Costs and Considerations for Elimination of Hepatitis C Virus in the United States

A scenario analysis of the costs and timeline associated with hepatitis C elimination

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Executive Summary

Hepatitis C virus (HCV) is a common infection of the liver with a high medical cost burden and is a public health concern in the United States and around the world. Direct-acting antivirals (DAAs) were introduced over the last decade and have resulted in HCV cure rates over 95% and better tolerability than older regimens, improving the outlook for patients with HCV.[i] The introduction of these treatments led the World Health Organization (WHO) to set targets for elimination of HCV by 2030, defined as an 80% reduction in new chronic infections and a 65% reduction in mortality from 2015 levels.[ii] While there is a high cost associated with HCV treatment, treating and eliminating HCV results in a reduction in the cost burden of the disease.[iii,iv,v]

The purpose of our study is to estimate the costs / savings and timeline associated with the elimination of HCV, utilizing the WHO definition of HCV elimination and current estimates of HCV treatment costs and other HCV-related metrics based on our review of existing literature. In this study, we additionally estimate variations in the savings and timeline required to reach WHO elimination targets for HCV in the United States (U.S.) under different scenarios of testing and treatment. Our findings indicate that, with current HCV treatment and testing rates, the U.S. will not achieve WHO elimination targets in the next 30 years (more than 20 years later than the WHO goal). According to our model, achieving these targets in the United States (U.S.) will require increased HCV screening and treatment.

Our analysis produced the following key findings:

- Our model indicates the U.S. is not on track to reach the WHO HCV elimination goal by 2030, even with a 15% increase in testing (8.5 million annual tests to 9.8 million annual tests) and a 15% increase in treatment (from 25% to 40%) above today's rates. According to our modeling, there are several combinations of testing and treatment scenarios that would result in HCV elimination in the next 30 years:
  - The U.S. could achieve HCV elimination by 2050 with a 7.5% increase in testing and a 10% increase in treatment from today's rates
  - The U.S. could achieve HCV elimination as early as 2035 with a 15% increase in testing and a 25% increase in treatment from today's rates
  - While each scenario tested would result in increased HCV testing and DAA treatment costs, the reduction in HCV-related medical spend results in overall national net savings over the 30-year period in every case.
- Current HCV testing and treatment rates result in $28 billion in net medical savings in 10 years and $238 billion in net medical savings in 30 years. These findings are consistent with estimates in the literature.[iii,iv,v]
- Increases in HCV testing and treatment rates from today's rates increases medical savings.

Background

OVERVIEW OF HEPATITIS C

Hepatitis C virus (HCV) is a viral infection of the liver transmitted through exposure to an infected person's blood that causes liver inflammation and can lead to serious liver damage and life-threatening health problems. HCV currently affects millions of Americans; however, due to the asymptomatic nature of the disease, particularly in early stages, roughly 44% of people who have HCV are unaware of their infection.[vi] Both

the CDC and the U.S. Preventive Services Task Force (USPSTF) have expanded screening recommendations for adults born between 1945 and 1965. In 2020, the CDC updated its recommendations for HCV screening to include one-time screening for all adults and with each pregnancy, while the USPSTF recommended one-time screening for adults aged 18 to 79. [vii,viii]

Aside from increasing awareness and testing for HCV, treatment of HCV plays a role in slowing the spread of disease. Within the last decade the launch of new therapies, called direct-acting antivirals (DAAs), has resulted in cure rates of roughly 96%.[ix] According to the CDC, the U.S. has experienced a decrease in the annual incidence of confirmed chronic HCV cases in recent years. Since 2017, the U.S. has experienced a 6% decrease in chronic HCV incidence each year, on average. Over the same time period, acute HCV cases have grown, according to the CDC. [x]

We estimate that there will be approximately 8.5 million HCV tests administered in the U.S in 2022.[xi,xii] Of those that are screened and diagnosed with HCV, a portion receive treatment. A recent study found that in recent years, approximately 25% of those diagnosed with HCV receive treatment with DAAs.[xi] A previous Milliman study estimated the net cost of HCV treatment courses to be approximately $14,250 per treatment course.[xiii]

ELIMINATION OF HCV

In addition to increased morbidity and mortality, chronic HCV is accompanied by economic burden for both patients and the healthcare system, including both direct medical costs and indirect costs resulting from loss of work productivity and impaired quality of life.[xiv] For these reasons, in 2016 the World Health Organization (WHO) set goals for the elimination of hepatitis C by 2030, defining elimination as an 80% reduction in the incidence of new HCV infections and a 65% reduction in HCV mortality by 2030.[ii] Using 2015 US numbers as a baseline, elimination occurs when fewer than 30,000 new chronic HCV diagnoses and fewer than 6,000 deaths caused by HCV occur nationally within the year. For this analysis, we are using 30,000 new chronic HCV diagnoses as our definition for HCV disease elimination.

