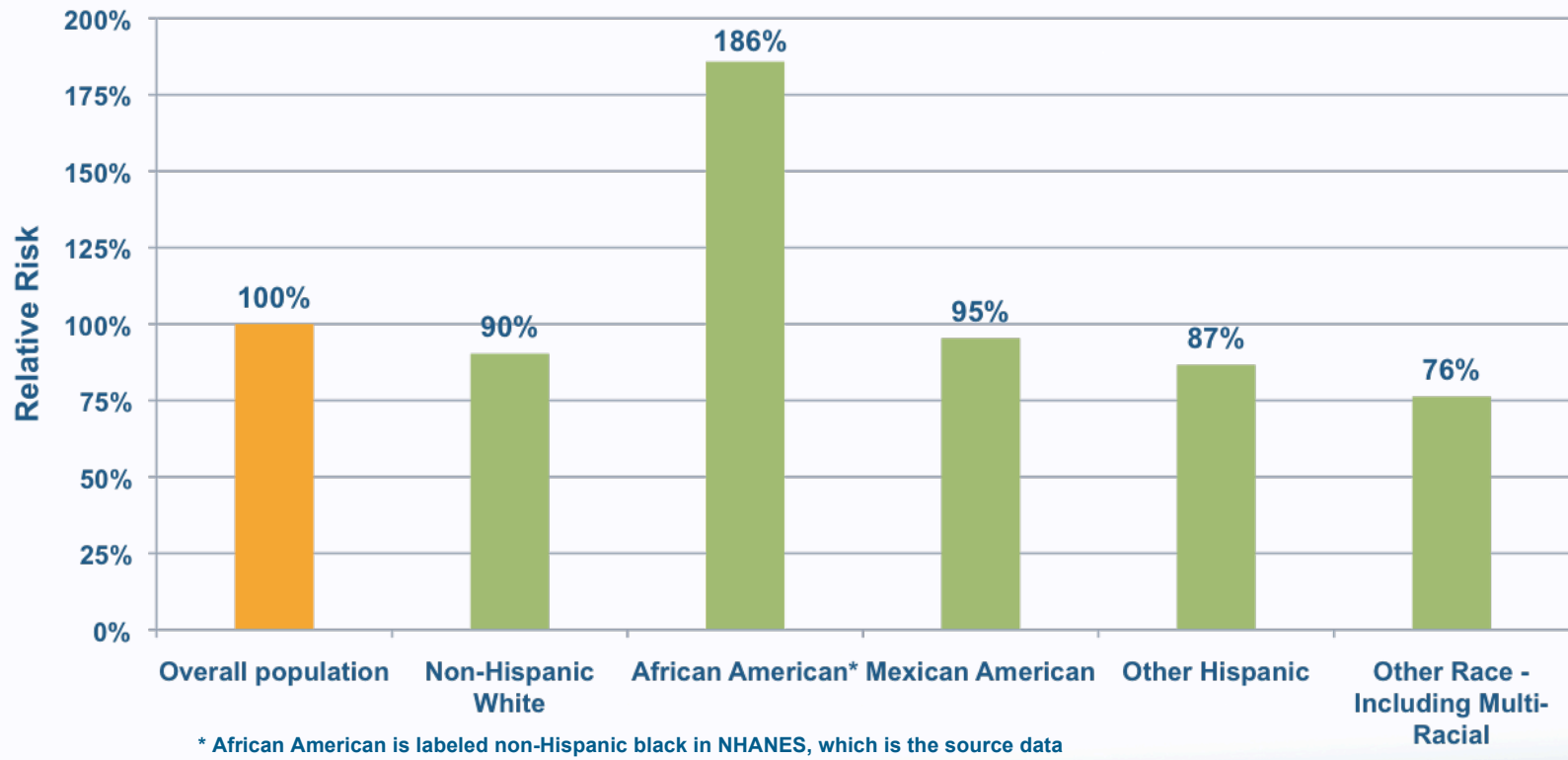


Total Infected= 2.94 million

Milliman estimates. VA = Veterans Administration

HCV Disproportionately Affects African-Americans


Relative Risk of Being HCV Positive by Race



HCV-RELATED LIVER DISEASE CAN BE PROGRESSIVE

- 
- Chronic HCV infection w/o cirrhosis

- 
- Compensated cirrhosis

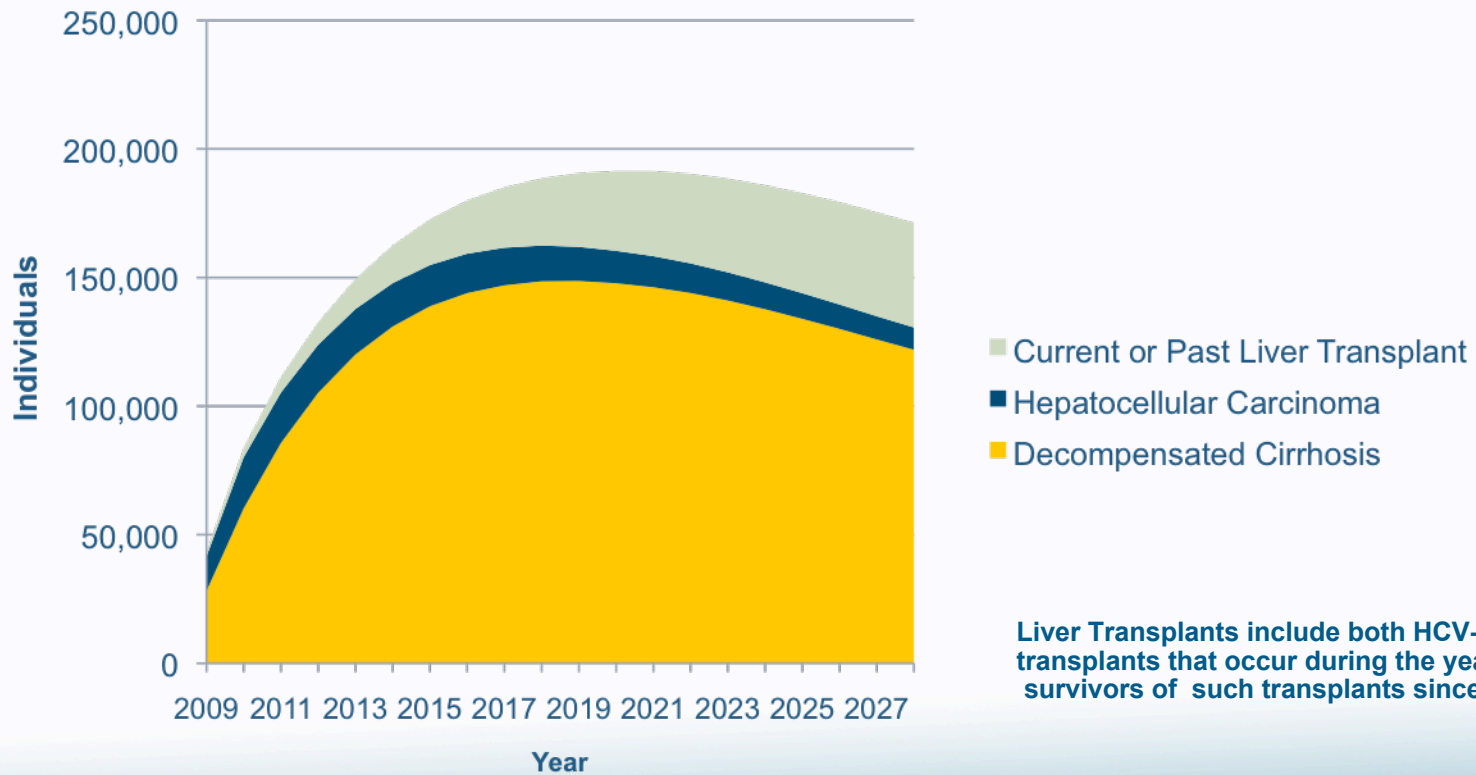
- 
- Advanced Liver Disease
 - Decompensated cirrhosis (includes complications such as ascites, variceal bleed, encephalopathy)
 - Hepatocellular carcinoma (HCC or liver cancer, an indication for liver transplant in a limited number of patients)
 - Liver transplant (including new transplants and survivors of liver transplants in previous years)

