



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of



DECISION

MPA/173737

PRELIMINARY RECITALS

Pursuant to a petition filed April 18, 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 May 20, 2016, at New Richmond, 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:



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

FINDINGS OF FACT

- 1. The petitioner (CARES # [Redacted]) is a resident of St. Croix County.
2. The petitioner with Fairview Specialty Pharmacy requested a 12-week supply of Harvoni to treat his hepatitis C on March 14, 2016. The department denied his request on March 22, 2016.

3. The petitioner is a 55-year-old man diagnosed with hepatitis C and cirrhosis of the liver.
4. The petitioner is not on a liver transplant list.
5. The petitioner's physician indicated that the petitioner had a CT, ultrasound, or MRI performed on "February 29, 2014." The request did not include results from any such test and February 29, 2014, is not an actual date because 2014 was not a leap year.
6. The petitioner's CTP score, which determines the severity of cirrhosis, was calculated as A(6) on March 7, 2016. Scores in the A range—5-6—are considered the least serious level of liver disease and are in the compensated range. The department recalculated the score to 8, which indicates moderate liver disease and is in the decompensated range.
7. The petitioner's medical records do not indicate when he stopped drinking alcohol.

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 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 his 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 his prescription would cost \$113,400.

The petitioner and his 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 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.

It appears that the petitioner's claim rests upon whether he has compensated or decompensated liver disease. His prior authorization indicates that his CTP score, which determines the severity of cirrhosis, was calculated as A(6) on March 7, 2016. Scores in the A range—5-6—are considered the least serious level of liver disease and are in the compensated range. The department recalculated the score after reviewing his medical records and determined it was 8, which indicates moderate liver disease and is in the decompensated range. Because those with decompensated liver disease are not eligible for benefits, it denied the request.

The petitioner has the burden of proving that he is entitled to Harvoni by the preponderance of the credible evidence. I lack the medical knowledge to determine which side's argument is correct. It would have helped if the department had provided a better explanation of why it changed the score. It would have helped even more if the petitioner's doctor testified and explained why the petitioner met the criteria set by the department. In addition, if the petitioner's doctor had testified, it could have cleared up other confusing information in the request. For example, the request indicates that the petitioner has been sober for years, but it also indicates he quit drinking in the last year. Perhaps the term *sober* refers to his IV drug use, although this is not the commonly understood meaning of that term. The petitioner's doctor also indicated that the petitioner had a CT, ultrasound, or MRI performed on "February 29, 2014." The request did not include results from any such test and February 29, 2014, is not an actual date because 2014 was not a leap year. Based on the evidence before me, I must find that the petitioner has not met his burden of proof and uphold the department's denial.

CONCLUSIONS OF LAW

The department has correctly denied the petitioner's request for Harvoni because he has not shown by the preponderance of the 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 2nd day of June, 2016

\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 June 2, 2016.

Division of Health Care Access and Accountability