



STATE OF WISCONSIN  
Division of Hearings and Appeals

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In the Matter of

[REDACTED]

DECISION

MPA/142875

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**PRELIMINARY RECITALS**

Pursuant to a petition filed August 04, 2012, 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 telephone hearing was held on September 18, 2012, at Waupaca, Wisconsin.

The issue for determination is whether the Division of Health Care Access and Accountability erred when it denied petitioner's request for prior authorization for Humira® (adalimumab) because it is an experimental treatment for uveitis.

There appeared at that time and place the following persons:

**PARTIES IN INTEREST:**

Petitioner:

[REDACTED]

Petitioner's representative:

[REDACTED]

Respondent:

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

By: 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:**

Peter McCombs  
Division of Hearings and Appeals

**FINDINGS OF FACT**

1. Petitioner (CARES # [REDACTED]) is a resident of Waupaca County who receives MA.

2. Petitioner is diagnosed with chronic bilateral anterior uveitis. This condition involves the eyes and can affect vision. Humira® is intended to control inflammation in her eyes. Petitioner presently receives Remicade® (infliximab) intravenous infusions to control the inflammation in her eyes.
3. On or about May 17, 2012, the Pamida Pharmacy requested prior authorization on behalf of the petitioner for approval of Humira®, 40 mg every two weeks, for the treatment of her uveitis at a cost of about \$2,200.00 per month.
4. Humira® (adalimumab) belongs to a PDL class of drugs called Cytokine and Cell-Adhesion Molecule (CAM) Antagonists. Drugs in this PDL class require prior authorization since this is a class of drugs that entails utilization problems, and these drugs are powerful biologic disease modifying drugs that carry significant warnings regarding potential side effects.
5. Humira® is not Food and Drug Administration (FDA) approved for the treatment of uveitis.
6. Humira® has only been approved for the treatment of six different medical conditions; and uveitis is not one of those six conditions.
7. By a letter dated July 3, 2012, the Division of Health Care Access and Accountability (DHCAA) denied the petitioner's PA request for approval of Humira® as a treatment for uveitis because that service was determined experimental pursuant to §DHS 107.035.
8. DHCAA pharmacy consultant, Lynn Radmer, R.Ph., sent detailed correspondence, dated August 22, 2012, to DHA and petitioner's representative with documentation explaining the factual and legal basis for the denial of petitioner's PA request for the use of Humira® to treat petitioner's uveitis.

### DISCUSSION

Under Wis. Adm. Code, §DHS 107.035, certain services are excluded from MA coverage if, after a departmental review, they are determined to be experimental. Wis. Adm. Code, §DHS 107.03(4), provides that services considered experimental are not covered services. The respondent has determined that Humira® is not a proven and effective treatment for uveitis, and notes that the pharmaceutical company that makes Humira® is presently conducting studies in this regard. Those studies have not been completed however, and therefore, no conclusions can yet be drawn regarding the drug's efficacy in treating uveitis generally.

The petitioner was represented at hearing by [REDACTED] who is to be commended for her strong advocacy on behalf of the petitioner. Her arguments addressed (1) the fact that petitioner has received prior approval (2010) from the respondent for the administration of infliximab therapy; (2) Humira® would be very cost effective as compared to infliximab, since Humira® does not require that petitioner undergo regular infusions overseen by trained medical staff; and (3) petitioner's physician, Calvin B. Williams, has successfully transitioned a number of patients from infliximab to Humira®.

While I certainly empathize with the petitioner, and find her representative's arguments potentially persuasive, I cannot conclude that they demonstrate that the respondent erred in denying the PA request for Humira®. The petitioner argues that, since infliximab has been approved for petitioner by the respondent, and infliximab is a tumor necrosis factor-alpha inhibitor similar to adalimumab (Humira®), then Humira® should logically be acceptable. However, the respondent points out that, while infliximab and Humira® may be similar, the Department does not have a PA requirement in place for infliximab. See, Exhibit 3. While prior authorization of a similar drug is relevant, I do not find that the Department is bound by previous prior authorization approvals when making a new prior authorization determination.