The purpose of our study is to estimate the costs / savings and timeline associated with the elimination of HCV, utilizing the WHO definition of HCV elimination and current estimates of HCV treatment costs and other HCV-related metrics. HCV-related medical cost is evaluated across the entire adult U.S. population, among three levels of disease severity: non-cirrhotic disease (NCD), compensated cirrhosis (CC), and end-stage liver disease (ESLD) including conditions like decompensated cirrhosis and hepatocellular carcinoma. For those with chronic HCV who have yet to be treated or cured of the disease, annual HCV related healthcare costs vary depending on disease severity. Those with lower disease severity, such as NCD and CC have annual HCV related healthcare costs of approximately $5,000 to $7,500, while those with ESLD have annual HCV related healthcare costs of almost $40,000, on average.[i] In our model we assume a portion of HCV-related medical costs can be reduced. Multiple scenarios are modeled to evaluate outcomes under different incremental treatment and testing rates. While it is possible that treatment rates may differ by disease severity, our model assumes that individuals with different disease severities are equally likely to receive treatment.

Results

TIMELINE TO ACHIEVE ELIMINATION OF HCV

Our study indicates the U.S. will not achieve the WHO HCV elimination goals in the next 30 years at current testing and treatment rates of 8.5 million HCV antibody tests annually and 25% of individuals diagnosed with chronic HCV receiving DAA treatment. Table 1 shows the year the U.S. is estimated to achieve elimination with variable incremental testing and treatment rates. Note, the incremental testing and treatment percentages are percentage point increases from today's levels.

Table 1. Year of HCV elimination with variable incremental testing and treatment rates

Incremental Treatment \ Incremental Testing	0.0%*	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%*	N/A	N/A	N/A	N/A	2050	2047	2044
5%	N/A	N/A	N/A	N/A	2047	2043	2041
10%	N/A	N/A	N/A	2050	2044	2041	2038
15%	N/A	N/A	N/A	2049	2044	2040	2038
20%	N/A	N/A	N/A	2047	2041	2038	2037
25%	N/A	N/A	N/A	2047	2041	2038	2035
30%	N/A	N/A	N/A	2044	2041	2038	2035

**Represents current HCV testing and treatment rates of 8.5 million annual HCV antibody tests and a 25% treatment rate. Incremental testing and treatment percentages are percentage point increases over today's rate.*
Note: Green cells indicate scenarios where our modeling indicates the U.S. will achieve HCV elimination in the next 30 years.

Holding treatment at 25% of diagnosed individuals, or 0% incremental treatment, we estimate testing would need to increase 10% above today's numbers (from 8.5 million annual tests to 9.4 million annual tests) to achieve HCV elimination by 2050. Holding testing steady at the current level of 8.5 million tests per year, or 0% incremental testing, even with a 30% incremental increase in treatment above today's rates (from 25% to 55%), the U.S. would not achieve HCV elimination in the next 30 years. Even with a significant increase in testing and treatment rates (15% and 30% increases, respectively), our model indicates the U.S does not meet the WHO HCV elimination target by 2030. According to our model, 2035 is the earliest the U.S. could reach HCV elimination, with a 25% incremental increase in treatment rate (from 25 to 50%) and 15% incremental testing rate (from 8.5 million annual tests to 9.8 million annual tests). Incremental treatment rates greater than 30% and incremental testing rates greater than 15% were not evaluated in our model.

PROJECTED 30-YEAR HCV TESTING AND TREATMENT COSTS

At current testing and treatment levels, we estimate after 30 years the U.S will have spent $4 billion on testing and $43 billion on HCV DAA treatment. We estimate the 30-year testing and treatment costs under variable increases in testing and DAA treatments, outlined in table 2 below.

