



STATE OF WISCONSIN  
Division of Hearings and Appeals

In the Matter of

[Redacted]

DECISION

[Redacted]

PRELIMINARY RECITALS

Pursuant to a petition filed February 26, 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 May 15, 2015, at Ladysmith, Wisconsin. Hearings scheduled for March 26, 2015, and April 15, 2015, were rescheduled at the petitioner’s request. The record was left open for 46 days at the petitioner’s request.

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]

Petitioner's Representative:

[Redacted]

Respondent:

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

By: [Redacted]

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

[REDACTED]

## FINDINGS OF FACT

1. The petitioner is a resident of Rusk County.
2. On February 5, 2015, the petitioner with [REDACTED] requested a Harvoni to treat hepatitis C. The cost of the request is \$90,000. The Office of Inspector General denied the request on February, 2015.
3. The petitioner is diagnosed with hepatitis C, genotype 1B,
4. The petitioner's Metavir score, which measures scarring of the liver, is "none."
5. The petitioner does not have cirrhosis.
6. The petitioner does not exhibit any serious manifestations of the hepatitis C virus outside of her liver.

## DISCUSSION

I note initially that this matter has been in the system for a long time. The petitioner requested Harvoni on February 5, 2015, and filed her appeal on February 26, 2015, after the Office of Inspector General's denial. Two hearings were postponed because her attorney had a scheduling conflict, and then the record was held open for 46 days so the attorney could file a brief. After receiving the brief, I asked the attorney if she would agree to leave the record open for additional time to give the department's attorneys an opportunity to respond to her arguments. I believe it is necessary for the department's attorneys to respond because if the Division of Hearings and Appeals adopts the petitioner's arguments, that decision would be in conflict with both the many decisions the division has previously written on the subject and the department's written policy. Part of my concern was fairness to the department, but a bigger concern was the need to issue a legally correct decision, something that is less likely without the participation of lawyers for both sides of the dispute. The petitioner's attorney indicated that she would ask her client about the request, but that she was concerned about the length of time this matter has gone on. Her concern is understandable. I have not heard from her since then. Therefore, I will issue this decision based upon the information I have and will do so consistent with our office's earlier decisions. The petitioner, of course, can challenge this decision in circuit court, in which case both parties will be represented by an attorney. Or she can file a new request. If that request eventually reaches me, I will issue a proposed decision if both parties are represented by an attorney.

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 controls their cost by dividing them into two classes, preferred and non-preferred. Preferred drugs are usually 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 liver damage from Hepatitis C. Harvoni is a non-preferred drug requiring prior authorization when used to treat hepatitis C because each treatment costs \$63,000 to \$189,000. The petitioner's request indicates her prescription would cost \$90,000.

The petitioner and her provider 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 concerning 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)

The drug must be prescribed by a “gastroenterologist or infectious disease provider practice,” and the recipient must be at least 18 years old diagnosed with chronic hepatitis C genotype 1. *Id.*

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.*

The Wisconsin MA program does cover the less expensive prescription drug Interferon to treat less severe hepatitis C complications. *Id.*, *Preferred Drug List-Quick Reference*.

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 has not had severe liver damage from hepatitis C and understandably seeks to avoid it. Nevertheless, I must determine her request according to whether she meets the criteria set by the department. Her provider indicated that the petitioner’s Metavir score was “none” and that she did not have cirrhosis. The Office of Inspector General pointed out that her actual Metavir score may be equivalent to 1, but this is still less than the required score of 3. Nor do her medical records contain evidence that she exhibits any serious manifestations of the hepatitis C virus outside of her liver. Because she does not meet the valid guidelines established by the department, I must uphold its decision.



**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 it is medically necessary.

**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 29th day of July, 2015

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



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## State of Wisconsin \DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator  
Suite 201  
5005 University Avenue  
Madison, WI 53705-5400

Telephone: (608) 266-3096  
FAX: (608) 264-9885  
email: [DHAmail@wisconsin.gov](mailto:DHAmail@wisconsin.gov)  
Internet: <http://dha.state.wi.us>

The preceding decision was sent to the following parties on July 29, 2015.

Division of Health Care Access and Accountability  
Attorney [REDACTED]