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*Michigan Department of Community Health
Pharmacy and Therapeutic Committee*

*Public Hearing
July 8, 2014*

*MAHP Position Statement and Recommendations
Hepatitis C Medications*

Introduction

The Michigan Association of Health Plans (MAHP), the leading trade association representing the Michigan's Health Plans and managed care industry, thanks the members of the Michigan Medicaid Pharmacy and Therapeutics Committee for holding this hearing. Members of MAHP deliver comprehensive health care services through various product lines for Commercial, Medicare and Medicaid beneficiaries in this state.

Of concern is the impact of the pending decision regarding inclusion of the product Sovaldi on the Medicaid formulary. Because of the State's reliance on Medicaid Health Plans, including serving the expanded population under the Healthy Michigan program, nearly all of the Medicaid and Healthy Michigan program beneficiaries who may benefit by this product, will be the responsibility of Medicaid Health Plans.

As you may also be aware, due to the State's Medicaid contract, the decisions made on the state's formulary directly affects the pharmacy benefit administered and paid for by Medicaid Health Plans.

While one of the major concerns is the high cost of this product and commentary is being provided directly to MDCH on that point, we have additional concerns regarding the projected number of beneficiaries to benefit by the product and the protocol and guidelines that should be developed and used. Further, we strongly encourage this committee, the MDCH and others to develop an overall strategy and framework for the discussion on specialty drugs rather than solely reacting to each product.



After surveying our members and reviewing other state projections and national estimates, the projected volume of patients in the Medicaid program that may benefit from taking Sovaldi will be substantial. With estimates that Medicare coverage of just this one drug would raise overall Medicare Part D drug spending by as much as 8% and Healthy Michigan Program rates would need to increase by more than 15%, the public policy considerations cannot be ignored. And we should not forget that it will be the Michigan taxpayers who will shoulder much of the cost of the drug because many Michigan residents living with hepatitis C get their health care from the government through Medicare, Medicaid or the state prison system.

As further research has taken place, questions are now being raised regarding the efficacy of the studies leading to the FDA approval. The summary conclusion of the Oregon based, Center for Evidence Based Policy, are reproduced below. This documentation should be taken seriously at this time as it concluded that “there is not yet clear evidence that this drug should be used routinely to treat patients.” The research report, dated May 2014, may be found at the following link: [http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir for HepatitisC FINALDRAFT 6 12 2014.pdf](http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir%20for%20HepatitisC%20FINALDRAFT%206%2012%202014.pdf)

“This rapid evidence review located 10 studies published in seven articles, although the majority of the studies were non-comparative and all but one was at high risk of bias. There were two comparative studies of sofosbuvir treatment for HCV-2 and HCV-3 infection, but no published comparative studies for the treatment of HCV-1. Based on the usual standards of comparative effectiveness research, currently available studies do not provide sufficient evidence for the routine use of sofosbuvir-containing regimens for the treatment of hepatitis C infection.

While initial, uncontrolled, response rates appear to be relatively high among carefully selected populations, response rates in “real world” populations are likely to be lower. Furthermore, there is evidence that relapse rates may be substantial, ranging from 5% to 28% even among patients who are fully treated with these regimens. Similarly, adverse effects have not been studied in large numbers of patients and among those with substantial other risk factors for harms. When the first two protease inhibitors began to be used in clinical practice, the risks of adverse events approximately tripled and there could be a similar concern with these even newer drugs as they are used in widespread clinical practice.

The recently published HCV treatment guideline published by AASLD and IDSA is of poor methodologic quality and does not adhere to international or US standards for guideline development. In addition, guideline authors had substantial and multiple conflicts of interest. Sofosbuvir may eventually be shown to be a valuable treatment for hepatitis C. However, due to the lack of well-designed comparative studies, there is not yet clear evidence that this drug should be used routinely to treat patients. While awaiting full disclosure of existing research and the production of more and better evidence on sofosbuvir, policymakers may decide to not allow use of, or to allow very limited use of this drug. If limited use is contemplated, this report details



factors to consider, such as limiting use to carefully selected HCV-2 and -3 infected individuals who are at great risk of shortly progressing to cirrhosis, and only as part of a regimen including RBV. Policymakers, clinicians, and patients should remain aware of upcoming drug research and carefully examine the quality of new research as it is made available.

(May 2014, “Sofosbuvir for the Treatment of Hepatitis C and Evaluation of the 2014 American Association for the Study of Liver Diseases Treatment Guidelines”, Center for Evidence-based Policy Oregon Health & Science University, pp 25-26).

