



January 28, 2014

**Toby Douglas**

*Director*

California Department of Health Care Services

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**RE: Urgent Request for Guidance and for Managed Care Carve-Out of Sovaldi for Treatment of Hepatitis C**

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Dear Mr. Douglas:

As President and Chief Executive Officer of Molina Healthcare, I am writing on an urgent basis regarding the recent FDA approval of the new Gilead drug, Sovaldi (sofosbuvir), for the treatment of hepatitis C. I am requesting that you provide emergency guidance as to how Medicaid managed care plans such as Molina Healthcare should handle prior authorization requests for the coverage of the cost of Sovaldi, and also to urge you, for the avoidance of doubt, to carve out of Medicaid managed care such pharmaceutical coverage.<sup>1</sup> Until such time as sufficient actuarial claims data may be developed, Sovaldi should be covered entirely on a traditional Medicaid fee-for-service basis.

My request is based on the fact that Sovaldi is an entirely new drug that was approved by the FDA just over six weeks ago – on December 6, 2013. Because of its approval for use only last month, claims for the treatment of hepatitis C using Sovaldi were not factored into the calculation of actuarially sound Medicaid managed care rates for 2014.

Further, as priced by Gilead, Sovaldi is an extraordinarily expensive drug, with a twelve-week course of treatment costing approximately \$84,000.<sup>2</sup>

Finally, the incidence of hepatitis C in the Medicaid population is substantially uncertain, but clearly non-negligible. According to the Centers for Disease Control (CDC), hepatitis C is the most common chronic blood borne infection in the United States, with an estimated 3.2 million persons chronically infected.<sup>3</sup> However, the actual incidence of hepatitis C may be significantly higher because of inadequate screening for the disease.

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<sup>1</sup> Molina Healthcare's request for clarification and managed care carve-out as made herein should not be construed as an admission that its Medicaid health plans may be contractually obligated to provide coverage of the cost of Sovaldi, or that such coverage is clinically indicated in a particular case. We reserve all rights and remedies under applicable federal and state law and our contracts.

<sup>2</sup> [www.gilead.com/news/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c](http://www.gilead.com/news/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c)

<sup>3</sup> [www.cdc.gov/hepatitis/hcv/](http://www.cdc.gov/hepatitis/hcv/)

In June 2013, the U.S. Public Health Services Task Force (USPSTF) released a new recommendation for hepatitis C screening.<sup>4</sup> Since that recommendation was made so recently and pre-existing data was not well-developed, the actual incidence of hepatitis C in the Medicaid population is unknown. Moreover, many of the newly insured under the Affordable Care Act Medicaid expansion have not received treatment in the past because they lacked health insurance or the ability to pay for treatment.<sup>5</sup> Further, we have seen reports, and heard anecdotally, that a number of medical providers have delayed initiating any alternative treatment regimen for their hepatitis C patients because they knew Sovaldi would soon become available. Thus, for all of these reasons, there is likely a significant pent-up demand for hepatitis C treatment with Sovaldi, and the number of Medicaid beneficiaries seeking such treatment will be substantial.

Molina currently covers over 2.1 million Medicaid beneficiaries in 11 states. If a commensurate percentage of those 2.1 million beneficiaries as relates to the incidence of hepatitis C in the general population were all provided a twelve-week course of treatment with Sovaldi, the cost to Molina Healthcare from this treatment alone would exceed \$1.7 billion.<sup>6</sup> Such a cost burden is not sustainable by Molina Healthcare, or by any other Medicaid managed care health plan.

The FDA approval of Sovaldi just six weeks ago, and its availability now as a pharmaceutical treatment of hepatitis C for the Medicaid population, is a supervening event. It was simply not taken into account in the calculation of actuarial sound rates for 2014. As an unaccounted for supervening event, the financial burden represented by Sovaldi must be regarded as a combined federal and state responsibility under the Medicaid program that is covered solely on a fee-for-service basis from the date of the drug's FDA approval. ***To avoid confusion, and to provide for the prompt treatment of those Medicaid members with hepatitis C, we urge you to take prompt action to provide guidance on the fee-for-service coverage of the cost of Sovaldi.***

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<sup>4</sup> [www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.pdf](http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.pdf)

<sup>5</sup> [nvhr.org/sites/default/files/Milliman%20HCV%20ACA.pdf](http://nvhr.org/sites/default/files/Milliman%20HCV%20ACA.pdf)

<sup>6</sup> This figure assumes a treatment uptake rate of 100%. We recognize that the actual uptake rate would be much lower. Nevertheless, this figure is indicative of the magnitude of the health policy issue presented by this recent drug approval, and the impracticability and inequity of requiring managed care health plans to bear this cost where their capitation rates were calculated assuming no such cost. As a point of comparison for the \$1.7 billion figure given above, the *total* annual pharmaceutical spending of Molina Healthcare for 2013, inclusive of all drugs, was approximately \$1.2 billion.

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Toby Douglas, Director  
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Thank you for your prompt consideration of this urgent matter. Please contact Richard Chambers at 888-562-5442, ext. 127090 if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Joseph M. Molina MD". The signature is written in a cursive style.

J. Mario Molina, MD  
President and Chief Executive Officer  
Molina Healthcare, Inc.

cc Marilyn Tavenner  
Cindy Mann  
David Sayen