



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[Redacted]
[Redacted]
Redact
[Redacted]
[Redacted]

DECISION

MPA/164128

PRELIMINARY RECITALS

Pursuant to a petition filed February 18, 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 in regard to Medical Assistance, a hearing was held on May 13, 2015, at Appleton, Wisconsin.

The issue for determination is

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[Redacted]
[Redacted]
Redact
[Redacted]
[Redacted]

Respondent:

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

By: *Redact*, R.Ph. (in writing)
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

John P. Tedesco
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Outagamie County.

2. On January 21, 2015, a prior authorization request (# Redact) was submitted on the petitioner's behalf for Norditropin, a human growth hormone product. The Division issued written notice of denial of that request on February 3, 2015.
3. The Division's basis for denial was that the product cannot be approved under MA rules/policies.
4. The petitioner, age ten, received a kidney transplant in May, 2006. From infancy up to the time of the transplant, the petitioner received daily shots of human growth hormone. His height and weight were within the normal range during that period. Post-transplant (and without getting the growth hormone), his growth hit a plateau. In September 2014, the petitioner was 50.5 inches tall, eight inches tall, and weighed 102 pounds. His mother is five feet, ten inches tall, and his father is five feet, six inches tall.
5. Petitioner underwent one growth hormone stimulation test on October 13, 2014. The test protocol calls for blood draws every 30 minutes over the course of several hours. In petitioner's test, there were 7 draws at the following times: 8:25am, 10:03am, 10:30am, 11:00am, 12:30pm, 12:45pm, 1:00pm.
6. Norditropin (generic name, somatropin) is a human growth hormone product. Somatropin has been approved by the Food and Drug Administration (FDA) for treatment of growth hormone deficiency and also for growth failure associated with specific medical conditions.

DISCUSSION

The Division may only reimburse providers for medically necessary and appropriate health care services and equipment listed in ss. 49.46(2) and 49.47(6)(a), Wis. Stats., as implemented by Ch. DHS 107, Wis. Adm. Code. Some services require prior authorization as a condition of MA reimbursement; that is the case with the prescription product, Norditropin. Prior authorization is the submission of a request, which is then approved by the Division in advance of receiving the service. In this case, prior authorization was requested for Norditropin, and the request was then denied.

At hearing, the petitioner's physician clarified that the basis of the request is not growth failure due to renal insufficiency. The Department argues that the medication would not be appropriate for this purpose as this child has had a transplant. Petitioner does not dispute this. Indeed, at least one previous PA was denied and appealed resulting in dismissal of the appeal on the basis that such use would be experimental and a non-FDA-approved use. *See* DHA Case No. MPA-92/113660 (October 6, 2010). Instead, petitioner now requests the Norditropin based on a growth hormone deficiency. Petitioner explains that petitioner did not experience the growth catch-up that was expected after the transplant.

The Division evaluated the prior authorization request against the 12 generic prior authorization criteria at Wis. Admin. Code §DHS 107.02. The criteria that are relevant here are the following:

- (e) *Departmental review criteria.* In determining whether to approve or disapprove a request for prior authorization, the department shall consider:
- (1) The medical necessity of the service;
 - (2) The appropriateness of the service;
 - ...
 - (12) The professional acceptability of unproven or experimental care, as determined by consultants to the department.

Id., §107.02(3)(e). Also, ForwardHealth Provider Information No. 2014-55 informed providers of changes to the PA requirements for growth hormone specifying that “growth failure or short stature associated with growth hormone deficiency must be confirmed with at least two appropriate growth hormone stimulation tests...(previously only one stimulation test was required).” In this case there was one test on 10/13/14. When asked during hearing, petitioner’s physician stated that the requirement is that two hormones be measured during the test, not that there be two separate tests. I disagree. I find the language of the policy to be clear in requiring two tests where only one test was previously required. This requirement was quite new when the October 2014 was conducted so I could easily understand the lapse. But, the policy is reasonable. I note that the Department objects to the growth hormone level measurements represented on the test results as there are significant lapses in the periods between measurements. Instead of the typical 30 minutes between measurements there are two 90 minute periods. My own review of test protocols on websites including Mt. Sinai Hospital and the University of Maryland Medical Center reflected an expectation of blood draws every 30 minutes. While I understand the physician’s opinion offered in testimony that it is hardly likely that the HGH spiked during either of these 90 minute periods, it does suggest that a second test would have been helpful in supporting this argument.

I also note that while the questionable results of the stimulation test reflect a HGH deficiency, the petitioner is showing normal results for bone age and also for current growth velocity. Petitioner’s mother claims in her letter requesting appeal that she fears that “he will be considered and classified as a little person.” Hearing testimony indicated that petitioner’s likely adult height will be around 5’4”. This appears to be hyperbole and not helpful to petitioner’s argument.

Because there were not the two required HGH stimulation tests, and because the one test which provided results was not in conformance with accepted testing protocols, the evidence in his record clearly supports the Division’s denial of this prior authorization request.

CONCLUSIONS OF LAW

The Division correctly denied the instant prior authorization request for Norditropin to treat apparent insufficient growth due to HGH deficiency.

THEREFORE, it is

ORDERED

That the petition be 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 5th day of June, 2015

\sJohn P. Tedesco
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 June 5, 2015.

Division of Health Care Access and Accountability