

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

**In the matter of:**

██████████

**Petitioner,**

v

**File No. 152600-001**

**Aetna Life Insurance Company,**

**Respondent.**

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**Issued and entered**  
**this 13<sup>th</sup> day of April 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 9, 2016, ██████████, (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on March 16, 2016.

The Petitioner receives prescription drug benefits through an individual plan underwritten by Aetna Life Insurance Company (Aetna). The Director immediately notified Aetna of the external review request and asked for the information it used to make its final adverse determination. Aetna responded on April 6, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on March 4, 2016.

**II. FACTUAL BACKGROUND**

The benefits are defined in Aetna's *Comprehensive Medical Expense Policy* (the policy). This policy was effective on January 1, 2016.

The Petitioner was diagnosed with type 2 diabetes in 1999. For the last ten years he has been using the insulin Lantus (along with the insulin Humalog) to control his diabetes. After his

insurance coverage changed to Aetna, his physician asked Aetna to pre-certify Lantus, a tier 3 drug,<sup>1</sup> so he could continue to use it. Aetna denied the request, saying the Petitioner does not meet its medical necessity criteria.

The Petitioner appealed the denial through Aetna's internal grievance process. At the conclusion of that process, Aetna affirmed its decision in a final adverse determination dated February 29, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did Aetna correctly deny prescription drug coverage for Lantus?

### IV. ANALYSIS

#### Petitioner's Argument

In an undated letter to Aetna accompanying the request for an external review, the Petitioner wrote:

I was diagnosed with diabetes in 1999. I took type 2 pills that held it under control for five years. My doctor . . . checked me and said I was going to need to start medication (insulin needles). We tried some different medications and we stuck with Lantus . . . in the morning and . . . in the evening (daily) and Humlog, daily, as needed. This was found . . . to work the best. Then, I even went to the University of Michigan to get checked out. They said I was in the top 2% of "all" people who were diabetic. My hc-1 [A1C] is 6.2, which I work on every day. This has been the same for ten years, always on Lantus . . . and Humalog.

Why would I change the way this product works? Why would you even try a different drug? That is the definition of insanity. When something is working, stick with it. Do not change it.

In a March 15, 2016, letter of support addressed to Aetna, the Petitioner's physician explained:

The [Petitioner] has been under my care for many years. This patient has diligently and tirelessly worked to regain his health, after becoming a Type II diabetic. It took us quite some time to find the correct mix of education, diet, exercise, hormone replacement and medication, including insulin, to gain control of his diabetes. Recently, after 10 years of good control of his diabetes, using Lantus and Humalog, your insurance company has reportedly denied this patient,

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<sup>1</sup> Under the Petitioner's prescription drug plan, tier 3 drugs are subject to precertification and step therapy.

his most workable medication for his diabetes, the Lantus Solostar insulin. He is a fairly brittle diabetic and I think it would be reasonable to maintain his current regimen, especially after he and I have worked so hard to find the best regimen to control his diabetes and prolong his life, as best as possible, with such a condition and a strong family history of hyperlipidemia. No matter what the science says or your bookkeepers say, I've found that when a patient attains good control of any medical condition with a workable set of lifestyle changes and medication after working so hard, and maintains that for many years, it is very frustrating and often ill-fated to change their medications, even if it "seems" as though there is a similar or "identical" substitute. You should be grateful for such a patient who would work so hard to recapture his greatest health potential, taking pride in his part to take responsibility for such a task. He has probably, in actuality, saved your company thousands upon thousands of dollars in medical costs by maintaining his regimen and his health religiously, spending untold dollars of his own on natural supplements, exercise regimens and countless other therapies too long to list here. . . . Therefore, I implore you to leave his regimen alone, to allow this patient to maintain good control of his diabetes and health, and, without delay, reward him by approving his request for coverage of his Lantus insulin prescription.

### Aetna's Argument

In its final adverse determination to the Petitioner, Aetna's representative explained to the Petitioner:

We have found that the medication requested does not meet medical necessity criteria and, therefore, is not covered under your plan of benefits. Below you will find the details of our review and the outcome of the appeal.