Table 2. Projected 30-year HCV testing and DAA treatment costs under variable testing and treatment rate increments.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$46B	$48B	$48B	$47B	$46B	$45B	$44B
5%	$46B	$47B	$47B	$46B	$44B	$43B	$42B
10%	$45B	$46B	$46B	$44B	$43B	$42B	$41B
15%	$45B	$46B	$45B	$43B	$42B	$41B	$39B
20%	$44B	$45B	$44B	$43B	$41B	$40B	$39B
25%	44B	$45B	$44B	$42B	$40B	$39B	$38B
30%	$44B	$44B	$43B	$41B	$40B	$39B	$38B

Note: Green cells indicate scenarios where our modeling indicates the U.S. will achieve HCV elimination in the next 30 years.

Please note, an increase in incremental treatment and testing does not always translate into larger 30-year costs. Scenarios with higher incremental testing and treatment rates result in reduced HCV transmission, and therefore, fewer individuals are expected to require HCV treatment over the 30-year timeframe.

We estimate the costs in table 2 will be offset by savings associated with avoided HCV-related medical expenses for individuals cured of HCV over the next 30 years. Table 3 shows the projected 30-year medical savings associated with variable HCV incremental testing and treatment rates.

Table 3. Projected 30-year HCV medical cost offsets under variable testing and treatment rate increments.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$284B	$298B	$303B	$304B	$302B	$299B	$295B
5%	$284B	$296B	$300B	$299B	$296B	$292B	$287B
10%	$284B	$294B	$297B	$295B	$290B	$285B	$280B
15%	$284B	$293B	$294B	$290B	$286B	$280B	$275B
20%	$283B	$291B	$291B	$287B	$282B	$276B	$270B
25%	$283B	$289B	$289B	$284B	$278B	$272B	$267B
30%	$282B	$288B	$286B	$282B	$276B	$269B	$264B

Note: Green cells indicate scenarios where our modeling indicates the U.S. will achieve HCV elimination in the next 30 years.

Lastly, Tables 4 and 5 show the projected 10-year and 30-year medical savings, net of testing and treatment costs, associated with variable HCV incremental testing and treatment rates. The medical savings, net of testing and treatment costs, at 5 and 20 years is provided in the Appendix. Using today's testing and DAA treatment rates, we projected $28B of net medical costs savings in 10 years and $238B of net medical cost savings in 30 years resulting from treatment of HCV with curative DAAs. If testing and treatment rates increased by 10% points each, it would result in an additional $9B in net savings ($247B compared to $238B) in 30 years.

Table 4. Projected 10-year medical savings (net of testing and treatment costs) with variable HCV incremental testing and treatment rates.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$28B	$28B	$29B	$30B	$30B	$31B	$32B
5%	$31B	$31B	$32B	$33B	$34B	$35B	$36B
10%	$33B	$34B	$35B	$36B	$37B	$38B	$39B
15%	$35B	$36B	$37B	$38B	$39B	$40B	$41B
20%	$37B	$38B	$39B	$40B	$41B	$42B	$43B
25%	$38B	$39B	$40B	$42B	$43B	$44B	$45B
30%	$39B	$40B	$42B	$43B	$44B	$45B	$46B

Table 5. Projected 30-year medical savings (net of testing and treatment costs) with variable HCV incremental testing and treatment rates.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$238B	$250B	$255B	$257B	$256B	$254B	$252B
5%	$239B	$249B	$253B	$254B	$252B	$249B	$245B
10%	$239B	$248B	$251B	$250B	$247B	$244B	$240B
15%	$239B	$247B	$249B	$247B	$244B	$240B	$235B
20%	$239B	$246B	$247B	$244B	$241B	$236B	$232B
25%	$238B	$245B	$245B	$242B	$238B	$233B	$229B
30%	$238B	$244B	$243B	$240B	$236B	$231B	$226B

Note: Green cells indicate scenarios where the U.S. will achieve HCV elimination in the next 30 years.

Current testing and treatment rates, as well as increases in HCV testing and treatment from today's rates, result in positive medical savings in 30 years. As HCV testing and treatment rates increase, transmission of HCV decreases and there are fewer individuals who require treatment. As such, the projected 30-year net medical savings do not always increase with increased testing and treatment rates.