FINDINGS

- The total number of patients with advanced liver disease will more than quadruple in 20 years.
- Over the next 10 years, the number of patients with decompensated cirrhosis will more than quadruple.

Advanced Liver Disease and HCV: Gloomy Forecast

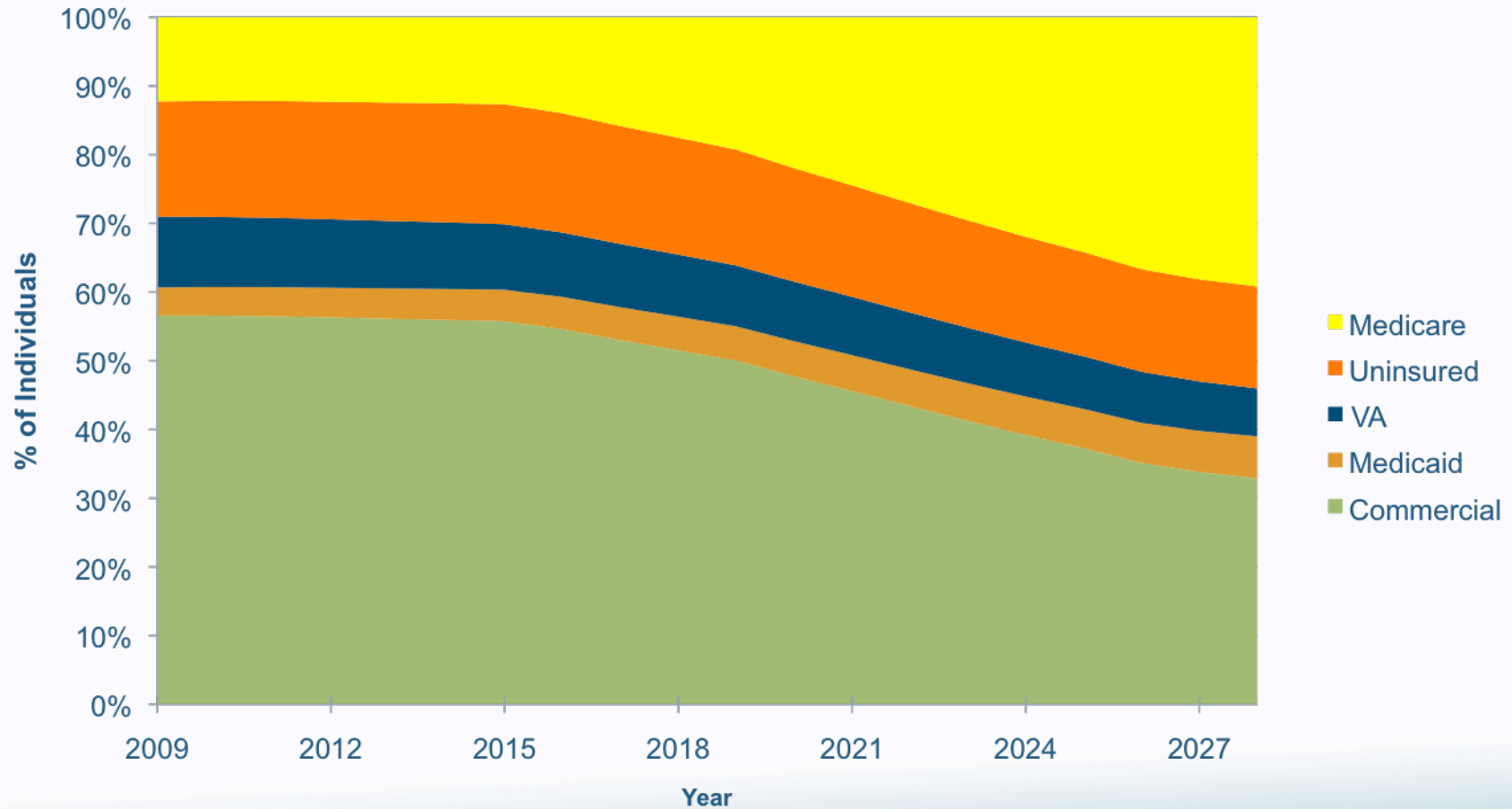
- In 20 years, the number of patients with advanced liver disease will more than quadruple.
- In 10 years, the number of patients with decompensated cirrhosis will more than quadruple.



