



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

Redacted case name

DECISION

MPA/163995

PRELIMINARY RECITALS

Pursuant to a petition filed February 12, 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 20, 2015, at Menomonie, Wisconsin.

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

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

Redacted petitioner name

Respondent:

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

By: Redacted name, 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 (CARES # Redacted) is a resident of Dunn County.

2. On January 9, 2015, the petitioner with Redact Health Systems Pharmacy requested a 12-week supply of Sovaldi at a cost of \$104,852.01. After reviewing additional information provided by Redact, the Office of Inspector General denied the request on January 23, 2015.
3. The petitioner is diagnosed with hepatitis C, genotype 2.
4. The petitioner does not have cirrhosis.
5. The petitioner's Metavir score, which measures scarring of the liver, was listed as "none."
6. The petitioner is not on a liver transplant waiting list.
7. The petitioner does not exhibit any serious manifestations of the hepatitis C virus outside of his liver.

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).

The 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; the petitioner's request would cost \$104,852.01 for a 12-week supply. The petitioner and his 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 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,%20A%20gents,%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.* Sovaldi will be denied under the following circumstances:

- The member has autoimmune hepatitis or other conditions that are contraindications for interferon or ribavirin.
- 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.
- 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*.

Sovaldi undoubtedly would also help those with less severe complications by preventing the complications from becoming more severe. But this knowledge 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 points out that Sovaldi has a 90% cure rate and contends that it will do a better job of treating him than interferon, the drug he has been receiving. He also seeks to avoid an invasive biopsy before getting Sovaldi. And he wants Sovaldi before, not after, his hepatitis C causes significant damage. These are all valid medical points. But I must determine his eligibility according to whether he meets the criteria set by the department.

His provider, Redact, submitted answers to questions the Office of Inspector General raised after receiving the request. Mayo was instructed to provide a score or write “none” if appropriate if it had calculated a Metavir score concerning scarring of the petitioner’s liver. It answered “none.” In answer to another question, the provider stated that the petitioner did not have cirrhosis. He is not on a liver transplant waiting list, and he does not exhibit any serious manifestations of the hepatitis C virus outside of his liver. Because he 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 Sovaldi because he 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 9th day of April, 2015

\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 9, 2015.

Division of Health Care Access and Accountability