

**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. 153664-001-SF**

**County of Oakland, Plan Sponsor**  
**and**

**Navitus Health Solutions, Plan Administrator**  
**Respondents**

---

**Issued and entered**  
**this 17<sup>th</sup> day of June 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On May 12, 2016, ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of prescription drug coverage issued by Navitus Health Solutions, the administrator of the Petitioner's health benefit plan which is sponsored by Oakland County.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan.

The Director notified Navitus of the appeal and asked it to provide the information used to make its final adverse determination. Navitus furnished its response on May 23, 2016, and the Director accepted the case for review on that date.

This case involves medical issues, so the Director assigned it to an independent review organization, which provided its recommendation to the Director on June 6, 2016.

## II. FACTUAL BACKGROUND

The Petitioner is eighteen years old and has a history of inappropriate sinus tachycardia (an abnormally high heart rate, even with minimal exertion) that has not been effectively managed with beta-blocker therapy, diltiazem therapy and a trial of flecainide. Her cardiologist prescribed the drug Corlanor (ivabradine) and requested Navitus approve coverage. Navitus denied the request, asserting that the Petitioner did not meet its criteria for coverage for the drug.

The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, Navitus issued a final adverse determination on March 23, 2016, affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

## III. ISSUES

1. Does the Petitioner meet the plan's criteria for use of Corlanor?
2. Are the plan's criteria consistent with accepted medical standards?
3. Is Corlanor medically necessary in the treatment of the Petitioner's condition?

## IV. ANALYSIS

### Navitus' Argument

In its final adverse determination, Navitus explained the reasons for its denial:

Based on the Pharmacy and Therapeutics Committee prior authorization criteria for Corlanor, this drug is covered for members who meet the following criteria: 1) Prescribed by a Cardiologist; 2) Patient has NYHA Class II-IV or ACCF/AHA/aha Class C or D chronic heart failure; 3) Patient has a baseline OR current left ventricular ejection fraction (LVEF) less than or equal to 35%; 4) Patient is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute (BPM); AND 5) Patient is on a maximally tolerated dose of a beta blocker (3.g. atenolol, bisoprolol, carvedilol, metoprolol), OR has a history of a documented intolerance, FDA labeled contraindication, or a hypersensitivity to beta blockers.

Based on the information we have received, you do not meet numbers 2 and 3 of the prior authorization criteria because you do not have heart failure.

### Petitioner's Argument

In the request for external review form, the Petitioner wrote:

I have an extreme rare condition. All my organs are on the opposite side of my body except *my* heart *which* is on the left *side* but is *not* normally connected with my arteries. My heart beat goes from 65 to 230 beats per minute for no reason. A catheter cannot go

in thru my leg as a normal person in attempt to fix my heart. The only option is thru my neck which is very risky. William Beaumont would not attempt it and sent me to the Cleveland Clinic. The risks include total paralysis and possibly death. Dr. [REDACTED] thinks Corlanor may help because it regulates heart beat. I need someone to think out of the box and approve Corlanor. I don't want to risk dying if there is a drug that may help me. While I *may* not meet all requirements for this drug every *day* researchers are finding drugs that help certain conditions that they were never intended for. This can only occur [if] someone will think out of the box. I DO have heart failure. My heart is not working normally. It cannot continue to beat 230 beats per minute. PLEASE approve coverage for this drug.

Included with the request for an external review is a letter dated March 4, 2016, from the Petitioner's Cleveland Clinic cardiologist, who wrote:

This letter is to appeal the recent denial of coverage for the medication Corlanor [ivabardine] that was issued on February 26, 2016.

[Petitioner] is an 18 year old female with a history of inappropriate sinus tachycardia. Thus far our attempts to suppress the tachycardia have not been successful including beta blocker therapy, flecainide and diltiazem. Ivabradine is a first specific heart rate lowering agent that has completed clinical development. It is selective for the IF current, lowering heart rate at concentrations that do not affect other cardiac ionic currents. Ivabradine lowers heart rate without any negative inotropic or lusitropic effects, thus preserving ventricular contractility.

Ivabradine was shown to reduce resting heart rate without modifying any major electrophysiological parameters not related to heart rate. [Petitioner] would benefit from the use of this medication and the cost should be covered by her medical insurance plan.

#### Director's Review

Whether the Petitioner meets the plan criteria for use of Corlanor, whether the plan's criteria are consistent with accepted medical standards, and whether the drug is medically necessary are medical questions which were evaluated by an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice for more than 15 years who is board certified in internal medicine and cardiology. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

Corlanor (ivabradine) is the first specific heart rate lowering medication that works by inhibiting the IF current, lowering heart rate without any negative inotropic or negative lusitropic effects....[W]hile this medication was initially studied to treat sinus tachycardia in patients with congestive heart failure, it has also been shown in both short and long-term trials to be safe and effective in treating the rare condition of inappropriate sinus tachycardia....[A]lthough the medical records do not support that the member has congestive heart failure and thus does not meet the Health Plan's coverage criteria for ivabradine, use of this medication is reasonable and appropriate in this setting and has become an accepted standard of medical care for her condition once other therapies have

been tried and failed, such as in this case.

Pursuant to the information set forth above and available documentation... Corlanor is medically necessary for treatment of the member's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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 review 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 certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the prescription drug Corlanor is medically necessary and appropriate for treatment of the Petitioner's condition and is therefore a covered benefit under her benefit plan.

#### V. ORDER

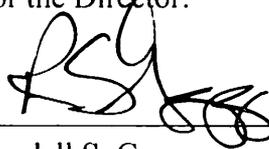
The Director reverses the final adverse determination dated March 23, 2015. Navitus shall immediately provide coverage for the prescription drug Corlanor and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6442.

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:



---

Randall S. Gregg  
Special Deputy Director