FH

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

Redact

DECISION

MPA/163142

PRELIMINARY RECITALS

Pursuant to a petition filed January 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 (DHCAA) in regard to Medical Assistance, a telephonic hearing was held on February 27, 2015, at Madison, Wisconsin.

The issue for determination is whether the Division 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:

Redact

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703
By: Redact, RPh., pharmacy consultant
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:
Gary M. Wolkstein
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Dane County who is certified for MA or BadgerCare Plus.

2. On December 5, 2014, a prior authorization request was submitted on the petitioner's behalf for Harvoni by Redact, a non-preferred prescription drug. The cost is listed as $113,420 for 84 tablets.

3. The Division issued to the petitioner written notice of denial of that request on December 16, 2014.

4. The Division's basis for denial is that the petitioner's condition does not meet the severity standards that the Division has set as a condition for approval.

5. The petitioner, age 59, has diagnoses of chronic hepatitis C with associated inflammatory arthritis and cutaneous vasculitis.

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
   - Hepatocellular carcinoma, if the s/he is on a liver transplant waiting list
   - Serious extra-hepatic manifestations of hepatitis C virus (HCV)

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
- Hepatocellular carcinoma, if the s/he is on a liver transplant waiting list
- 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 , Topic #17697, (viewed March 2015). The Wisconsin MA program does cover prescription Interferon (brand names Pegasys and Peg-Intron Redipen) for hepatitis C treatment. *Id.*, *Preferred Drug List-Quick Reference*. I conclude that the above policy is reasonable.

There is no dispute that the petitioner's condition has not deteriorated to the levels identified in the above policy. He does not have cirrhosis of the liver, and his Metavir score is F1. The petitioner is not on a liver transplant waiting list, and the prescriber did not identify serious extra-hepatic manifestations of the hepatitis C virus.

The petitioner is not currently on medication to treat his hepatitis C. The petitioner's testimony did not identify current hepatitis C symptoms or other physical problems. However, he would prefer to be proactive regarding his health, and obtain this new medication to prevent future complications.

The petitioner has not established that he meets the program's authorization requirements for Harvoni. The Division's position is not unreasonable, and it is therefore sustained.

CONCLUSIONS OF LAW

1. The requested non-preferred prescription drug Harvoni is not a medical necessity, nor is it the most appropriate or cost effective method of treating the petitioner's condition at this time.

2. The Division correctly denied the prior authorization request for Harvoni.

THEREFORE, it is **ORDERED**

The petition for review herein be and the same is hereby 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 30th day of March, 2015

\sGary M. Wolkstein
Administrative Law Judge
Division of Hearings and Appeals

State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator
Suite 201
5005 University Avenue
Madison, WI 53705-5400

Telephone: (608) 266-3096
FAX: (608) 264-9885
email: DHAmail@wisconsin.gov
Internet: http://dha.state.wi.us

The preceding decision was sent to the following parties on March 30, 2015.

Division of Health Care Access and Accountability