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Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients

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ABSTRACT

Background: Interferon-free hepatitis C treatment regimens are effective but very costly. The cost-effectiveness, budget, and public health impacts of current Medicaid treatment policies restricting treatment to patients with advanced disease remain unknown. **Objectives:** To evaluate the cost-effectiveness of current Medicaid policies restricting hepatitis C treatment to patients with advanced disease compared with a strategy providing unrestricted access to hepatitis C treatment, assess the budget and public health impact of each strategy, and estimate the feasibility and long-term effects of increased access to treatment for patients with hepatitis C. **Methods:** Using a Markov model, we compared two strategies for 45- to 55-year-old Medicaid beneficiaries: 1) Current Practice—only advanced disease is treated before Medicare eligibility and 2) Full Access—both early-stage and advanced disease are treated before Medicare eligibility. Patients could develop progressive fibrosis, cirrhosis, or hepatocellular carcinoma, undergo transplantation, or die each year. Morbidity was reduced after successful treatment. We calculated the incremental cost-effectiveness ratio and compared the costs and public health effects of each strategy from the perspective of Medicare alone as well as the Centers for Medicare & Medicaid Services perspective. We varied model inputs in one-way and probabilistic sensitivity analyses. **Results:** Full Access was less costly and more effective than Current Practice for all cohorts and perspectives, with differences in cost ranging from $5,369 to $11,960 and in effectiveness from 0.82 to 3.01 quality-adjusted life-years. In a probabilistic sensitivity analysis, Full Access was cost saving in 93% of model iterations. Compared with Current Practice, Full Access averted 5,994 hepatocellular carcinoma cases and 121 liver transplants per 100,000 patients. **Conclusions:** Current Medicaid policies restricting hepatitis C treatment to patients with advanced disease are more costly and less effective than unrestricted, full-access strategies. Collaboration between state and federal payers may be needed to realize the full public health impact of recent innovations in hepatitis C treatment.

Keywords: cost-effectiveness, hepatitis C, interferon-free, Medicaid, Medicare.

Introduction

Hepatitis C affects more than 3.2 million patients in the United States and is a common cause of chronic liver disease worldwide [1,2]. Most infected patients develop chronic disease that can remain asymptomatic for decades. However, left untreated, chronic hepatitis C causes progressive hepatic fibrosis, which can result in severe complications. After developing cirrhosis, patients are at risk for hepatocellular carcinoma, may require liver transplantation, and have an increased risk of early mortality [3–5]. Successful treatment can reduce morbidity and improve patients' quality of life [5–7]. In fact, if recent advances in drug regimens are widely implemented, hepatitis C could become a rare disease as early as 2036 [8].

New hepatitis C treatments are highly effective and have few adverse effects, but high costs could limit access to these medications. The preceding generation of interferon-based treatment regimens were poorly tolerated by patients, and required lengthy treatment durations, so many patients have remained untreated [9]. Recently approved interferon-free drug regimens for patients with genotype 1 disease are more than 94% effective in as few as 8 weeks for many patient subgroups, but can cost up to $190,000 per patient [10–12]. Despite their high cost, interferon-free regimens have been demonstrated to be cost-effective at thresholds of $50,000 to $100,000 per quality-adjusted life-year (QALY) [13–15].

Resource-constrained government health insurance programs, including Medicaid and Medicare, cover a substantial

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proportion of US patients with hepatitis C and are heavily impacted by the high prices of these drugs. Most state Medicaid programs restrict treatment of hepatitis C to patients with advanced liver disease because of medication costs [16]. Because hepatitis C is most prevalent in patients aged 45 years and older, many Medicaid patients with early-stage disease may not develop advanced disease or complications until after becoming eligible for Medicare [17,18].

Restrictive hepatitis C treatment policies are likely to reduce short-term costs to state Medicaid programs. However, it is unclear how these policies might shift the financial burden of hepatitis C management to the Medicare program or impact overall costs to the Centers for Medicare & Medicaid Services (CMS). In addition, the public health impact of delaying treatment for early-stage patients until after disease progression remains unknown. Thus, this study evaluated the cost-effectiveness of current Medicaid policies restricting hepatitis C treatment to patients with advanced disease compared with a strategy providing unrestricted access to hepatitis C treatment. We also assessed the budget and public health impact of each strategy and estimated the feasibility and long-term effects of increased access to treatment for patients with hepatitis C.

Methods

Model Structure and Perspective

Using a Markov state-transition model, we conducted cost-effectiveness, budget, and public health impact analyses from the perspectives of 1) the Medicare program alone, which included costs and effects accrued after patients became eligible for Medicare benefits, and 2) CMS, which incorporated costs and effects accrued during the entire study period. We considered lifetime costs and outcomes, used 3% annual discounting (varied in sensitivity analysis), and adjusted all prices to 2015 US dollars using the Consumer Price Index.