Milliman estimates

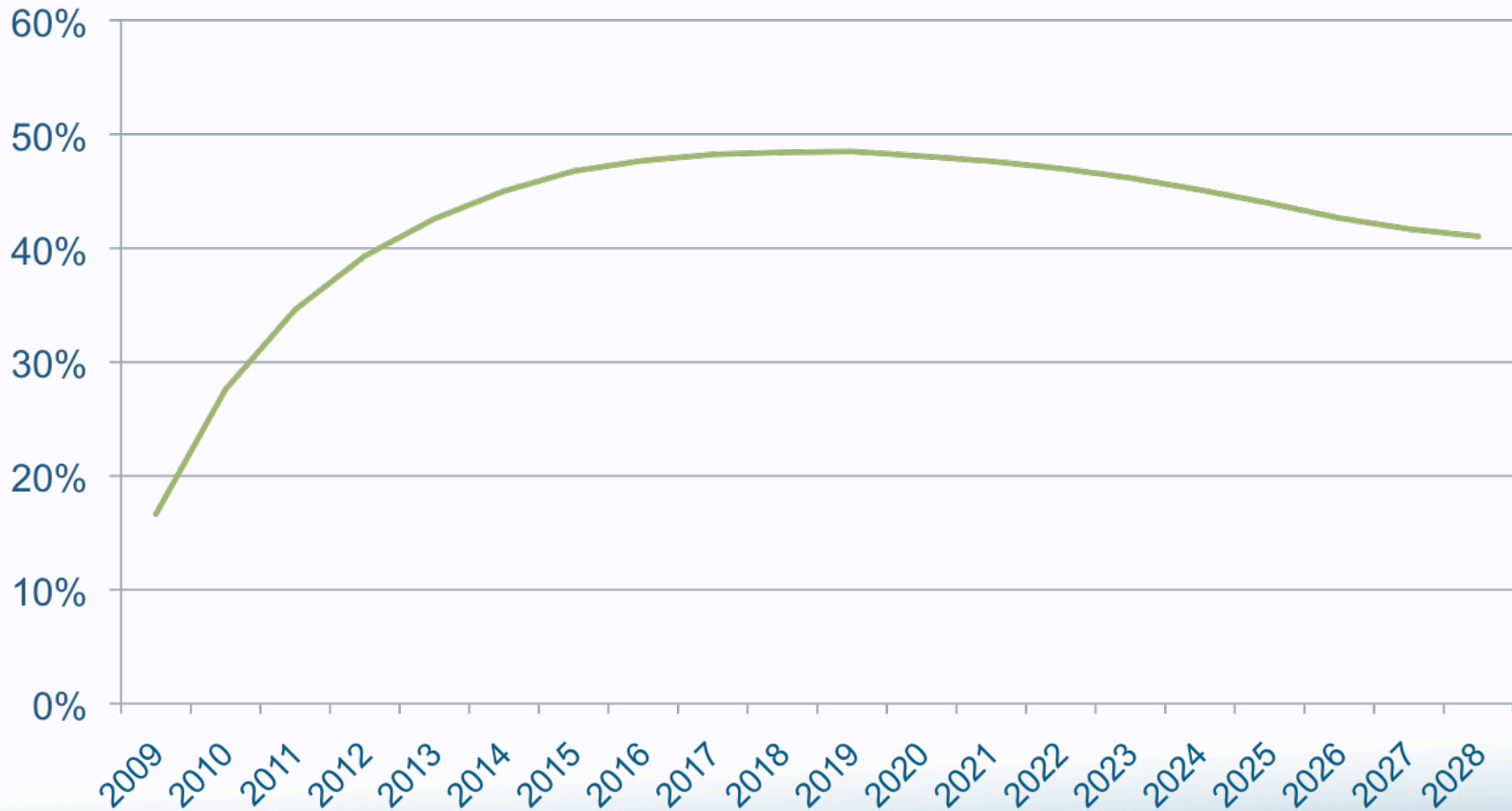
Medicare will Play an Increasing Role in Covering People with HCV

