

Limited Access to New Hepatitis C Virus Treatment Under State Medicaid Programs

Lauren A. Canary, MPH; R. Monina Klevens, DDS, MPH; and Scott D. Holmberg, MD, MPH

The burden of fatal liver disease is increasing in the estimated 3.2 million adults chronically infected with hepatitis C virus (HCV) in the United States (1-3). Sofosbuvir (Sovaldi, Gilead Sciences), which was approved by the U.S. Food and Drug Administration in December 2013, is a new oral HCV treatment that, when combined with other therapies, has a therapeutic efficacy (cure) greater than 90% across the 4 major HCV genotypes, limited adverse effects, and a shorter treatment window (usually 12 weeks) than its interferon-based predecessors (4). However, this drug currently retails at \$84 000 per patient, forcing many payers to ration this lifesaving treatment. As such, Medicaid programs, which cover approximately 25% of patients with HCV infection who are hospitalized but have limited budgets, face the challenge of deciding who should receive new, costly treatments (4, 5).

To understand policies that might affect patient access to new HCV therapies, we obtained preferred drug lists and prior authorization criteria from state Medicaid fee-for-service program Web sites and, when these were unavailable, elicited feedback from Medicaid programs through direct communication. We compared the guidelines used by state Medicaid programs with those published by the Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) (www.hcvguidelines.org). On the basis of data collected from May through November 2014, Medicaid programs in 31 states had designated sofosbuvir a “nonpreferred” drug, the prescription of which requires that clinicians provide evidence of medical necessity as defined by state-specific laws. Seventeen states applied a “preferred” designation, and although demonstrated medical necessity is not necessarily required in these states, all but 2 required clinicians to seek “prior authorization” for sofosbuvir prescription (Table).

Approval criteria vary widely by state, but most programs require scoring of liver fibrosis for sofosbuvir approval. Per IDSA/AASLD guidelines, treatment is of “highest priority” for persons with METAVIR fibrosis scores of F3 or F4 and “high priority” for those with a score of F2. In 33 state Medicaid programs, patients must have a score of F3 or F4, indicative of severe liver disease, to receive treatment with sofosbuvir. Of note, 4 states require liver biopsy to prove the level of fibrosis rather than allowing for the use of less invasive blood or imaging tests. Many state Medicaid programs limit treatment to patients at the most immediate risk for death from liver disease.

Newer HCV therapies have been hailed by the IDSA and the AASLD for their improved simplicity and

safety compared with older, interferon-based treatments; thus, nonspecialist physicians, rather than a limited number of specialists, may be able to manage treatment for most HCV-infected persons (that is, non-relapsing patients without serious comorbid conditions). However, 30 states require that sofosbuvir be prescribed by, or in consultation with, a specialist—usually a hepatologist, gastroenterologist, or infectious disease physician. The extent to which finding a specialist who accepts Medicaid may pose a barrier to HCV treatment remains unclear, although some Medicaid directors reported concern for patients living in rural areas. The IDSA/AASLD guidelines recommend collaboration with specialists (through the use of telemedicine, if needed) for treatment management when primary care physicians have limited experience.

Many prior authorization criteria require abstinence from the use of alcohol, illicit drugs, or both in the months leading up to treatment approval (ranging from 1 to 12 months before treatment for both). Thirty-five states require that patients abstain from alcohol use or abuse, and 30 states require abstinence from any illicit drug use before treatment approval. An additional 4 states require abstinence only from injection drug use.

Drug screens may further stigmatize a key population at risk for HCV infection that already faces substantial barriers to care despite its demonstrably similar adherence to HCV treatment compared with that of the general population (6). The IDSA/AASLD guidelines recommend that patients abstain from alcohol and drug use but do not suggest that treatment be withheld. Rather, they recommend that patients be provided with counseling and education and simpler and less toxic regimens, such as the newer sofosbuvir-based therapies, and receive referrals for psychiatric and opioid substitution therapies. In fact, the guidelines highlight the public health benefit of treating persons likely to transmit infection to others, such as those who inject drugs.

