



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/173714

PRELIMINARY RECITALS

Pursuant to a petition filed April 15, 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 19, 2016, at Milwaukee, Wisconsin.

The issue for determination is whether the Department correctly denied a prior authorization request for a non-preferred prescription drug, Harvoni.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

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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:

Corinne Balter
Division of Hearings and Appeals

FINDINGS OF FACT

1. The petitioner is a resident of Milwaukee County. He has Hepatitis and is HIV positive.
2. On March 11, 2016 the petitioner's provider submitted a medical prior authorization request for Harvoni. The total cost for this drug is \$89,784.45.

3. On March 22, 2016 the Department sent the petitioner a notice stating that they denied his request for Harvoni.
4. On April 18, 2016 the Division of Hearings and Appeals received the petitioner's Request for Fair Hearing.
5. The petitioner is 52 years old. He is diagnosed with Hepatitis C. He is also HIV positive.
6. Currently, the petitioner's hepatitis C has not 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)
7. The petitioner has a few extra-hepatic manifestations of hepatitis C including severe thrombocytopenia, possible porphyria, and the possibility for cryoglobulinemia as the petitioner suffers from chronic kidney disease (CKD) stage 2. He also has a history of pancreatitis and diabetes.

DISCUSSION

Federal MA rules do not require a state to cover prescription drugs; such coverage is at state option. 42 C.F.R. § 440.225. The Wisconsin MA program opted to pay for some prescription drugs. Wis. Admin. Code § DHS 107.10. Non-preferred prescription drugs must receive prior authorization as a condition of payment. *Id.*, 107.10(2)(d). In evaluating a prior authorization 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 for consistent authorization request evaluation/approval for non-preferred, high-priced hepatitis C drugs, the Division'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 bridging fibrosis
- Serious extra-hepatic manifestations of hepatitis C virus (HCV)

ForwardHealth Update, 2014-74 (November 2014) 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, (viewed March 2015).

In this case the petitioner and his doctor argue that the petitioner has "serious extra-hepatic manifestations of hepatitis C virus (HCV)", and thus qualifies for the drug Harvoni. The petitioner and his doctor acknowledge that effective April 1, 2016 the guidelines changed, and these guidelines now define "serious extra-hepatic manifestations of hepatitis C virus (HCV), such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, symptomatic cryoglobulinemia, or porphyria cutanea tarda (laboratory – confirmed diagnosis). *ForwardHealth Update*, 2016-14. The petitioner and his doctor argue that "serious" was not defined prior to this update, and that this PA request was submitted prior to April 1, 2016. Therefore, the old guidelines apply, and that petitioner's extra-hepatic manifestations are serious because these conditions are "serious enough to affect [the petitioner's] quality of life."

I agree with the petitioner and his doctor that serious was not defined prior to April 1, 2016. However, this does not allow the petitioner to create his own definition of the term. The petitioner's definition of "serious enough to affect [a person's] quality of life" could include nearly everyone with extra-hepatic manifestations of HCV. These manifestations are relatively common in patients with HCV.

The petitioner further argues that he could have porphyria cutanea tarda. The Department highlights that there is no diagnosis of this. They point to a March 9, 2016 dermatology consult note that favors follicular eczema, rather than a diagnosis of porphyria cutanea tarda. The petitioner's doctor argued that he would have to do a biopsy for a confirmed diagnosis. This does not appear to refer to porphyria cutanea tarda as the preferred screening test for this disease is a measurement of porphyrins in plasma. *American Porphyria Foundation*, <http://www.porphyrifoundation.com/about-porphyrin/types-of-porphyrin/PCT> (last viewed June 2016).

The petitioner's most convincing argument is that he suffers from cryoglobulinemia, and that diagnosis is impossible because it requires a biopsy, which cannot be done due to the petitioner's medical condition. This argument was not well developed. The petitioner's medical records also do not appear to support this argument. For example, a March 3, 2016 medical record states, "in term of hep C, [the petitioner's] only option would be Harvoni for 12 weeks, but unfortunately this is not an option yet for him considering current restrictive Medicaid guideline." His doctor goes on to note "possibility for cryoglobulinemia as patient as CKD stage 2." There is no note stating that diagnosis is impossible due to the impossibility of a biopsy. In addition, the petitioner presents no medical literature showing what is required for a diagnosis of cryoglobulinemia. Is a biopsy done in conjunction with other tests? If so, what other tests are required? What are the results of these tests for the petitioner? Is there medical literature supporting that a biopsy should not be performed on a patients like the petitioner who are in renal failure?

The burden of proof is on the petitioner by a preponderance of the evidence. This is a difficult denial of Harvoni as the petitioner is precluded from taking many Hepatitis C drugs due to his HIV medication and history of pancreatitis. However, at this point, he does not have compensated cirrhosis, his metavir score is F0-F1, and he has failed to demonstrate that he has serious extra-hepatic manifestations of HCV. If the petitioner believes that he can demonstrate that he has cryoglobulinemia, but that a diagnosis is impossible, or if his HCV worsens to a point where he meets the MA approval guidelines for Harvoni, his provider may file a new prior authorization request.

CONCLUSIONS OF LAW

The Department correctly denied a prior authorization request for a non-preferred prescription drug, Harvoni.

THEREFORE, it is

ORDERED

That the petition 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 23rd day of June, 2016

\sCorinne Balter
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 23, 2016.

Division of Health Care Access and Accountability