Discussion

HCV ELIMINATION

Our findings indicate that, with current HCV incidence trends and current treatment and testing rates, the U.S. will not achieve the WHO elimination targets by 2030. This is consistent with other publications. One study used 2013-2017 prevalence, treatment, and diagnosis information from each state to project HCV elimination.[xv] According to this study, only three states (Connecticut, South Carolina, and Washington) are on track to meet the WHO elimination targets by 2030, with seven states not achieving elimination until after 2050 (Hawaii, North Dakota, Ohio, Oregon, Rhode Island, South Dakota, and West Virginia). The study projected that the US would meet the WHO elimination targets in 2037. Another study used a disease progression model using updated HCV prevalence, testing and diagnostic data and projected the U.S. would not meet WHO HCV elimination targets until beyond 2050.[xvi] Due to the large number of variables required for this type of modeling, variation is expected for the estimated year of elimination, and ultimately these studies are consistent with our model, which indicates the US will not meet WHO elimination goals by 2030 at current diagnosis and treatment rates.

CURRENT HCV INCIDENCE TRENDS

According to the CDC, the U.S. has reported a 6% average decrease in the annual incidence of confirmed chronic HCV cases since 2017. Over the same time period, acute HCV cases have grown, according to the CDC.[x] It is uncertain the root cause of these reporting trend discrepancies, and as such, we did not include explicit adjustments to the annual HCV incidence.

COSTS AND SAVINGS ASSOCIATED WITH HCV ELIMINATION

A key finding of our study is that the costs associated with HCV testing and treatment are offset by the medical cost savings that occur as a result of cured infections, regardless of when elimination occurs. The cost of HCV treatments is often cited as a barrier to high treatment rates, and subsequently, a barrier to elimination. However, our findings reveal that, in aggregate, the cost of treating HCV is less than the prolonged HCV-related medical costs for uncured patients. Our model does not consider the indirect costs and societal burdens associated with HCV.

When considering the cost effectiveness of an intervention, traditional methodologies typically consider the cost of the treatment itself, the avoided costs resulting from the intervention, as well as improvements in mortality and quality of life, typically measured in quality-adjusted life years (QALY). Since the availability of DAAs, many studies have estimated the incremental cost-effectiveness ratio (ICER) of DAAs is <$100,000 per QALY.[xvii] In the United States the $100,000 to $150,000 per QALY threshold is generally considered good value.[xviii] According to a study evaluating the cost effectiveness of targeted screening of PWID versus universal HCV screening, they found targeted screening of PWID to be cost effective and universal HCV screening not to be cost effective. Relative to status quo, screening and treating PWID for HCV increased costs an average of $10,457 per person and resulted in almost three months increase in QALYs, resulting in an estimated $44,815 per QALY, which is considered cost effective in the U.S. The study also found that universal screening of US adults increased costs by $2,845 with a 0.01 increase in QALY, which equates to $291,277 per QALY, which is not considered cost effective in the US.[xix]

HCV TRANSMISSION

Our model has an implied transmission rate of 11.1%, which represents a blend of the general population and the at-risk population, which is primarily people who inject drugs (PWID). Injection drug use is the primary risk factor for new HCV infections in the U.S., accounting for approximately 70% of new HCV cases.[vii] Although difficult to quantify, a 2017 study estimated that 53% of PWID in the U.S. have HCV, with statewide variation ranging from 38.1% to 68.0%.[xx] Additionally, a 2013 study found that each PWID infected with HCV is likely to infect 20 other people.[xxi] While this population is associated with higher transmission rates than the general population, we recognize that it is a relatively small group of individuals – a study using data from 2018 estimates that there are 3,694,500 PWID in the U.S.[xxii] There are many factors that would influence trends in injectable drug use in the U.S. and it is uncertain if injectable drug use will continue to increase, plateau, or decrease in the next 30 years.

BARRIERS TO HCV ELIMINATION

Testing, diagnosis, and treatment rates appear to have a major impact on model outcomes and the time period to reach HCV elimination. There are a number of barriers that may prevent higher testing and treatment rates and that may also impact HCV elimination in the US.

Potential barriers to achieving HCV elimination:

- The HCV care cascade shows that there is drop off at each step in the HCV continuum of care.[xxiii] The care cascade includes HCV testing, diagnosis, treatment and achieving a sustained viral response. Barriers may exist at each step in the care cascade and include affordability and access.

