



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

██████████ ██████████
c/o ██████████ ██████████
██████████
██

DECISION

MPA/153177

PRELIMINARY RECITALS

Pursuant to a petition filed October 28, 2013, 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 January 08, 2014. An initial hearing scheduled for December 2, 2013, was rescheduled to allow the respondent time to review further information submitted by the petitioner's provider.

The issue for determination is whether the Division of Health Care Access and Accountability correctly denied the petitioner's request for Exome Sequencing with Reflex Testing.

There appeared at that time the following persons:

PARTIES IN INTEREST:

Petitioner:

██████████ ██████████
c/o ██████████ ██████████
██████████
██

Respondent:

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

By: Dr. Lora Wiggins

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 three year old resident of Wood County.
2. The petitioner has suffered from multiple congenital anomalies since birth; the anomalies have thus far eluded diagnosis.
3. The Division of Health Care Access and Accountability denied the petitioner's request for Exome Sequencing with Reflex Testing on October 8, 2013.

DISCUSSION

The petitioner is a three year old with multiple undiagnosed congenital anomalies, including a congenital heart abnormality, rib and vertebral bone fusion, low muscle tone, and abnormalities of her palate and head shape. Exhibit 4. She has undergone extensive testing without receiving a specific diagnosis. The petitioner submitted a request for whole exome gene sequencing to hopefully identify an underlying diagnosis. Such a diagnosis would arguably identify other unknown birth defects or other organ abnormalities, and also suggest whether other testing could be employed to address future complications. See, Exhibit 2.

The Division of Health Care Access and Accountability denied the request because it contends that it does not meet its guidelines. The respondent noted:

The initial Exome Sequencing looks at genes with defined clinical characteristics. If nothing is found in the initial test, a second, more extensive test is performed that includes genes with limited or unknown significance, at additional cost. Multiple insurers (Humana, BlueCross BlueShield, Priority Health) have policies stating that they do not cover these tests, and clinical use has not been clearly established. In addition, the significance of a finding may not be understood and may not be treatable. A search of the literature did not reveal any published reports of the percent of cases where whole Exome Sequencing led to a diagnosis that impacted care, but only a few individual case reports.

...

Exhibit 3.

When determining whether a service is necessary, the Division must review, among other things, whether the service is medically necessary and an effective and appropriate use of available services. Wis. Admin. Code, § DHS 107.02(3)(e)1 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. 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.

...

Wis. Admin. Code, § DHS 101.03(96m)

The fifth standard noted above, indicates that the proven medical value of the proposed service is to be considered when determining whether that service is medically necessary. Furthermore, the Wisconsin Administrative Code provides that:

- (1) Definition. "Experimental in nature," as used in s. [DHS 107.03 \(4\)](#) and this section, means a service, procedure or treatment provided by a particular provider which the department has determined under sub. [\(2\)](#) not to be a proven and effective treatment for the condition for which it is intended or used.
- (2) Departmental review. In assessing whether a service provided by a particular provider is experimental in nature, the department shall consider whether the service is a proven and effective treatment for the condition which it is intended or used, as evidenced by:
 - (a) The current and historical judgment of the medical community as evidenced by medical research, studies, journals or treatises;
 - (b) The extent to which medicare and private health insurers recognize and provide coverage for the service;
 - (c) The current judgment of experts and specialists in the medical specialty area or areas in which the service is applicable or used; and
 - (d) The judgment of the MA medical audit committee of the state medical society of Wisconsin or the judgment of any other committee which may be under contract with the department to perform health care services review within the meaning of s. [146.37](#), Stats.
- (3) Exclusion of coverage. If on the basis of its review the department determines that a particular service provided by a particular provider is experimental in nature and should therefore be denied MA coverage in whole or in part, the department shall send written notice to physicians or other affected certified providers who have requested reimbursement for the provision of the experimental service. The notice shall identify the service, the basis for its exclusion from MA coverage and the specific circumstances, if any, under which coverage will or may be provided.
- (4) Review of exclusion from coverage. At least once a year following a determination under sub. [\(3\)](#), the department shall reassess services previously designated as experimental to ascertain whether the services have advanced through the research and experimental stage to become established as proven and effective means of treatment for the particular condition or conditions for which they are designed. If the department concludes that a service should no longer be considered experimental, written notice of that determination shall be given to the affected providers. That notice shall identify the extent to which MA coverage will be recognized.

Wis. Admin. Code, § 107.035.

The petitioner and her provider have the burden of proving by the preponderance of the credible evidence that the Exome Sequencing is medically necessary, and the Division's decision depends upon the information submitted by the provider. The Division's representative has reviewed all of the information submitted by the petitioner, and concluded that it was insufficient to establish even a likelihood that Exome Sequencing will find a diagnosis that would change petitioner's clinical care. I agree.

The petitioner's providers have argued that this test presents the latest best chance for a definitive diagnosis for the petitioner. Unfortunately, the exhibits tend to reflect the speculative nature of Exome Sequencing, as opposed to establishing the likelihood of identifying a diagnosis. The respondent's representative noted that she was not aware of any commercial insurer in the state that would cover this testing. The petitioner's representatives do not dispute this point, but petitioner's provider noted that the petitioner's condition is simply a mystery at this point. Unfortunately, the respondent cannot approve any and all testing that is requested. There is a process in place whereby the request is evaluated, and a determination is made based on fairly explicit instructions. In the present matter, I find that the petition has not proven by the preponderance of the credible evidence that Exome Sequencing is medically necessary, as that term is defined by the Wisconsin Administrative Code. Based upon this, I must uphold the Division's denial.

Nothing prevents the petitioner's provider from submitting a new request for Exome Sequencing; in fact, the respondent has conceded that this is a rapidly developing area of medicine. If petitioner does reapply, she would be well-served by the introduction of further (future) studies identifying the establishment of successful exome sequencing with reference to clinical applications and outcomes.

CONCLUSIONS OF LAW

The Division of Health Care Access and Accountability correctly denied the petitioner's request for Exome Sequencing because she has not established that the test is medically necessary.

THEREFORE, it is

ORDERED

The petitioner's appeal is 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, 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 28th day of February, 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 February 28, 2014.

Division of Health Care Access and Accountability