



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/155700

PRELIMINARY RECITALS

Pursuant to a petition filed February 20, 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 (Division or DHCAA) in regard to Medical Assistance (MA)/BadgerCare Plus, a hearing was held on April 8, 2014.

The issue for determination is whether the Division correctly denied a prior authorization request for Marinol capsules, which contain a synthetic component of marijuana.

There appeared at that time the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

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

By written submission 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:

Nancy J. Gagnon
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Brown County. She is certified for MA.

2. On February 4, 2014, a prior authorization request was submitted on the petitioner's behalf for Marinol 2.5 mg capsules. The Division issued a written denial of that request on February 6, 2014.
3. The Division's basis for denial was that this drug, which requires prior authorization from the Division, did not meet the Division's policy for approval. Specifically, the petitioner does not have any of the clinical conditions for which the FDA has approved the use of this drug as treatment.
4. Marinol must receive prior authorization from the Division as a condition of MA payment. It is in a class of drugs called Antiemetics, Cannabinoids. This class of drugs receives special scrutiny because it "entail[s] utilization problems for the program." Marinol is the brand name of a drug with the active ingredient dronabinol. It is a synthetic delta-9-tetrahydrocannabinol (delta-9-THC); delta-9-THC is a naturally occurring component of marijuana.
5. The Division's authorization criteria for Marinol use are a paraphrasing of the Food and Drug Administration's (FDA) approved indications for the drug, as well as the drug manufacturer's product literature. Those documents identify the two approved uses for Marinol as being for:
 - (1) Treatment for weight loss or cachexia caused by HIV or AIDS, or
 - (2) Nausea/vomiting associated with cancer chemotherapy in patients who have not responded to conventional antiemetic treatments.
6. The petitioner, age 33, does not have HIV or AIDS, and is not undergoing cancer chemotherapy. She has a diagnosis of Complex Regional Pain Syndrome (CRPS) Type 2. Approximately two years ago, the petitioner injured her left wrist and arm, including nerve damage. She underwent surgery for repair, but continues to suffer great pain. She has tried a variety of painkillers, but they did not provide adequate relief; she is allergic to gabapentin. A physician at the Mayo Clinic prescribed Marinol for the petitioner, even though it is an "off-label" use of this medication. The cost of a one year supply (4 capsules daily) of this prescription is \$16,079.88.

DISCUSSION

Medically necessary prescription drugs can be an MA-covered service, and many are subject to prior authorization. Wis. Admin. Code §DHS 107.10(1),(2)(d). Marinol is subject to prior authorization, because the Division has determined that it entails utilization problems for the MA program.

State code only allows for MA coverage of a drug if it is medically necessary and appropriate for a given condition. Wis. Admin. Code §DHS 107.02(3)(e). A drug is not medically necessary or appropriate if its use for a given condition is "experimental in nature." *Id.*, §DHS 107.03(4). A treatment is "experimental in nature" if it is not "a proven and effective treatment for which it is intended or used. ... [The Department looks at] the current and historical judgment of the medical community as evidenced by medical research, studies, journal or treatises; *Id.*, §107.035.

The Department has determined that there are only two sets of patients for whom use of Dronabinol is not experimental: (1) HIV/AIDS patients with anorexia, or (2) cancer patients experiencing nausea/vomiting associated with chemotherapy, and which has not responded adequately to conventional antiemetic treatments. The Department has shared this determination in a policy document, *ForwardHealth Update*, No. 2009-77 and again in No. 2013-35.

The Department's policy determination relied upon the U.S. Food and Drug Administration's (FDA) determination that the only two indications for use of Dronabinol are those in the paragraph above. The petitioner concedes that she does not have either of those two conditions. This Judge reviewed the package insert from Marinol's manufacturer, Unimed Pharmaceuticals. The insert contains the same

limitations for use as the FDA instructions. It makes no mention of recommended use for treatment of CRPS.

The petitioner provided several articles pertaining to CRPS. There is no doubt that she has this condition and that it is severe. She also provided articles discussing medical use of cannabis. I adopt the discussion from the Division's March 24, 2014 letter with respect to these articles. *See*, Exhibit 1, pp. 4-5.

I find the Division's position in this case to be reasonable and consistent with state code.

CONCLUSIONS OF LAW

1. MA coverage of Dronabinol/Marinol is not permissible, medically necessary or appropriate for treatment of a patient with the petitioner's diagnosis.

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 Madison,
Wisconsin, this 25th day of April, 2014

\sNancy J. Gagnon
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 April 25, 2014.

Division of Health Care Access and Accountability