Source of Insurance



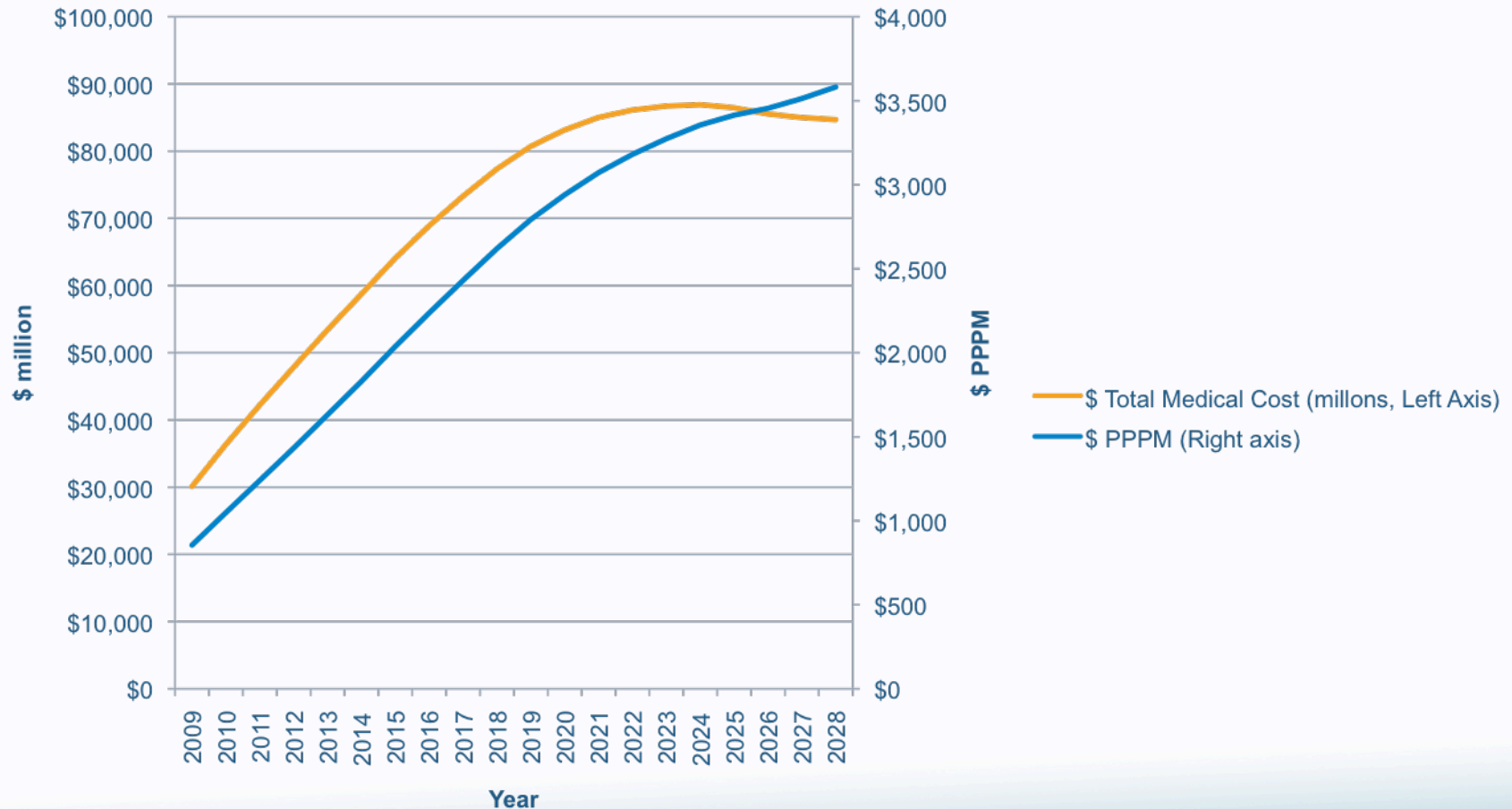
Milliman estimates

Advanced Liver Disease Will Make up an Increasing Portion of Costs for People with Chronic HCV infection



Milliman estimates

Chronic HCV infection Population Annual Total Medical Costs and Per-Patient-Per Month Costs: 2009 to 2028



Milliman estimates

Methodology

- The results reported in this presentation are based on applying disease progression assumptions to payer-distinct populations of HCV infected people. We linked age and sex of the infected individual, costs, and mortality, to chronic HCV infection disease progression. We used a Monte Carlo simulation approach, applying transition probabilities on a monthly basis for 20 years.
- We emphasize that most of the disease progression assumptions we used are based on limited data. We implicitly assumed that current treatment practices and cost levels would continue over the projection period.
- No forecast can capture all important factors, and this limitation applies to our work. Actual results are likely to differ from those we present.
- Please see the full report for additional, important information.

Data Sources

- Agency for Healthcare Research and Quality, The Medical Expenditure Panel Survey (MEPS) for 2007 for the demographics of the uninsured.
- California Medicaid 20% Sample (MediCal) 2002. For claims-based estimates of HCV infection and disease state prevalence.
- Centers for Disease Control and Prevention (CDC), Death rates for 1999 through 2004.
