



STATE OF WISCONSIN  
Division of Hearings and Appeals

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In the Matter of

[REDACTED]  
[REDACTED]  
[REDACTED]

DECISION

MPA/171784

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**PRELIMINARY RECITALS**

Pursuant to a petition filed January 29, 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, a hearing was held on March 08, 2016, at Fond Du Lac, Wisconsin.

The issue for determination is whether a prior authorization request for Sovaldi for Petitioner was correctly denied.

There appeared at that time and place the following persons:

**PARTIES IN INTEREST:**

Petitioner:

[REDACTED]  
[REDACTED]  
[REDACTED]

█  
█

Respondent:

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

By: [REDACTED], 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:**

David D. Fleming  
Division of Hearings and Appeals

**FINDINGS OF FACT**

1. Petitioner is a resident of Fond Du Lac County.
2. A prior authorization request was filed on behalf of Petitioner on December 30, 2015 seeking Medicaid payment for a 24 week supply (168 tablets) of Sovaldi. The cost is noted to be

\$201,640.39. The prior authorization included only an ultrasound of the liver which showed a normal liver and the results of a blood draw but none on the medical records necessary to evaluate Petitioner's hepatitis C.

3. Petitioner is 46 years old (DOB [REDACTED]). He is diagnosed with hepatitis C. The prior authorization does not indicate cirrhosis of the liver. He is not on a transplant list. There is no medical evidence of a Metavir score of F3 or greater or bridging fibrosis or serious extra-hepatic manifestations of the hepatitis C virus.
4. This prior authorization request has been denied as the Department concluded that prior authorization submission did not demonstrate that Petitioner's condition meets the criteria necessary for Medicaid payment for Sovaldi.

### 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 generally 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). Medicaid recipients and their providers must prove by the preponderance of the credible evidence that the drug is needed.

Petitioner seeks payment from the medical assistance program for Sovaldi to treat his liver damage from Hepatitis C. Sovaldi is a non-preferred drug requiring prior authorization when used to treat hepatitis C because each treatment costs at least \$84,000; Petitioner's request would cost \$201,640.39 for a 24-week supply.

As with any request for a medical assistance service, 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 Sovaldi. These guidelines, which are found in the department's online medical assistance handbook, Topic 17357, 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%20C,%20Agents,%20Sovaldi&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 of bridging fibrosis.
- HCC [hepatocellular carcinoma], if the member is on a liver transplant waiting list.
- Serious extra-hepatic manifestations of HCV [Hepatitis C virus].

The drug must be prescribed by a "gastroenterologist or infectious disease provider practice," and the recipient must be at least 18 years old. *Id*

Petitioner does not have cirrhosis. He is not on a liver transplant waiting list. There is no medical evidence to demonstrate that Petitioner meets any of the criteria necessary for approval of Sovaldi. Because he does not meet the guidelines established by the Department, I must uphold its decision.

**CONCLUSIONS OF LAW**

That the Department of Health Services correctly denied Petitioner's request for Sovaldi because he has not shown by the preponderance of the credible evidence that it is medically necessary.

**THEREFORE, it is ORDERED**

That this 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 15th day of April, 2016

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\sDavid D. Fleming  
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 15, 2016.

Division of Health Care Access and Accountability