- PWID are a difficult-to-access population who often face stigma and discrimination.xxiv One study found that only 7.7% of people suspected of injection drug use between 2010-2017 were tested for HCV.[xxv] PWID are also particularly susceptible to low treatment rates following diagnosis.[xxvi,xxvii] PWID are also at a higher risk of re-infection.

- Barriers to treatment are implemented by some payers to restrict treatment to those who have evidence of more advanced liver fibrosis and / or those who have been abstinent from drug use for a specified period of time. The 2020 Medicaid Access Grade provided by the National Viral Hepatitis Roundtable assessed state Medicaid restrictions on DAA treatment (i.e., fibrosis / liver disease treatment restrictions, sobriety treatment restrictions, and prescriber restrictions).[xxviii] As of May 2021, 4 states had fibrosis restrictions to receiving treatment, 13 state Medicaid programs had sobriety restrictions ranging from one month to six months, 15 states required drug or alcohol screening or counseling, and 18 states had prescriber restrictions, either requiring a specialty prescriber or in consultation with a specialist.

- The COVID-19 pandemic reduced access to healthcare, including HCV testing and treatment. In an effort to slow the spread of COVID-19, in 2020 the CDC released guidance to delay nonessential procedures, postpone routine clinical visits, and utilize telemedicine when possible.[xxix] According to an analysis of weekly HCV testing volume between 2018 and 2020, HCV testing volume decreased in mid-March and at its lowest point in 2020, weekly testing declined by 65% compared to the same week in 2018 and

2019.[xxx] Another study of DAA utilization between found a statistically significant 24% decrease in DAA utilization from March 2020 through August 2020 compared to March 2019 through August 2019.[xxxi] Reduced access to testing and treatment may have a prolonged impact on overall control of the spread of the disease, and therefore, its elimination.

- HCV elimination requires an upfront investment with savings that may not be realized until future years.[xxxii] One potential barrier to HCV elimination is the payer mix responsible for HCV treatment and testing costs may be different than the payer mix that experiences the medical cost savings associated with treating HCV.

HCV ELIMINATION EFFORTS IN MEDICAID

According to data analyzed across five National Health and Nutrition Examination Surveys (NHANES) from 2001 to 2010, HCV prevalence in the U.S. is highest in the Medicaid and uninsured populations.[xxxiii] Some state Medicaid programs with higher HCV prevalence in their Medicaid population have expressed concern over providing universal treatment and some states have implemented barriers to receiving HCV treatment.[xv] However, the results of a 2022 study suggest that the costs of HCV treatment are offset within one year in the Medicaid population.[xxxiv] Other states have implemented policies aimed at eliminating HCV.

In 2019, Louisiana and Washington implemented subscription-based payment models (SBPM) for HCV DAA treatments in Medicaid in an effort to increase treatment rates at a capped annual cost and make progress toward elimination. While the final outcomes of these initiatives are not yet available, early data indicates that this model resulted in a 534.5% increase in HCV DAA prescription fills in Louisiana but did not result in a significant change in fills in Washington.[xxxv] Louisiana focused HCV screening and treatment efforts on Medicaid enrollees and incarcerated persons, while Washington focused screening and treatment efforts on people who inject drugs. Additionally, prior to implementing the SBPM, Louisiana removed liver damage and sobriety requirements that previously restricted access to treatment. These results indicate that although impact of these alternative models may vary by state, the alternative payment models and removal of access restrictions have the potential to cause significant increase in HCV DAA treatment.

Covering the cost of treatment remains a challenge for some state Medicaid programs. Maryland's Total Cost of Care model is a proposed policy designed to form a Medicaid / Medicare partnership where Maryland's Medicaid program would receive a credit from Medicare to offset the State's investments in HCV treatment that could lead to Medicare savings by reducing the impact of HCV symptoms on Medicare's budget. An analysis of this proposed policy estimated $1.4 billion could be saved over 25 years and highlights a Medicaid / Medicare partnership may be a solution for funding initial costs associated with treatment.[xxxvi] The analysis also estimated that the break-even point of total HCV treatment coverage would occur after 10 years. This analysis supports our model, which indicates that the costs associated with HCV elimination are offset by the medical cost savings that occur as a result of cured infections.

