



STATE OF WISCONSIN  
Division of Hearings and Appeals

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In the Matter of

[REDACTED]  
*Redact*  
[REDACTED]

DECISION

MPA/164384

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**PRELIMINARY RECITALS**

Pursuant to a petition filed February 25, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on March 26, 2015, at Shell Lake, Wisconsin.

The issue for determination is whether the petitioner is entitled to medical assistance reimbursement for Harvoni.

There appeared at that time and place the following persons:

**PARTIES IN INTEREST:**

Petitioner:

[REDACTED]  
*Redact*  
[REDACTED]

Respondent:

Department of Health Services  
1 West Wilson Street, Room 651  
Madison, Wisconsin 53703

By: *Redact*, R.Ph.  
Division of Health Care Access and Accountability  
1 West Wilson Street, Room 272  
P.O. Box 309  
Madison, WI 53707-0309

**ADMINISTRATIVE LAW JUDGE:**

Michael D. O'Brien  
Division of Hearings and Appeals

**FINDINGS OF FACT**

1. The petitioner is a resident of Washburn County.

2. On December 30, 2014, the petitioner with [Redacted] Pharmacy requested 28 doses of Harvoni. The request does not indicate the cost of the drug. After reviewing additional information, the Office of Inspector General denied the request on February 12, 2015.
3. The petitioner is diagnosed with hepatitis C, genotype 1a.
4. The petitioner has decompensated cirrhosis.

### DISCUSSION

Federal medical assistance rules allow, but do not require, states to pay for prescription drugs. 42 C.F.R. § 440.225. Wisconsin pays for prescription drugs (Wis. Admin. Code § DHS 107.10), but uses the discretion granted by the federal government to control their cost by dividing them into two classes, preferred and non-preferred. Preferred drugs are generally older, often generic, and almost always less expensive than non-preferred drugs. Wisconsin requires prior authorization before paying for non-preferred prescription drugs, which it refers to as those it “has determined entail substantial cost or utilization problems for the MA program.” Wis. Admin. Code, § DHS 107.10(2)(d).

The petitioner seeks payment from the medical assistance program for Harvoni to treat her Hepatitis C. Harvoni is a non-preferred drug requiring prior authorization when used to treat hepatitis C because each treatment costs between \$63,000 and \$189,000; the petitioner’s request does not indicate how much the drug will cost for her.

The petitioner and her provider have must prove by the preponderance of the credible evidence that the drug is needed. As with any request for a medical assistance service, the petitioner must prove, among other things, that the drug is medically necessary and appropriate. The Department must consider the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Admin. Code § DFS 107.02(3)(e)1.,2.,3.,6. and 7. “Medically necessary” means a medical assistance service under ch. HFS 107 that is “[r]equired to prevent, identify or treat a recipient's illness, injury or disability” and, among other things, “[w]ith respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient. Wis. Admin. Code, § DHS 101.03(96m)(a) and (b)8.

The department has developed guidelines on when to pay for Harvoni. These guidelines, which are found in the department’s online medical assistance handbook, Topic 17717, at [https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Hepatitis C, Agents, Harvoni&adv=Y](https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Hepatitis%20C,%20Agents,%20Harvoni&adv=Y), allow the drug to be considered for those whose hepatitis C has advanced to any of the following stages:

- Compensated cirrhosis
- Metavir score of F3 or greater or evidence bridging fibrosis
- Serious extra-hepatic manifestations of hepatitis C virus (HCV)

But regardless of the stage that the person’s hepatitis has advanced to, Harvoni will be denied under the following circumstances:

- The member has autoimmune hepatitis.
- The member has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- The member has decompensated cirrhosis.
- The member has acute hepatitis C.
- The member has received a liver transplant.

- The member is currently abusing drugs or alcohol.
- The member is co-infected with HIV.
- The member has taken or is currently taking Sovaldi™.
- Non-compliance with approved hepatitis C treatment regimen (for renewals only).

*Id.*

Harvoni undoubtedly would also help those with less severe complications. But this must be viewed in the context of the high cost of the drug, the need for the medical assistance program to treat all sorts of people with all sorts of medical problems, and the fact that because the state does not have to cover any prescription drugs it could end the prescription drug portion of the medical assistance program if it cannot control costs. Viewed in this context, the policy is reasonable, even if it does not provide the best possible medical care for all who have hepatitis C.

The petitioner's medical records indicate that she has a history of "mild decompensation." Redact *Clinic Office Note*, December 17, 2014. The petitioner points out that other drugs have failed to help her and her condition is severe. These are all valid medical points. But I must determine his eligibility according to whether she meets the criteria set by the department. Because her records indicate she has decompensation, she does not.

I note to the petitioner that if provider disagrees with this diagnosis, she should file a new request. If the Office of Inspector General again denies the request, she can file a new appeal. I suggest that if this happens, she try to obtain legal help from a volunteer organization such as Legal Action of Wisconsin or Judicare and have a medical expert ready to testify. I don't usually suggest this, but I also don't usually hear matters where the recipient seeks a service that can cost well over \$100,000. However, if there is another hearing, its focus will be on whether the petitioner meets the Harvoni guidelines and not whether those guidelines constitute the wisest course of action for those with hepatitis C.

### **CONCLUSIONS OF LAW**

The Office of Inspector General correctly denied the petitioner's request for Harvoni because she has not shown by the preponderance of the credible evidence that she meets the department's guidelines required to receive the treatment.

**THEREFORE, it is**

**ORDERED**

The petitioner's appeal is dismissed.

### **REQUEST FOR A REHEARING**

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

**APPEAL TO COURT**

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as “PARTIES IN INTEREST” **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,  
Wisconsin, this 13th day of April, 2015

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\sMichael D. O'Brien  
Administrative Law Judge  
Division of Hearings and Appeals



**State of Wisconsin\DIVISION OF HEARINGS AND APPEALS**

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The preceding decision was sent to the following parties on April 13, 2015.

Division of Health Care Access and Accountability