

3. On May 24, 2016 the petitioner's provider submitted a medical prior authorization request for the drug Tresiba.
4. Tresiba is a long acting insulin that first became available in October 2015. There are other long acting insulins available that are significantly less expensive than Tresiba. MA pays 1000% more for Tresiba than other long acting insulins including Lantus and Levemir. Both Lantus and Levemir are preferred drugs, while Tresiba remains a non-preferred drug.
5. Although the petitioner has tried Lantus, there is no documentation or testimony that he has also tried Levemir. In addition, the petitioner is able to take Lantus to control his diabetes.
6. On June 27, 2016 the Department sent the petitioner a notice stating that they denied his prior authorization request for Tresiba.
7. On July 11, 2016 the Division of Hearings and Appeals received the petitioner's Request for Fair Hearing.

DISCUSSION

The Department 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 the Wisconsin Administrative Code, Ch. DHS 107. The specific medical necessity requirements at issue are as follows:

"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 diagnosis, 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 with 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). It is the provider's responsibility to justify the need for the service. Wis. Admin. Code, §DHS 107.02(3)(d)6.

Tresiba is a non-preferred drug in a class of long acting insulins. Tresiba is in the Hypoglycemic Insulin class. When drugs first become available drugs remain on the non-preferred drug list until a Pharmacy PA Advisory Committee meeting. Prior this meeting, for a new drug to be approved, the provider had to submit the Prior Authorization / Drug Attachment form. Forward health Update no. 2013-46. This form requires the provider to "document the clinical rationale to support the medical necessity of the drug being requested." "Documentation of previous treatments and detailed reasons why other covered drug treatments were discontinued or not utilized as required. Medical records and peer-reviewed medical literature should be provided as necessary to support the PA request." In addition, "if the prescriber writes a prescription with a diagnosis outside the ForwardHealth-allowed diagnoses for a drug, the prescriber is required to attach peer-reviewed medical literature to support the proven efficacy and safety of the requested use of the drug."

The Pharmacy PA Advisory Committee met in May 2016. As a result of that meeting the Committee issued a new ForwardHealth update in July 2016 specifically regarding the drug, Tresiba. This update revised the prior authorization approval criteria for Hypoglycemics, including Tresiba; however, this update came out after the petitioner's prior authorization request, and thus is not applicable to this decision. Tresiba remains a non-preferred drug. ForwardHealth Update no. 2016-22 (viewable online at <https://www.forwardhealth.wi.gov/kw/pdf/2016-22.pdf>). For Tresiba to be approved under this update a recipient must have diabetes, have tried both Lantus and Levemir for three consecutive months, have been unable to control fasting glucose levels with Lantus, and have experienced continued episodes of hypoglycemia with Levemir. *Id.* The recipient must also have tried adjusting these drugs to optimize glycemic control. *Id.* If the recipient is using 80 or more units per day of Lantus or Levemir, then the recipient only needs to try one of the two drugs. *Id.*

Here, the petitioner's mother testified that the petitioner has tried Lantus, and although it was not ideal, it was effective to treat the petitioner's diabetes. In the prior authorization request the provider notes that the petitioner is a "30 year old man with uncontrolled Type I diabetes. [] He has had difficulty managing glucose and experiences wide glucose fluctuations, while on [] Lantus." There is no indication from the petitioner's doctor what these fluctuations are, when they occur, or if the Lantus has been adjusted to prevent these fluctuations. I also do not know the petitioner's dosage of Lantus. There is no indication or documentation that he has tried Levemir. The provider notes that the petitioner completed a trial of this drug and that he noticed improvement in hyperglycemia. This improvement is not documented in medical records. It is also not quantified. If the petitioner believes that he now meets the criteria for the prior authorization of Tresiba contained in ForwardHealth Update no. 2016-22, he may submit a new prior authorization with documentation supporting that assertion. Given that Lantus is 1000% times less expensive than Tresiba, and that Lantus has worked for the petitioner in the past, Lantus appears to be the most cost-effective drug given the evidence presented at hearing.

CONCLUSIONS OF LAW

The Department correctly denied the petitioner's prior authorization request for the drug, Tresiba.

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, **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 24th day of August, 2016

\s _____
Corinne Balter
Administrative Law Judge
Division of Hearings and Appeals



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The preceding decision was sent to the following parties on August 24, 2016.

Division of Health Care Access and Accountability