



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/155813

PRELIMINARY RECITALS

Pursuant to a petition filed February 26, 2014, 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 (MA), a telephonic hearing was held on April 7, 2014.

The issue for determination is whether the Division correctly denied the petitioner's prior authorization (PA) request for approval of the prescription drug Humira to treat Hidradenitis Suppurativa.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]
[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 is a 51 year old resident of Outagamie County who receives MA.

2. Petitioner is diagnosed with Hidradenitis Suppurativa, a painful disease that causes nodules under the skin.
3. On or about December 20, 2013, Diplomat Pharmacy requested prior authorization (no. [REDACTED]) on behalf of the petitioner for approval of the drug, Humira for the treatment of his Hidradenitis Suppurativa at a cost of \$2,814.00 per month.
4. Humira (Adalimumab) belongs to a PDL class of drugs called Cytokine and Cell-Adhesion Molecule (CAM) Antagonists. All drugs in this PDL class require prior authorization since this is a class of drugs that entail utilization problems, and 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 Hidradenitis Suppurativa.
6. Humira has only been approved for the treatment of seven different medical conditions; Hidradenitis Suppurativa is not one of those conditions.
7. The record presents no definitive peer-reviewed medical literature to demonstrate the safety and effectiveness of Humira in the treatment of Hidradenitis Suppurativa.
8. By a letter dated February 3, 2014, the Division of Health Care Access and Accountability (DHCAA) denied the petitioner's PA request for approval of Humira as a treatment for Hidradenitis Suppurativa because that is not identified as a clinical condition that cytokine and CAM antagonist drugs are approved to treat.

DISCUSSION

The Division may only reimburse providers for medically necessary and appropriate health care services and equipment listed in Wis. Stat. §§ 49.46(2) and 49.47(6)(a), as implemented by Wis. Adm. Code § DHS 107. Some services and equipment are covered if a prior authorization request is submitted and approved by the Division in advance of receiving the service.

In determining whether to grant prior authorization for services or equipment, the Division must always follow the general guidelines in Wis. Adm. Code § DHS 107.02(3)(e). That subsection provides that the Division, in reviewing prior authorization requests, must consider the following factors:

1. The medical necessity of the service;
2. The appropriateness of the service;
3. The cost of the service;
4. The frequency of furnishing the service;
5. The quality and timeliness of the service;
6. The extent to which less expensive alternative services are available;
7. The effective and appropriate use of available services;
8. The misutilization practices of providers and recipients;
9. The limitations imposed by pertinent federal or state statutes, rules, regulations or interpretations, including medicare, or private insurance guidelines;
10. The need to ensure that there is closer professional scrutiny for care which is of unacceptable quality;
11. The flagrant or continuing disregard of established state and federal policies, standards, fees or procedures; and
12. The professional acceptability of unproven or experimental care, as determined by consultants to the department.

"Medical necessity" is defined in the Wis. Adm. Code § DHS 101.03(96m) as follows:

"Medically necessary" means a medical assistance service under ch. DHS 107 that is:

(a) Required to prevent, identify or treat a recipient's illness, injury or disability; and

(b) Meets the following standards:

1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
3. Is appropriate with regard to generally accepted standards of medical practice;
4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;
6. Is not duplicative with respect to other services being provided to the recipient;
7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
8. With 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; and
9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient. (Emphasis added.)

The petitioner seeks prior authorization for Humira to treat Hidradenitis Suppurativa. His request is supported by his treating physician, who notes that it, unlike other drugs and therapies he has tried, Humira has alleviated his symptoms well. The respondent denied this request because Hidradenitis Suppurativa is not specifically listed as one of the uses of the drug.

Petitioner's treating physician does not contest that conclusion, but instead argues that Hidradenitis Suppurativa is a rather rare disease, and therefore is receiving only very limited funding for the needed research to complete the necessary clinical trials to obtain for FDA approval for the use of Humira to treat Hidradenitis Suppurativa. It should be noted that petitioner's physician is commended as a strong advocate for his patient, and he credibly explained that Humira presents the best option for petitioner, as he noted that petitioner has responded well to this medication.

On behalf of the respondent, its pharmacy practices consultant reviewed all the medical articles sent to her by petitioner's physician. See, Exhibit 3. She concluded that while Humira in the treatment of Hidradenitis Suppurativa is a potential new area of treatment, "...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." *Id.* She notes that there are two phase III trials studying the efficacy of adalimumab in the treatment of Hidradenitis Suppurativa. Unfortunately, based upon the evidence in the record I am unable to conclude that the respondent has erred in denying coverage of Humira *at this time* based upon its determination that Humira is not a proven and effective treatment for Hidradenitis Suppurativa.

Humira has only been approved for the treatment of seven different medical conditions: Ankylosing Spondylitis, Crohn's Disease, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Polyarticular Juvenile Rheumatoid Arthritis, and Ulcerative Colitis. Petitioner's physician testified that a case could be

made for a diagnosis of rheumatoid arthritis or Ankylosing Spondylitis in petitioner. However, the record does not disclose that such diagnoses yet exist. The PA request did not identify any such diagnoses, either.

The Division of Hearings and Appeals 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 Hidradenitis Suppurativa should be added to the list of conditions that Humira is approved to treat. While I do not doubt that petitioner has responded positively to the use of Humira, I note to petitioner that I have no equitable powers that would allow me to consider the fairness of the situation and must apply the law as it is written. Therefore, I must find that the respondent correctly denied coverage of Humira for the treatment of Hidradenitis Suppurativa.

CONCLUSIONS OF LAW

The Division correctly denied the petitioner's prior authorization (PA) request for approval of the prescription drug, Humira because Humira has not been approved for the treatment of Hidradenitis Suppurativa.

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 29th day of May, 2014.

\sPeter McCombs
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 May 29, 2014.

iCare
Division of Health Care Access and Accountability



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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