Model Cohort

We modeled hypothetical cohorts of 45-, 50-, and 55-year-old treatment-naive and treatment-experienced Medicaid patients diagnosed with genotype 1 hepatitis C. Our selected age groups comprise approximately 95% of the Medicaid hepatitis C population [19]. Our cohorts excluded patients with any history of decompensated cirrhosis, liver transplantation, or HIV coinfection. Chronic hepatitis C disease severity is measured using the Meta-analysis of Histologic Data in Viral Hepatitis (METAVIR) score, which describes five stages of liver fibrosis: F0, no hepatic fibrosis; F1, portal fibrosis without septa; F2, portal fibrosis with few septa; F3, many septa without cirrhosis; and F4, cirrhosis [20]. We estimated the baseline distribution of METAVIR scores using model-based predictions of the hepatitis C virus (HCV)-infected population in 2014 (Table 1) [8,13].

Natural History Model

We created a Markov model to simulate the natural history and epidemiology of hepatitis C infection (Fig. 1). Patients accrued liver-related treatment and follow-up costs as well as QALYs for their Markov state at the end of each 1-year cycle. Patients could make one state transition each year. Mortality was possible during each model stage; we estimated age-specific, annual all-cause mortality rates using US life tables [21]. Disease progression and excess liver-related mortality occurred according to stage-specific transition probabilities and relative risks of mortality established in previous studies (Table 1).

We grouped patients into three stages of baseline disease severity: early-stage disease (METAVIR F0-F2), advanced fibrosis (METAVIR F3), and compensated cirrhosis (METAVIR F4). Patients with compensated cirrhosis could later develop complications including decompensated cirrhosis, liver transplantation, and hepatocellular carcinoma. Patients with early-stage disease, advanced fibrosis, or compensated cirrhosis could receive hepatitis C treatment. We assumed that after successful treatment, patients with early-stage disease would return to full health and accrue no further hepatitis C infection–related costs. In contrast, patients with advanced fibrosis or cirrhosis would have markedly reduced risks of disease progression, complications, and mortality, but no reduction in follow-up costs after successful treatment (Table 1).

Treatment

We assumed that all patients would be treated with one of two currently available interferon-free hepatitis C drug regimens: a single-dose two-drug combination of sofosbuvir/ledipasvir (SOF/LDV) or a multidose three-drug combination of ombitasvir, paritaprevir, and ritonavir with dasabuvir (3D). At the time of analysis, the American Association for the Study of Liver Diseases recommended both these treatments for patients with genotype 1 hepatitis C (see Appendix Table 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2016.01.010). Because utility data were not available for the 3D regimen at the time of our analysis, we performed our primary analysis using data for SOF/LDV (Table 2) and used estimates for 3D in sensitivity analyses. We estimated the efficacy of each treatment regimen using data from recently published clinical trials [22–30]. In patient subgroups for which several alternative treatment options have demonstrated similar effectiveness, we chose the least costly drug regimen.

We determined SOF/LDV treatment disutility using data from a quality-of-life study conducted alongside recent clinical trials [31]. Because utility data for the 3D and 3D with ribavirin regimens were not available, we used treatment disutility data for the SOF/LDV and SOF/LDV with ribavirin regimens, respectively, in our sensitivity analysis (Table 2).

Costs and Effectiveness

We estimated treatment and follow-up costs for patients with hepatitis C (Table 1). In the base case, we included a 23.1% discount from the national average drug acquisition price for each drug regimen, which is required as part of the Medicaid drug rebate program; we varied drug prices in sensitivity analysis. We used the Medicare physician fee schedule to calculate the costs of on-treatment medical monitoring [32], including a single pre-treatment office visit, complete blood cell count, complete metabolic panel, and viral load measurement; monthly office visits, viral load measurements, and metabolic panels during treatment; and a single post-treatment office visit, viral load measurement, and metabolic panel. We assumed that patients using ribavirin-containing regimens were monitored more frequently, with twice-monthly office visits and complete blood cell counts (Table 2).

From the Medicare perspective, costs and QALYs began to accrue upon Medicare eligibility at age 65 years (or earlier for the share eligible due to disability). From the CMS perspective, costs and QALYs accrued throughout the study period. Because Medicare Part D can involve substantial cost sharing for seniors not receiving low- income subsidies, we subtracted expected patient out-of-pocket costs estimated using current Part D coverage rules [33], but assumed that the prescription drug coverage gap (i.e.,