



FH
[REDACTED]

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]

DECISION

FCP/143843

PRELIMINARY RECITALS

Pursuant to a petition filed September 15, 2012, under Wis. Admin. Code § DHS 10.55, to review a decision by the Jefferson County Department of Human Services in regard to Medical Assistance, a telephonic hearing was held on October 30, 2012, at Jefferson, Wisconsin. At the request of the parties, the record was held open for 60 days for consecutive written closing argument with documentation to be submitted to the Division of Hearings and Appeals.

The issue for determination is whether the Family Care Program correctly denied the petitioner's request for payment for the over the counter brand name supplement, Isotonix.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]

Respondent:

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

By: Nancy Blodgett, RN nurse manger
Care Wisconsin, Inc.
2802 International Lane
P.O. Box 14017
Madison, WI 53708-0017

ADMINISTRATIVE LAW JUDGE:

Gary M. Wolkstein
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES # [REDACTED]) is a resident of Jefferson County who is enrolled in the Family Care Program (FCP).
2. The petitioner is diagnosed with the following medical conditions: asthma, arthralgia, degenerative disc disease, heart failure, diabetes, diabetic neuropathy, mitral valve insufficiency, pulmonary hypertension, osteoarthritis, depression, anxiety, and morbid obesity.
3. Isotonix is a brand name “nutraceutical” by Market America that offers various supplements and enzymes. The petitioner has been paying with her own funds for the Isotonix brand name supplements
4. On March 18, 2012 and again on June 5, 2012, the petitioner requested that the Family Care Program agency, Care Wisconsin, pay for the over the counter vitamin supplement, Isotonix.
5. Care Wisconsin sent a June 8, 2012 Notice of Action to the petitioner denying the request for payment for Isotonix supplements. See Exhibit 1. The reasons for the denial of petitioner’s request for Isotonix supplements as not a covered FCP services are the following: a) Isotonix supplements do not have a valid National Drug Code (NDC) as an over the counter supplement; b) the statements Isotonix makes about effectiveness of its products have not be evaluated by the FDA; c) there are not evidence based studies to validate that Isotonix supplements are effective or safe; and d) Isotonix does not meet some of the approval criteria for MA Over the Counter Guidelines.
6. Care Wisconsin offered to work with petitioner’s health care team and NP Mary Beck Metzger suggested prescribing for the petitioner the following as an approved alternatives to Isotonix: generic CO-enzyme Q 10 Qd, fish oil 1,000 mg TID, and Pyenogenol 300 mg qd. Those supplements all have NDC codes.
7. The petitioner was unable to provide any letter from a primary physician or other health professional that would confirm or clinically document the medical necessity of the brand name supplement, Isotonix.
8. The petitioner reported to her Care Wisconsin team that she had no interest in taking other generic alternatives (as stated in Finding of Fact #6 above), and only wants to continue taking Isotonic specific brand supplements. See December 6, 2012 Care Wisconsin written closing argument.
9. The petitioner does feel better and is functioning better while taking Isotonix supplements.
10. Care Wisconsin sent an August 21, 2012 letter to the petitioner stating that the grievance and appeals committee decided after petitioner’s August 20, 2012 hearing that the June 8, 2012 denial of petitioner’s request for Isotonix should be upheld.

DISCUSSION

The Family Care program, which is supervised by the Department of Health Services, is designed to provide appropriate long-term care services for elderly or disabled adults. Whenever the local Family Care program decides that a person is ineligible for the program, or when the CMO denies a requested service, the client is allowed to file a local grievance. The petitioner did apparently file a local grievance, per Wis. Admin. Code §DHS 10.53, and the original service denial was upheld in that review. The petitioner then appropriately sought a fair hearing for a further, *de novo* review of the denial decision.

The Family Care Program (FCP) correctly denied the petitioner's request for the over the counter supplement Isotonix for the reasons set forth in Finding of Fact #5 - #8 above. The state code language on the scope of permissible services for the FC reads as follows:

DHS 10.41 Family Care services . . .

(2) SERVICES. Services provided under the family care benefit shall be determined through individual assessment of enrollee needs and values and detailed in an individual service plan unique to each enrollee. As appropriate to its target population and as specified in the department's contract, each CMO shall have available at least the services and support items covered under the home and community-based waivers under 42 USC 1396n(c) and ss.46.275, 46.277 and 46.278, Stat., the long-term support services and support items under the state's plan for medical assistance. In addition, a **CMO may provide other services that substitute** for or augment the specified services if these services are **cost-effective** and meet the needs of enrollees as identified through the individual assessment and service plan.

Wis. Admin. Code §DHS 10.41(2)

The medical assistance program requires prior authorization for nutritional supplements such as Isotonix. *See*, Wis. Adm. Code § DHS 107.10(2)(c). It does not cover “[e]nteral nutritional products that do not meet the criteria established by the department under sub.(2)(c) to verify medical need, when an alternative nutrition is available, or that are solely for the convenience of the caregiver or the recipient.” Wis. Adm. Code § DHS 107.10(4)(t). Like any service, a request for an enteral product must meet the generic medical assistance prior authorization criteria including, among other things, the medical necessity, appropriateness, and cost of the service; the extent to which less expensive alternative services are available; and whether the service is an effective and appropriate use of available services. Wis. Adm. Code, § DHS 107.02(3)(e)1.,2.,3.,6. and 7. “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. HFS 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.

During the October 30, 2012 hearing and in her written closing argument, the petitioner argued without any clinical evidence that only the brand name supplement could support the improvement that she has experienced. While Care Wisconsin agrees that some of petitioner's functioning has improved, petitioner was unable to provide any medical documentation to establish that no generic, non-brand name alternatives could provide the nutritional support that has helped the petitioner to improve her functioning. Furthermore, petitioner was unable to submit any letter from a doctor or other health professional that supported Isotonix as medically necessary and the only over the counter supplement that could help the petitioner. See Finding of Fact #6 - #8 above. Finally, petitioner was unable to refute that Isotonix is not FDA approved to address any safety or health concerns.

While I am sympathetic to the general argument of supporting greater independence or functioning for Family Care members, such independence with the requested brand name supplement is not of proven medical value, cost effective, and could be a safety concern as Isotonix has no FDA approval and no valid NCD code. Accordingly, based upon the entire hearing record, I conclude that the Family Care Program (FCP) correctly denied the petitioners' request for payment of the supplement Isotonix.

CONCLUSIONS OF LAW

The Family Care Program correctly denied the petitioner's request for payment for the over the counter supplement, Isotonix.

THEREFORE, it is

ORDERED

The petition for review herein be and the same 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 served and 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, 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 22nd day of January, 2013

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



State of Wisconsin \DIVISION OF HEARINGS AND APPEALS

David H. Schwarz
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 January 22, 2013.

Jefferson County Department of Human Services
Office of Family Care Expansion