



**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

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

DECISION

MPA/163822

PRELIMINARY RECITALS

Pursuant to a petition filed February 06, 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 (MA), a telephonic hearing was held on April 28, 2015.

The issues for determination are 1) whether petitioner is eligible for payment by the MA program for Cytra-K and 2) whether there is jurisdiction to consider petitioner’s prior authorization (PA) request for Cystagon.

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 written submittal 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:

Kelly Cochrane
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Waukesha County.
2. On September 17, 2014 petitioner's pharmacy submitted a prior authorization (PA) request to the DHCAA on petitioner's behalf requesting approval of the drug Cystagon.
3. On September 22, 2014 the DHCAA returned the PA to the pharmacy requesting additional information.
4. On October 22, 2014 the DHCAA inactivated the PA request because the pharmacy did not provide the requested information.
5. On March 3, 2015, the petitioner's pharmacy submitted a PA request for the drug Cytra-K.
6. On April 16, 2015, the DHCAA denied the PA for the drug Cytra-K as a noncovered service because it is considered a "less than effective drug" pursuant to the FDA's designation of this drug as a DESI-5.

DISCUSSION

1. Cytra-K

The DHCAA 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. Admin. Code ch. DHS 107. Some services and equipment are covered if a prior authorization request is submitted and approved in advance of receiving the service. Some services and equipment are never covered by the MA program. In this case petitioner is seeking PA approval for the drug Cytra-K. Thus, the question becomes whether or not Cytra-K is a drug that is covered under the MA program.

The pertinent MA rule provides:

HFS 107.10 Drugs. (1) COVERED SERVICES. Drugs and drug products covered by MA include legend and non-legend drugs and supplies listed in the Wisconsin medicaid drug index which are prescribed by a physician ...

(4) NON-COVERED SERVICES. The department may create a list of drugs or drug categories to be excluded from coverage, known as the medicaid negative drug list. These non-covered drugs may include drugs determined "less than effective" by the U.S. food and drug administration (FDA), drugs not covered by [42 USC 1396r-8](#), drugs restricted under [42 USC 1396r-8](#) (d) (2) and experimental or other drugs which have no medically accepted indications.

Wis. Admin. Code §HFS 107.10(1),(4).

The DHCAA asserts that the requested drug is not covered by MA because of its status pursuant to the FDA's "Drug Efficacy Study Implementation" (DESI). In this case, Cytra-K is considered a "less than effective drug" pursuant to the FDA's designation of this drug as a DESI-5. Such a classification renders the drug as "less than effective for all indications." The DHCAA denied the PA because of this designation from the FDA. It did so according to the rule cited above, as well as policy which states that reimbursement is not available from Wisconsin Medicaid for less-than-effective drugs. See *MA Handbook*, Topic #2319, available [online](#) at [at](#)

<https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=5&c=63>.

Because the requested drug is non-covered by MA, the DHCAA correctly denied payment here.

2. Cystagon

If PA is requested it is the provider's responsibility to justify the need for the service. Wis. Admin. Code §DHS 107.02(3)(d)6. The rationale for requiring prior authorizations is as follows:

1. To safeguard against unnecessary or inappropriate care and services;
2. To safeguard against excess payments;
3. To assess the quality and timeliness of services;
4. To determine if less expensive alternative care, services or supplies are usable;
5. To promote the most effective and appropriate use of available services and facilities;
6. To curtail misutilization practices of providers and recipients.

See Wis. Adm. Code §DHS 107.02(3)(b). The Department requires that, at a minimum, a PA request contain the following:

1. The name, address and MA number of the recipient for whom the service or item is requested;
2. The name and provider number of the provider who will perform the service requested;
3. The person or provider requesting prior authorization;
4. The attending physician's or dentist's diagnosis including, where applicable, the degree of impairment;
5. A description of the service being requested, including the procedure code, the amount of time involved, and dollar amount where appropriate; and
6. Justification for the provision of the service.

See Wis. Adm. Code §DHS 107.02(3)(d).

In determining whether to approve or disapprove a request for prior authorization, the Division is required to consider the following criteria found at Wis. Adm. Code §107.02(3)(e):

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.

“Medically necessary” is defined in the administrative code as any MA service under chapter DHS 107 that is required to prevent, identify or treat a recipient's illness, injury or disability. Wis. Adm. Code §DHS 101.03(96m)(a).

In addition, providers are responsible for submitting truthful, accurate, complete, legible and concise documentation to support a prior authorization request. Wis. Adm. Code §DHS 106.02(9)(e). Specifically, the Code states:

Each provider is solely responsible for the truthfulness, accuracy, timeliness and completeness of claims, cost reports, prior authorization requests and any supplementary information relating to the provider's MA certification or reimbursement for services submitted to MA or to medicare or any other third party payer for claims or requests for MA recipients, whether or not these claims, reports and requests are submitted on paper or in electronic form. This includes but is not limited to the truthfulness, accuracy, timeliness and completeness of the documentation necessary to support each claim, cost report and prior authorization request. The use or consent to use of a service, system or process for the preparation and submission of claims, cost reports or prior authorization requests, whether in electronic form or on paper, does not in any way relieve a provider from sole responsibility for the truthfulness, accuracy, timeliness and completeness of claims, cost reports, prior authorization requests and any supplementary information relating to the provider's MA certification and claims for reimbursement for services submitted to MA or to medicare or any other third party payer in the case of claims, reports or requests for MA recipients. The provider is responsible whether or not the provider is charged for the services, systems or processes and whether or not the department or its fiscal agent consents to the electronic preparation and submission of claims, cost reports, prior authorization requests and any supplementary information relating to the provider's MA certification and claims for reimbursement for services.

Wis. Adm. Code §DHS 106.02(9)(e)1. The DHCAA is not allowed to reimburse for services or equipment unless the documentation requirements are satisfied. Wis. Adm. Code §DHS 106.02(9)(f).

In this case, the DHCAA received an incomplete PA for Cystagon on September 17, 2014. The DHCAA returned the PA to the provider on September 22 requesting that it complete the PA and include the National Drug Code for the requested drug as well as a written description of the petitioner's diagnosis. It advised the provider that if the corrected information within 30 days that the PA would be inactivated and therefore a new PA would be needed after that time. The provider did not return that information and therefore the PA was inactivated. Because no complete PA was provided to the DHCAA to approve, deny or modify, there was no denial of benefits, and therefore no appeal rights. Therefore, there is no jurisdiction conferred to me under this action. See Wis. Adm. Code §§HA 3.03, 3.04.

Petitioner's provider may submit another PA request; however, it must comply with the requirements that the request is complete in order to determine if the service may be covered.

I add, assuming petitioner finds this decision unfair, that it is the long-standing position of the Division of Hearings & Appeals that the Division's hearing examiners lack the authority to render a decision on equitable arguments. See, Wisconsin Socialist Workers 1976 Campaign Committee v. McCann, 433 F.Supp. 540, 545 (E.D. Wis.1977). This office must limit its review to the law as set forth in statutes, federal regulations, and administrative code provisions.

CONCLUSIONS OF LAW

1. The petitioner is not eligible for payment by the MA program for Cytra-K as it is considered a “less than effective drug” pursuant to the FDA’s designation of this drug as a DESI-5; and
2. There is no jurisdiction to consider petitioner’s prior authorization request for Cystagon as no PA was completed for which the DHCAA to deny or modify.

THEREFORE, it is**ORDERED**

The petition for review herein 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 19th day of May, 2015

\sKelly Cochrane
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 19, 2015.

Division of Health Care Access and Accountability