Medicaid Calls Evidence for Sovaldi Lacking and Biased

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The National Association of Medicaid Directors has denounced as poor and potentially biased the available evidence and guidelines supporting the use of Gilead Sciences' hepatitis C virus (HCV) therapy Sovaldi (sofosbuvir), MedPage Today reports. In a report, Medicaid called into question whether Sovaldi, which costs $1,000 a day and is placing a substantial financial burden on both private and governmental insurers, is a substantial improvement over the standard of care of interferon, ribavirin and either Victrelis (boceprevir) or Incivek (telaprevir).

The report points out that the published research on Sovaldi is limited to just 10 studies, nine of which were sponsored by Gilead, and that none of them compared the drug's use among those with genotype 1 of hep C with an alternate drug regimen. Nor did any of the studies include comparisons to a Victrelis- or Incivek-based regimen. While the cure rates were relatively high in these trials, the report questions if such figures will remain as elevated in real-world use of Sovaldi.

The Medicaid directors scorned the guidelines on Sovaldi issued by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), calling them "methodologically flawed." Four in five of the chairs of the guidelines panel and 15 out of 21 of the entire panel had financial ties to Gilead, indicating potential conflicts of interest. The report says that the guidelines "do not give assessments of the quality of individual studies nor the strength of the evidence for recommendations."

The AASLD has countered by stating that the report has failed to grasp that the organization, along with IDSA, never actually issued guidelines, per se. Rather, they issued "a guidance, not a practice guideline."

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