The petitioner also argues that Humira® would be cost-effective, as petitioner's use of Humira® would remove the necessity of regular infusions that she currently receives at Children's Hospital. Additionally, petitioner's provider submitted written testimony asserting that he (Dr. Calvin Williams) has successfully transitioned several patients from infliximab to Humira®. Unfortunately, neither of these two lines of argument serves to sufficiently undermine the determination by the respondent that the use of Humira® in the treatment of uveitis remains experimental.

In this same vein, Ms. Radmer reviewed the medical articles submitted on the petitioner's behalf. She concluded that Humira® in the treatment of uveitis is a "potentially promising area of treatment," but also concluded that "at this time the efficacy, safety, patient selection, when to initiate treatment, when to stop treatment, and correct dose to use in treatment are still being studied." See, Exhibit 3. As noted above, Ms. Radmer addressed the fact that the pharmaceutical company that makes Humira® is conducting clinical studies with the United States National Institute of Health. However, no conclusions have yet been published.

I see no authority for the Division of Hearings and Appeals to reverse the department's conclusion that the use of Humira® to treat uveitis is experimental. Nothing in §DHS 107.035 suggests that the department's conclusion is appealable. The Wisconsin Administrative Code makes clear that if a service is determined to be experimental, it is not covered by MA. I must conclude that the use of Humira® to treat uveitis is at this time an experimental service, and thus I must conclude that the respondent did not err in determining that it is not covered by MA.

This result only makes sense. The Division of Hearings and Appeals (DHA) does not have the expertise to review medical treatises and other such documentation to determine whether the department's review and determination were correct. It is up to the medical community to convince the department that the drug Humira® should be removed from the "experimental" designation in the treatment of uveitis.

### **CONCLUSIONS OF LAW**

The Division correctly denied the petitioner's prior authorization (PA) request for approval of the prescription drug Humira® based upon its determination that Humira® is an experimental treatment for Uveitis and thus is not a covered service.

**THEREFORE, it is**

**ORDERED**

The petition for review is hereby dismissed.

### **REQUEST FOR A REHEARING**

This is a final administrative decision. If you think this decision is based on a serious mistake in the facts or the law, you may request a rehearing. You may also ask for a rehearing if you have found new evidence which would change the decision. Your request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and tell why you did not have it at your first hearing. If you do not explain these things, your request will have to be denied.

To ask for a rehearing, send a written request to the Division of Hearings and Appeals, P.O. Box 7875, Madison, WI 53707-7875. Send a copy of your request to the other people named in this decision as "PARTIES IN INTEREST." Your request for a rehearing must be received no later than 20 days after the date of the decision. Late requests cannot be granted.

The process for asking for a rehearing is in Wis. Stat. § 227.49. A copy of the statutes can be found 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 appropriate court no more than 30 days after the date of this hearing decision (or 30 days after a denial of rehearing, if you ask for one).

For purposes of appeal to circuit court, the Respondent in this matter is the Department of Health Services. After filing the appeal with the appropriate court, it must be served on the Secretary of that Department, either personally or by certified mail. The address of the Department is: 1 West Wilson Street, Room 651, Madison, Wisconsin 53703. A copy should also be sent to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400.

The appeal must also be served on the other "PARTIES IN INTEREST" named in this decision. The process for appeals to the Circuit Court is in Wis. Stat. §§ 227.52 and 227.53.

Given under my hand at the City of Madison,  
Wisconsin, this 21st day of September, 2012

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Peter McCombs  
Administrative Law Judge  
Division of Hearings and Appeals

c: Division of Health Care Access And Accountability - email  
Department of Health Services - email



**State of Wisconsin \DIVISION OF HEARINGS AND APPEALS**

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The preceding decision was sent to the following parties on September 21, 2012.

Division of Health Care Access And Accountability