<http://www.cdc.gov/nchs/datawh/statab/unpubd/mortabs.htm> Accessed February 24, 2008.
- Centers for Disease Control and Prevention (CDC), NHANES III, 1999-2000, 2001-02, 2003-04, 2005-06.
<http://www.cdc.gov/nchs/nhanes.htm>. Accessed November 18, 2008. For population estimates of HCV infection and antibody positive prevalence rates.
- Centers for Medicare & Medicaid Services (CMS), Medicare 5% Sample Datasets 2002-2006. For claims-based estimates of HCV infection, costs, and disease state prevalence.
- Dominitz JA, Boyko EJ, Koepsell, TD, et al, Elevated Prevalence of Hepatitis C Infection in Users of United States Veterans Medical Centers, *Hepatology*, 2005 Jan, 41(1):88-96.
- MedStat MarketScan Database 2002-2006. For claims-based estimates of HCV infection, costs, and disease state prevalence.
- Milliman 2008 Health Cost Guidelines. For standard employer demographics.
- Milliman Medical Index 2008. For trend assumptions.
- U.S. Census Bureau Population Division, Monthly Population Estimates by Age, Sex, Race and Hispanic Origin for the United States: April 1, 2000 to July 1, 2007, www.census.gov/popest/national/asrh/files/NC-EST2007-ALLDATA.doc Accessed February 24, 2009
- U.S. Department of Veterans Affairs, Veteran Population 2007, Table 5L: Veterans 2000-2036 by Race/ Ethnicity, Gender, Period, Age.
<http://www1.va.gov/vetdata/page.cfm?pg=15> Accessed February 24, 2009
- U.S. Department of Veterans Affairs, Geographic Information, Expenditure Data by Locality, <http://www1.va.gov/vetdata/page.cfm?pg=3> Accessed February 24, 2009

