



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of



DECISION

MPA/174357

PRELIMINARY RECITALS

Pursuant to a petition filed May 11, 2016, 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 (MA), a hearing was held on June 15, 2016, at Milwaukee, Wisconsin.

The issue for determination is whether the agency properly denied the Petitioner's PA request for Harvoni.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:



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:

Debra Bursinger
Division of Hearings and Appeals

FINDINGS OF FACT

- 1. Petitioner (CARES # [Redacted]) is a resident of Milwaukee County.
2. On April 8, 2016, the Petitioner's pharmacy provider, [Redacted], submitted a PA request on behalf of the Petitioner for Harvoni.

3. Petitioner has primary diagnosis of Hepatitis C. On February 24, 2016, a Fibroscan was performed and Petitioner had a resulting Metavir score of F0-F1. She does not have a diagnosis of cirrhosis. She does not have any signs or symptoms of extra-hepatic manifestations of HCV. She has a contraindication for Viekira Pak.
4. On April 14, 2016, the agency issued a notice to the Petitioner informing her that it had denied her PA request.
5. On May 11, 2016, the Petitioner filed an appeal with the Division of Hearings and Appeals.

### DISCUSSION

The Wisconsin MA program pays for some prescription drugs. Wis. Admin. Code § DHS 107.10. Clinical prior authorization for all hepatitis C agents, including preferred drugs, is required as a condition of payment. ForwardHealth Update 2015-50 (October, 2015).

In evaluating a PA request, the program considers the authorization standards at § DHS 107.02(3)(e). Those standards include the requirements that the requested service be a medical necessity, appropriate, and cost effective, and that the existence of less expensive alternative services be considered. *Id.* The petitioner bears the burden of proving that these standards are met.

As an aid to assure consistent authorization request evaluation/approval for hepatitis C drugs, the agency's consultants have implemented policy standards related to severity. In June, 2015, Update 2015-27 became effective. It states that Viekira Park is a preferred Hepatitis C agent. Harvoni, Olysio and Sovaldi remain non-preferred Hepatitis C agents. Specifically with regard to Harvoni, the update provides as follows:

Hepatitis C, Agents, Harvoni®

Prior Authorization Requests That Will Be Considered for Review

Only PA requests for Harvoni® for members whose hepatitis C liver disease has advanced to any of the following stages ***and*** who are clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication may be considered for review:

- Compensated cirrhosis (i.e., CTP class A).
- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater).
- Serious extra-hepatic manifestations of HCV.

In addition, only PA requests for members who have chronic hepatitis C genotype 1 infection will be considered for review.

For treatment-naïve members who have HCV without cirrhosis and an HCV-RNA level less than 6 million IU/ml ***and*** who meet the above criteria for PA review consideration, only eight weeks of Harvoni treatment will be considered for review.

Conditions or Circumstances for Which Prior Authorization Requests Will Be Denied

Prior authorization requests for Harvoni® will be denied in the following circumstances:

- The member does not have a medical or medication contraindication for treatment with Viekira Pak™.
- The member has acute hepatitis C.

- The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C). (Note: If the member is currently on a liver transplant wait list with an elevated MELD score, individual circumstances will be considered for review.)
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol.
- Members with compensated cirrhosis must be abstinent from alcohol for the six months prior to and during HCV treatment.
- Members must no longer be abusing drugs for at least six months prior to HCV treatment.
- Active participation in a recovery program is required for members with a recent history of alcohol or drug abuse.
- The member has taken a prior course of therapy with Harvoni® or Sovaldi™.
- The member has not been compliant with approved hepatitis C treatment regimen.

Note: The member's other medications will be evaluated to determine if a significant drug interaction would occur that may result in denial of the PA request.

ForwardHealth Update 2015-27 (June 2015) (emphasis added)

In order for review of a request for Harvoni to take place, a member must first demonstrate that her disease has advanced to one of the following stages: compensated cirrhosis, evidence of bridging fibrosis or serious extra-hepatic manifestations of HCV. In addition, the member must also demonstrate that the preferred drug Viekira Pak is contraindicated.

For certain members who are treatment-naïve and have HCV without cirrhosis or and an HCV-RNA level less than 6 million IU/ml, an 8 week course of Harvoni will be considered for review but the individual must still demonstrate that the disease has advanced to one of the cited stages (compensated cirrhosis, evidence of bridging fibrosis or serious extra-hepatic manifestations of HCV).

For members who demonstrate that they meet the criteria for a review, the policy requires denial of the request if the member also meets any of the denial criteria listed.

In this case, the Petitioner asserted that Viekira Pak is contraindicated for her, that her HCV-RNA level is under 6 million IU/ml and she does not meet any of the denial criteria. The Petitioner is correct on all of those points. However, a request for Harvoni is only considered for review if the disease has advanced to one of the listed stages. It is undisputed that the Petitioner's disease has not advanced to one of those stages. An administrative law judge has no equitable authority and must apply the law and policies as they are written. Therefore, I have no authority to reverse the agency's determination and must conclude that the agency properly denied the Petitioner's PA request.

### **CONCLUSIONS OF LAW**

The agency properly denied the Petitioner's PA request for Harvoni.

**THEREFORE, it is**

**ORDERED**

That 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**

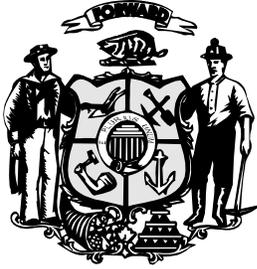
You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those 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 Milwaukee,  
Wisconsin, this 20th day of June, 2016

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\sDebra Bursinger  
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 June 20, 2016.

Division of Health Care Access and Accountability