These conclusions were taken into account in a recent statement by the National Association of State Medicaid Directors, (May 20th). In this statement NASM noted that the “The Center’s report is a key step in solidifying the evidence base for this drug. Based on its rigorous review of the ten published sofosbuvir studies, the Center found that each was of “poor” methodologic quality, noting risks of bias and lacking comparison to current standards of hepatitis C treatment. None of the studies were designed to answer the question of whether these drugs work better than current treatments and for the people most likely to have them prescribed. (emphasis added). The NASM recommended that, “Medicaid programs must be deliberate in their decisions and may need to adapt their strategies over time as more detailed clinical research becomes available”.

(Link to the NASM statement:

http://medicaiddirectors.org/sites/medicaiddirectors.org/files/public/namd_statement_med_project_report_140520_3.pdf)

Recommendations

As currently recommended by the manufacturer, the minimum treatment time for Sovaldi is 12 weeks which may extend to 24 or 48 weeks depending on individual patient circumstances, such as the ability to take a recommended drug in combination with Sovaldi or if the patient is waiting to receive a liver transplant. However, because Sovaldi must be used in combination with other drugs, the actual treatment is more complex and the costs for hepatitis C are even greater. This suggests that careful procedures be followed in the administration of this product.

Taking into account the recent research findings of the Center for Evidence Based Policy, as noted above, and the recommendations of the National Association of State Medicaid Directors, MAHP recommends that the P & T Committee **defer** any final decision regarding the inclusion of Solvaldi to the formulary until the following steps have been taken:

1. **Establish a consensus framework for the use of new Hepatitis C Drugs.** Either the P & T Committee or the MDCH should convene a Hepatitis C work group comprised of clinical experts, Medicaid managed care plan medical directors, state policy and fiscal



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analysts, and staff from the MDCH to develop clinical criteria for use of new Hepatitis C drugs and to explore the fiscal implications for Medicaid and Medicaid managed care plans. This is a step that other states have and are undertaking.

2. **Develop Standards prior to the Introduction of Hepatitis C Drugs.** Further as the Department drafts its criteria for the hepatitis C drugs, the MAHP Medical and Pharmacy Directors recommend including the following standards as benchmarks to receiving these medications.
 - a. Limit each fill of Sovaldi to a 14-day supply to avoid waste from patients who stop taking the medication because he or she could not tolerate one of the medications used in the treatment or experience an adverse drug effect. Intolerance, of lack of response will be evident in less than 30 days. The manufacturer states pills are good for 45 days after the bottle is opened (see attached ⁱ)
 - b. Establish Futility guidelines for instances where the disease state maybe too far advanced for the drug to have any beneficial impact.
 - c. Limit treatment to only patients with advanced liver fibrosis (defines as MATAVIR scores of F3 or F4.)
 - d. Mandatory alcohol and illegal drugs testing to ensure that healthy lifestyles have been adopted to avoid re-infection, confirmed by laboratory drug testing.
 - e. Discontinue coverage of treatment for patients who do not take the medication as prescribed.
 - f. Provider restrictions that limit prescribing to the most appropriate prescribers (gastroenterologist, hepatologist, or infectious disease specialist.)
 - g. Require Sovaldi to be dispensed from a specialty pharmacy who agrees to provide certain case management services, including adherence, tolerance, and effectiveness monitoring.
 - h. Clinical guidelines be established that define clinical intolerance or contraindications to pegylated interferon therapy.
 - i. Provide timely notification to Managed Medicaid Health Plans when one of their enrollees starts hepatitis C treatment.



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- j. Limit coverage to once in a lifetime treatment.
 - k. Develop national repository that all health plans and their delegates can access to see if the patient has already received the drug before.
 - l. In absence of a national data base, a state registry such as MCIR should be re-purposed to allow Health Plans access to this important information.
3. **Create a Policy Framework for review/approval of Specialty Drugs.** What is also clear is that the Medicaid Formulary must be based on a prudent baseline of aggressive approval criteria to ensure that products are used for the most appropriate patients. MAHP further encourages this committee, MDCH and others to establish a state policy framework regarding specialty drugs as we expect further similar specialty products to be forthcoming. The link below is the recent Op-Ed by Karen Ignati, CEO of America's Health Insurance Plans, AHIP, which makes this point much more emphatically:
http://www.cnn.com/2014/07/07/opinion/ignagni-hepatitis-c-drug/index.html?hpt=op_t1

As Michigan works to provide coverage and allocated scarce funds for treatment provided in 2014, (the costs of which was not included in the adopted budget nor in the capitated rates), and develops policy criteria to cover these products in 2015 and beyond, MAHP looks forward to working with you and MDCH to help provide technical and clinical assistance to assure fiscal solvency for Michigan's Medicaid programs and actuarially sound rates for plans during the current fiscal year.

Thank you again for all you and MDCH do for the Medicaid program and the beneficiaries we serve and we stand ready to assist in any way possible to establish appropriate policies and protocol for this and other products affecting Medicaid beneficiaries.

¹ SOVALDI (sofosbuvir) Tablets, for use oral use. US Prescribing Information Gilead Sciences, Inc. Foster City CA December 2013.