References

- Alter MJ. The epidemiology of acute and chronic hepatitis C. *Clinics in Liver Disease* 1997; 1:559-568.
- Alter MJ, Kruszon-Moran D, Nainan OV, McQuillan GM, Gao F, Moyer LA, et al. The prevalence of hepatitis C virus infection in the United States, 1988 through 1994. *N Engl J Med* 1999; 341:556-562.
- Butt AA. Hepatitis c virus infection: the new global epidemic. *Expert rev anti infect ther* 2005; 3:241-249.;
- Cawthorne CH, Rudat KR, Burton MS, et al. Limited success of HCV antiviral therapy in United States veterans. *Am J Gasgtroent.* 2002; 97:149-155.
- Davis GL, Albright JE, Cook SF, Rosenberg DM. Projecting the future healthcare burden from hepatitis C in the United States. *Liver Transplantation* 2003; 9:331-338.
- Falck-Ytter Y, Kale H, Mullen KD, et al. Surprisingly small effect of antiviral treatment in patients with hepatitis C. *Ann Intern Med.* 2002; 136:288-292.
- Muir AJ, prvenzale D. A descriptive evaluation of eligibility for therapy among veterans with chronic hepatitis C virus infection. *J Clin Gastroenterol.* 2002; 34:268-271.
- Disease State Transition Rates including Mortality Loads
- Davis GL, Albright JE, Cook SF, Rosenberg DM. Projecting future complications of chronic hepatitis C in the United States. *Liver Transplant.* 2003;9 : 331-338.
- Degos F, Christidis C Ganne-Carrie N, et al. Hepatitis C virus related cirrhosis: time to occurrence of hepatocellular carcinoma and death. *Gut.* 2000; 47:131-136.
- Fattovich G, Giustina G, Degos F, Tremolada F, Diodati G, Almasio P, et al. Morbidity and mortality in compensated cirrhosis type C: a retrospective follow-up study of 384 patients. *Gastroenterology.* 1997 Feb;112(2):463-72.
- Hornberger J, Farci P, Prati D, et al. the economics of treating chronic hepatitis C patients with peg-interferon x-2a plus ribavirin presenting with persistently normal aminotransferase. *J Viral Hepatitis.* 2006;13:377-386
- Forman LM, Lewis JD, Berlin, JA, Feldman HI, Lucey MR, The Association Between Hepatitis C Infection and Survival After Orthotopic Liver Transplantation, *Gastroenterology* 2002;122:889–896
- McHutchinson JG, Bacon BR, Owens GS. Making it happen: managed care considerations in vanquishing hepatitis C. *Am J Managed Care.* 2007; 13:S327-S336.
- Rousseau CM, Ioannou GN, Todd-Stenberg JA, Sloan KL, Larson MF, Forsberg CW, Dominitz JA. Racial differences in the evaluation and treatment of hepatitis C among veterans: a retrospective cohort study. *Am J Public Health.* 2008;98:846-52.
- Sangiovanni A, Prati GM, Fasani P, Ronchi G, Romeo R, Manini M, Del Ninno E, Morabito A, Colombo M. The natural history of compensated cirrhosis due to hepatitis C virus: A 17-year cohort study of 214 patients. *Hepatology.* 2006 Jun;43(6):1303-10.
- Ward RP, Kugelman M, Libsch KD. Management of hepatitis C: evaluating suitability for drug therapy. *Am Family Physician.* 2004;69:E1429-E1438.
- Wong JB. Understanding the natural history of hepatitis C: can decision analysis help? [Abstract] *Hepatology.* 2000;32(Pt 2):426-A.