CONCLUSION

Our findings indicate that, with current HCV incidence trends and current treatment and testing rates, the U.S. will not achieve WHO elimination targets in the next 30 years – thus missing the initial 2030 WHO goal. Achieving elimination in the next 30 years is dependent on increases in testing and treatment levels. At current testing and treatment levels, we estimate the net medical savings to be $238 billion over 30 years. If testing and treatment incremental rates increased by 10% each, it would result in an additional $9B in net savings ($247B compared to $238B) over 30 years.

Data, Methodology, and Limitations

DATA SOURCES

We relied on published literature and HCV-related studies of medical costs and epidemiology as sourced throughout. Medical cost estimates developed in past years' studies were trended to 2022 using the Medical Consumer Price Index for All Urban (CPI-U)[xxxvii] and then projected from 2022 to 2042 using the Milliman Medical Index.[xxxviii]

METHODOLOGY

Our model applies HCV prevalence assumptions to the U.S. population and distinguishes between the diagnosed and undiagnosed subsets of the HCV population using diagnosis assumptions from the literature. Each year we assume that there are newly infected individuals adding to the HCV population, however, we also assume a mortality rate that will remove some individuals form the HCV population. As more individuals are tested, we have people moving from the undiagnosed to the diagnosed group, although this does not change the net HCV prevalence. At the end of each year, we take the starting HCV population, add in the newly infected individuals, subtract out the individuals who have died, and subtract out the individuals who have been cured by DAAs. This number then becomes the starting point for the subsequent year. We referenced published literature regarding HCV-related medical costs and HCV epidemiology in the U.S. to estimate the medical cost offset associated with a reduction in HCV-related costs and avoided liver disease progression from treatment of HCV with DAAs.

- Population: We derived the starting 2022 national HCV population from Datamonitor's Hepatitis C Datapack Patient-Based Market Forecast.[xxxix] This resulted in a starting US prevalence of 1.65 million people, or roughly 0.5% of the total US population. An estimated 56% of patients with HCV have been diagnosed; therefore, we assumed that 56% of the total HCV population would be eligible for treatment.[vii] The population is segmented into three disease severities: non-cirrhotic disease (NCD), compensated cirrhosis (CC), and end-stage liver disease (ESLD). Starting distribution among the disease severities is derived from the literature.[xl,xli,xlii,xliii,xliv,xlv,xlvi] Among each disease severity, we assumed differing levels of annual mortality.[xlvii] We did not explicitly apply any factors for timing of disease progression, which may change the estimates for HCV-related medical costs. We applied an annual growth of 0.6% to the U.S. population.[xlviii] We also applied a mortality rate that varied depending on the disease severity of the population, with higher mortality rate affecting the ESLD population.

- At-risk population: Injectable drug use is the most common mode of transmission of HCV in the U.S.[xlix] The next most common mode of transmission is birth to an HCV-infected mother and other less common modes of transmission include sexual contact with an HCV-infected person, unregulated tattooing, blood transfusions prior to 1992 when blood screening became available, and invasive healthcare procedures.[xlix] A study that analyzed reports published between 1993 and 2008 estimates that the prevalence of PWID at some point in their lifetime to be 2.6%.[l] Another study that analyzed births between 2011 to 2014 estimated that 0.3% of infants are born to HCV-infected mothers.[li] As such, we assumed that 2.9% of the population is at a high risk of contracting HCV.

- Testing: Each year we assume only a portion of the U.S. population will be tested for HCV. We assume a baseline annual HCV testing of 8.5 million tests. We also modeled various incremental HCV testing rates in addition to the baseline 8.5 million annual HCV tests.

- Treatment: Each year we assume 25% of the diagnosed population will receive treatment.[xi] Of those who receive treatment, we assume that 96% will be cured.[ix]

- Medical costs: In year 1 of the model, we calculated a weighted mean of the annual HCV-related medical costs by disease severity as reported in the literature.[xliii,xliii,xliv] We applied inflation adjustments to bring historical estimates to 2022 U.S. dollars using the medical CPI-U.[xxxvii] We trended medical costs forward from 2022 to 2042 using the average annual per person medical cost trend from the Milliman Medical Index.[xxxviii] Consistent with previous Milliman research, during each year of projection (including 2022 as year 1), we assume a portion of HCV-related medical costs can be reduced. The proportions account for patients treated midyear in the first year, and some patients may have lingering HCV-related or liver-related medical needs, depending on disease progression. Higher reductions are assumed for patients with NCD as their liver damage is typically reversible and disease is less severe, therefore we expect a majority of HCV-related costs will go away following DAA treatment. We assume lower reductions in HCV-related medical costs for CC and ESLD patients due to the irreversible nature of their liver damage.