Additional hurdles not outlined here include denial of prescription based on parameters of HIV co-infection (such as a minimum CD4⁺ cell count and maximum viral load and demonstrated stable HIV treatment), requirements of weekly refills, the investigation of prior pharmacy refill records to estimate patient adherence, and the use of nonvalidated standardized tests to assess “patient readiness.” Some states also allow prescribing physicians to subjectively rate patients' likelihood of completing treatment.

A major limitation is that this review did not include criteria for Medicaid managed care organizations,

Table. Prior Authorization Criteria for Sofosbuvir Prescription Under State Medicaid Fee-for-Service Programs

State	Status	Abstain From Alcohol Use Before Treatment	Abstain From Alcohol Abuse Before Treatment	Abstain From Drug Use Before Treatment	Abstain From Injection Drug Use Before Treatment	Minimum METAVIR Fibrosis Score	Specialist Prescriber
Alabama	NP	✓	✓	✓	✓	F2	-
Alaska	NP	✓	✓	✓	✓	F3*	-
Arizona	NP	-	✓	✓	✓	F3	✓
Arkansas	NP	-	✓	-	✓	F3*	-
California	NP	-	-	-	-	F3	-
Colorado	NP	-	✓	✓	✓	F3	✓
Connecticut	P†	-	-	-	-	-	-
Delaware	NP	✓	✓	✓	✓	F4	-
District of Columbia	NP	✓	✓	✓	✓	F2	✓
Florida	NP	✓	✓	✓	✓	F3	✓
Georgia	NP	-	-	-	-	F3	-
Hawaii	P	-	✓	✓	✓	F3	✓
Idaho	NP	-	✓	-	✓	F3	✓
Illinois	NP	✓	✓	✓	✓	F4	✓
Indiana	NP	-	-	-	-	F4	✓
Iowa	NP	✓	✓	✓	✓	F3*	✓
Kansas	NP	-	✓	✓	✓	F3	✓
Kentucky	P	-	✓	✓	✓	F3	✓
Louisiana	NP	-	✓	✓	✓	F3*	✓
Maine	P	-	-	-	-	F1	✓
Maryland	P	✓	✓	✓	✓	F2	✓
Massachusetts	P	-	-	-	-	NA	-
Michigan‡	NA	-	-	-	-	-	-
Minnesota	P	-	-	-	-	-	-
Mississippi	P	✓	✓	✓	✓	-	✓
Missouri	NP	✓	✓	✓	✓	F3	-
Montana	P	✓	✓	✓	✓	F3	✓
Nebraska	NP	✓	✓	✓	✓	F3	-
Nevada	P†	-	-	-	-	-	-
New Hampshire	NP	-	✓	✓	✓	F3	✓
New Jersey‡	P	-	-	-	-	-	-
New Mexico	NA	-	-	-	-	F3	-
New York	NP	-	-	-	-	F3	✓
North Carolina	NP	-	✓	-	-	-	-
North Dakota	NP	✓	✓	✓	✓	F2	✓
Ohio	NP	✓	✓	✓	✓	F3	✓
Oklahoma	NP	-	✓	-	✓	F2	✓
Oregon	P	-	✓	✓	✓	F4	✓
Pennsylvania	P	✓	✓	✓	✓	F3	✓
Rhode Island	NP	-	-	-	-	F3	-
South Carolina‡	NP	-	-	-	-	-	-
South Dakota	NP	✓	✓	✓	✓	F3	✓
Tennessee	NP	-	✓	✓	✓	F3	✓
Texas‡	NA	-	-	-	-	-	-
Utah‡	P	-	-	-	-	-	-
Vermont	P	✓	✓	✓	✓	F3	✓
Virginia	NP	✓	✓	✓	✓	F3	✓
Washington	NP	✓	✓	-	✓	F3	✓
West Virginia	NP	✓	✓	✓	✓	F3	✓
Wisconsin	P	-	✓	✓	✓	F3	✓
Wyoming	P	-	✓	✓	✓	-	-

METAVIR = Meta-analysis of Histologic Data in Viral Hepatitis; NA = not available; NP = nonpreferred; P = preferred.