\* \* \*

### **Our decision**

Based on our review . . . we are upholding the denial of coverage for the medication Lantus (insulin glargine).

### **How we made our decision**

You are requesting coverage for the medication Lantus (insulin glargine). You have submitted information to support this request.

After review of the information submitted and presented, we are upholding the denial of coverage for the medication Lantus (insulin glargine). The information submitted indicates that you have type 2 diabetes treated with insulin glargine. There is no documentation of a failure with, contraindication to, or inability to

take the preferred agent, Levemir. This determination was made utilizing the Aetna Pharmacy Clinical Policy Bulletin pertaining to Insulins.

Please reference the Certificate of Coverage (COC) provided through Aetna Advantage Plans off Exchange. The section titled "Medical Benefit Exclusions" states in part the following:

"Not every medical service or supply is covered by the plan, even if prescribed, recommended, or approved by your physician or dentist. The plan covers only those services and supplies that are medically necessary and included in the What the Medical Benefit Covers section. Charges made for the following are not covered except to the extent listed under the What the Medical Benefit Covers section or by amendment attached to this Policy.

#### Director's Review

The policy (p. 60) excludes coverage for drugs that are not medically necessary as determined by Aetna. "Medically necessary" is defined in the policy (p. 102). Aetna determined that Lantus was not medically necessary for the Petitioner based on criteria in its "2016 Aetna Pharmacy Drug Guide" which requires the following:

A documented diagnosis of type I or type II diabetes AND

A documented contraindication or intolerance or allergy or failure of an adequate trial of one month of the preferred alternative, Levemir

The policy (p. 71) says an Aetna member "may seek a medical exception to obtain coverage for drugs not listed on the preferred drug guide (formulary) or for which coverage is denied through precertification." However, Aetna declined to make an exception for the Petitioner's continued use of Lantus.

The question of whether Lantus is a medically necessary to treat the Petitioner's condition and whether he met Aetna's criteria for coverage was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in internal medicine and endocrinology, has been in active practice for more than 12 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

#### **Recommended Decision:**

The MAXIMUS physician consultant determined that Lantus is not medically necessary treatment of the member's condition.

**Rationale:**

\* \* \*

The results of the consultant's review indicate that this case involves a 56 year-old male who has a history of insulin dependent diabetes, which he has managed with multiple daily injections of insulin. At issue in this appeal is whether Lantus is medically necessary treatment of the member's condition.

The member's glycemic control has been good on Lantus and Humalog, with a recent HbA1c of 6.2%. The Health Plan has denied coverage for Lantus on the basis that the member should use its preferred basal insulin, Levemir.

The MAXIMUS physician consultant explained that insulin therapy is often essential for effective management of type 2 diabetes, as well as type 1 diabetes. Optimization of insulin therapy reduces the progression of diabetes and the development of diabetes-related complication. While there has long been a struggle to replicate the natural physiology of insulin secretion, the continued development of improved injectable insulin formulations with superior pharmacokinetics and pharmacodynamics represents important clinical advances in the treatment of both type 1 and type 2 diabetes. The main basal insulin analogues that are available are insulin detemir (Levemir) and glargine (Lantus). The physician consultant explained that while these insulins do have some subtle differences, studies have shown that Levemir and Lantus are both effective and safe treatments for glycemic control in a basal-bolus regimen for type 2 diabetes. Therefore, the consultant indicated that it is reasonable for the member to use Levemir insulin rather than Lantus at this point as his basal insulin. The consultant also explained that unless the member has demonstrated treatment failure with or inability to use Levemir, it would not be considered medically necessary for him to use Lantus instead of Levemir at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Lantus is not medically necessary treatment of the member's condition at this time. [References omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b).

The IRO's analysis is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO recommendation should be rejected, finds that Lantus at this time is not medically necessary to

treat the Petitioner, and is therefore not a benefit under the terms of the certificate.

**V. ORDER**

The Director upholds Aetna's February 29, 2016, final adverse determination.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin  
Director

For the Director:

A handwritten signature in black ink, appearing to read 'RSG', written over a horizontal line.

Randall S. Gregg  
Special Deputy Director