



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[Redacted]

DECISION

MPA/164283

PRELIMINARY RECITALS

Pursuant to a petition filed February 27, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Department of Health Services (DHS) in regard to Medical Assistance (MA), a telephonic hearing was held on March 24, 2015, at Milwaukee, Wisconsin. The record was held open 45 days at petitioner’s request so that he could submit additional information, which was received from his doctor, and which was forwarded to the DHCAA for review and comment.

The issue for determination is whether the petitioner is entitled to MA reimbursement for Harvoni.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[Redacted]

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Respondent:

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

By written submittal of: Lynn Radmer, 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:

Kelly Cochrane
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Milwaukee County.

2. On December 18, 2014, AMC Pharmacy requested prior authorization (PA) for 84 doses of Harvoni at the cost of \$90,682.20.
3. The Department of Health Services (DHS) denied the request on February 12, 2015.
4. The petitioner is diagnosed with hepatitis C, genotype 1a.
5. The petitioner has decompensated cirrhosis.

DISCUSSION

Federal MA rules allow, but do not require, states to pay for prescription drugs. See 42 C.F.R. §440.225. The Wisconsin MA program pays for some prescription drugs. Wis. Admin. Code §DHS 107.10. Non-preferred prescription drugs must receive PA as a condition of payment. *Id.*, 107.10(2)(d). 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 by the preponderance of the credible evidence that these standards are met.

The petitioner seeks payment from the MA program for Harvoni to treat his Hepatitis C. Harvoni is a non-preferred drug requiring PA when used to treat hepatitis C. As an aid to assure consistent PA request evaluation/approval for non-preferred, high-priced hepatitis C drugs, the agency's consultants prepared policy standards related to severity, which became effective in December 2014. Those published standards require that the patient's hepatitis C must have advanced to any of the following stages:

- Compensated cirrhosis
- Metavir score of F3 or greater or evidence of bridging fibrosis
- Hepatocellular carcinoma, if the s/he is on a liver transplant waiting list
- Serious extra-hepatic manifestations of HCV (hepatitis C virus).

ForwardHealth Update, 2014-74 (November 2014) available online at <https://www.forwardhealth.wi.gov/kw/pdf/2014-74.pdf>, and *ForwardHealth Online Handbook*, 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), Topic #17697 and *see also* Topic #17717, (viewed June 2015).

But regardless of the stage that the person's hepatitis has advanced to, 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. (emphasis added).

Harvoni may help those with less severe complications than those listed above, but this must be viewed in the context of the high cost of the drug, the need for the MA program to treat different people with

different 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 MA 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, as asserted by petitioner's provider.

As part of the PA process here, the agency requires that the provider answer the following questions: "Does the member have cirrhosis of the liver?", "If yes, is the cirrhosis compensated?" and "If yes, what was the member's most recent Child-Turcotte-Pugh Score?". See *Prior Authorization Drug Attachment for Hepatitis C Agents*, available online at <https://www.dhs.wisconsin.gov/forms/f0/f01247.pdf>. On the PA here, the petitioner's provider checked the boxes indicating that he has compensated cirrhosis and entered petitioner's score as "7+B". See Exhibit 1. The petitioner's provider points out that other drugs have failed to help petitioner, his condition is severe, and that cirrhosis is a dynamic state not to be considered a single stage evidenced by a CTP score. These are all valid medical points. But I must determine his eligibility according to whether he meets the criteria set by the agency. Because his records indicate he has decompensation, as evidenced by the CTP score currently standardized as decompensation, he does not meet the criteria set by the agency.

The agency here determined that the petitioner's cirrhosis was decompensated with the CPT score of 7, Class B, based on the American Association for the Study of Liver Diseases' (AASLD) definition that decompensation includes Class B. See, e.g., <http://www.hcvguidelines.org/full-report/unique-patient-populations-patients-decompensated-cirrhosis>. The agency also asserts that decompensation is further defined by the development of jaundice, ascites, and variceal hemorrhage. See Exhibit 2. The agency asserts that the petitioner's May 2014 CT scan showed early changes of ascites. Additionally, the agency provided further support for its current position in the last post-hearing exchange between the parties. See Radmer letter dated June 2, 2015, citing to <http://www.hepatitis.va.gov/pdf/2009cirrhosis-guidelines.pdf>; <http://www.hepatitis.va.gov/provider/tools/child-pugh-calculator.asp>. Moreover, because the producer of the drug and the FDA approved labeling for it indicate that safety and efficacy have not been established for persons with decompensated cirrhosis, the agency continues to maintain its position. See http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf (specifically at page 9). The position is reasonable and supported by evidence. Because the cirrhosis is considered decompensated, the agency correctly denied the PA request under the denial criteria set forth above.

I note that the Update states that "Harvoni is a non-preferred drug that is scheduled to be reviewed by the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee as part of the PDL review in summer 2015 in the hepatitis C drug class. Until the summer PDL review has occurred, PA criteria have been established for Harvoni." *ForwardHealth Update*, 2014-74. This statement indicates that another review may occur, which may change the criteria. Petitioner can always submit another PA if better evidence is available to show that he meets the criteria as it stands or if it changes.

This is not a decision I make lightly. I add, assuming petitioner finds this decision unfair, that it is the long-standing position of the Division of Hearings & Appeals that the Division's hearing examiners lack the authority to render a decision on equitable arguments. See, Wisconsin Socialist Workers 1976 Campaign Committee v. McCann, 433 F.Supp. 540, 545 (E.D. Wis.1977). This office must limit its review to the law as set forth in statutes, federal regulations, and administrative code provisions.

CONCLUSIONS OF LAW

The agency correctly denied the petitioner's request for Harvoni because he has not shown by the preponderance of the credible evidence that he meets the agency's guidelines required to receive the treatment.

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 Milwaukee,
Wisconsin, this 17th day of June, 2015

\sKelly Cochrane
Administrative Law Judge
Division of Hearings and Appeals



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The preceding decision was sent to the following parties on June 17, 2015.

Division of Health Care Access and Accountability