* Biopsy required.

† No prior authorization required.

‡ No published criteria.

which cover most Medicaid recipients in some states. Prior authorization criteria used by such programs often, but do not necessarily, align with fee-for-service criteria in those states.

This listing of prior approval criteria by state Medicaid offices provides insight into the pressure that approval of new, costly HCV treatments places on state Medicaid programs and the resultant warehousing policies that limit access to lifesaving treatment. It also re-

veals the decision-making processes being used by drug utilization review boards that are reportedly choosing approval criteria on the basis of a mix of medical evidence, cost considerations, and perhaps-unmeasured preferences. The financial burden necessitating warehousing strategies for HCV treatment is not unique to Medicaid programs, and investigation of prior authorization strategies used by other public and private payers is warranted.

Treatment of patients with HCV infection is cost-effective from a societal point of view (7), but the combination of the high cost of treatment and insufficient Medicaid budgets precludes programs from providing widespread access to treatment. Under any financial context, when payers make decisions about HCV treatment, it will be important to consider the ethics and public health implications of prioritizing patients for treatment. The effects of prior approval policies for new HCV treatments on patient outcomes warrant continued investigation.

From the Centers for Disease Control and Prevention, Atlanta, Georgia.

Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Acknowledgment: The authors thank Cecily Campbell, JD, LLM (ORISE Fellow, Division of Viral Hepatitis, Centers for Disease Control and Prevention), and the Center for Health Law and Policy Innovation at Harvard Law School for providing their expert knowledge of Medicaid law and structure.

Disclosures: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-0320.

Requests for Single Reprints: Lauren A. Canary, MPH, Division of Viral Hepatitis, National Foundation for the Centers for

Disease Control and Prevention, Mailstop G-37, Atlanta, GA 30329; e-mail, icanary@cdc.gov.

Current author addresses and author contributions are available at www.annals.org.

Ann Intern Med. doi:10.7326/M15-0320

References

1. Denniston MM, Jiles RB, Drobeniuc J, Klevens RM, Ward JW, McQuillan GM, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med.* 2014;160:293-300. [PMID: 24737271] doi:10.7326/M13-1133
2. Ly KN, Xing J, Klevens RM, Jiles RB, Ward JW, Holmberg SD. The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007. *Ann Intern Med.* 2012;156:271-8. [PMID: 22351712] doi:10.7326/0003-4819-156-4-201202210-00004
3. Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Hepatitis C in the United States. *N Engl J Med.* 2013;368:1859-61. [PMID: 23675657] doi:10.1056/NEJMp1302973
4. Lawitz E, Mangia A, Wyles D, Rodriguez-Torres M, Hassanein T, Gordon SC, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med.* 2013;368:1878-87. [PMID: 23607594] doi:10.1056/NEJMoa1214853
5. Kim WR, Gross JB Jr, Poterucha JJ, Locke GR 3rd, Dickson ER. Outcome of hospital care of liver disease associated with hepatitis C in the United States. *Hepatology.* 2001;33:201-6. [PMID: 11124837]
6. Grebely J, Dore GJ. Can hepatitis C virus infection be eradicated in people who inject drugs? *Antiviral Res.* 2014;104:62-72. [PMID: 24468275] doi:10.1016/j.antiviral.2014.01.002
7. Leidner AJ, Chesson HW, Xu F, Ward JW, Spradling PR, Holmberg SD. Cost-effectiveness of hepatitis C treatment for patients in early stages of liver disease. *Hepatology.* 2015;61:1860-9. [PMID: 25677072] doi:10.1002/hep.27736

Current Author Addresses: Ms. Canary: Division of Viral Hepatitis, National Foundation for the Centers for Disease Control and Prevention, Mailstop G-37, Atlanta, GA 30329.

Dr. Klevens: Centers for Disease Control and Prevention, 12 Corporate Square Boulevard, Atlanta, GA 30329.

Dr. Holmberg: Division of Viral Hepatitis, Mailstop G-37, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333.