- Treatment costs: We referenced a previous Milliman study for the net cost of treatment courses of roughly $200 per day and used an equal blend of eight week and twelve week treatment regimens, resulting in 10-week treatment costs of $14,250 per treatment course.[xiii] The prior study showed historical decreases in net cost; however, for this projection we assume DAA treatment net costs will remain level in future years and therefore did not assume negative future cost trends from 2020 and forward.

LIMITATIONS

Our model utilizes a number of assumptions derived from the literature to inform the results described herein. We note that these assumptions may vary for a variety of reasons, one notable reason being the COVID-19 pandemic. Since the start of the COVID-19 pandemic in March 2020, utilization of healthcare services has changed in unpredictable ways. Specific to HCV, diagnostic testing for HCV decreased substantially and, as a result, diagnosis rates and DAA prescription volume have also decreased.[lii] Kaufman et al. found that, in 2020, HCV treatment prescriptions decreased by 43% in May, 37% in June, and 38% in July compared to the corresponding months in 2018 and 2019. Because of the lack of predictability and available information regarding COVID-19 and its ongoing impact on HCV diagnosis and treatment, our model does not include adjustments for COVID-19. Any adjustments for COVID-19 would extend the timeline required to reach elimination and therefore reduce any net medical cost savings achievable over a 30-year period.

Our analysis and methodology are limited to information available in the literature. Our analysis did not account for the following:

- Variations in cost (including medical costs and DAA net costs) across different U.S. lines of business (commercial, Medicare, Medicaid) or the uninsured.

- Fluctuations in diagnosis and treatment rates as a result of the COVID-19 pandemic, changing testing recommendations, and other factors, such as further decreases to the net cost of DAA treatment.

- Historical analysis of HCV patient cost changes compared to model estimates.

- Adjustments to account for speed of disease progression in HCV patients.

- Outreach costs associated with encouraging individuals, especially PWID, to get tested for HCV, educating individuals about HCV, and connecting those with known HCV infection to treatment.

- The impact of needle and syringe exchange programs and opiate substitution therapy.

This report was prepared for Gilead Sciences, Inc., a life sciences company that manufactures several HCV therapies. Our findings are based on a review of available literature regarding the medical costs associated with chronic HCV. Results from this analysis may not be applicable to other therapeutic areas. The results presented herein are estimates based on the best information available as of the date of publication. Differences between our results and other analyses may arise due to variations in definitions, methodology, or data updates.

This report represents the opinion of the authors and is not representative of the views of Milliman. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Susan Silseth is a consulting actuary for Milliman. She is a member of the American Academy of Actuaries and meets the qualification standards to render the actuarial opinion contained herein.

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APPENDIX

Projected 5-year medical savings (net of testing and treatment costs) with variable HCV incremental testing and treatment rates.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$2B	$2B	$1B	$1B	$1B	$1B	$0B
5%	$3B	$2B	$2B	$2B	$2B	$1B	$1B
10%	$4B	$3B	$3B	$3B	$2B	$2B	$2B
15%	$4B	$4B	$4B	$4B	$3B	$3B	$3B
20%	$5B	$5B	$5B	$4B	$4B	$4B	$4B
25%	$6B	$6B	$6B	$5B	$5B	$5B	$5B
30%	$7B	$7B	$6B	$6B	$6B	$6B	$6B

Projected 20-year medical savings (net of testing and treatment costs) with variable HCV incremental testing and treatment rates.

Incremental Treatment \ Incremental Testing	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%
0%	$109B	$116B	$122B	$126B	$130B	$132B	$134B
5%	$113B	$120B	$126B	$130B	$133B	$135B	$137B
10%	$115B	$123B	$128B	$132B	$135B	$137B	$138B
15%	$117B	$124B	$129B	$133B	$136B	$138B	$139B
20%	$118B	$125B	$130B	$134B	$137B	$138B	$139B
25%	$119B	$126B	$131B	$135B	$137B	$138B	$139B
30%	$120B	$127B	$132B	$135B	$137B	$138B	$139B

Note: Green cells indicate scenarios where our modeling indicates the U.S. will achieve HCV elimination in the next 20 years.

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