

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

In the matter of:

██████████
Petitioner

v

File 233408-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 14th day of March 2025
by Jeffrey Hayden
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On February 13, 2025, ██████████, M.D., authorized representative for ██████████ (Petitioner), filed with the Director of the Department of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 et seq. The request for review concerns the denial of prior authorization for a prescription drug. The Director accepted the request for review on February 21, 2025.

The Petitioner receives health care benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's ██████████ *ABC with 5-Tier Rx Prescription Coverage Booklet* (the coverage booklet). The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM responded on February 28, 2025.

The Director assigned an independent review organization to analyze the medical issues in this appeal. The review organization submitted its report to the Director on March 5, 2025.

II. FACTUAL BACKGROUND

The Petitioner is obese with a BMI of 38.4 and has a history of chest pain with nonobstructive coronary disease after catheterization showed in the form of a long, tubular area of coronary stenosis in the left anterior descending coronary artery. The Petitioner's physician recommended the prescription drug Wegovy for cardiovascular disease and elevated BMI and requested prior authorization from BCBSM.

BCBSM denied the request on the basis it is excluded from coverage under the Petitioner's drug plan.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion

III. ANALYSIS

Petitioner's Argument

In a letter submitted with the request for review, the Petitioner's cardiologist wrote:

I am writing to appeal the initial denial for the medication Wegovy for patient [the Petitioner].

I believe that there is a misunderstanding regarding the indication and criteria for treatment of Wegovy for this patient. Your letter of denial refers to the need for the patient to have lifestyle modifications to lose weight for at least 6 months. However, as you know, Wegovy has now been approved for treatment of patients with known cardiovascular disease and an elevated BMI. As detailed in my office note of 11/1/24, a recent cardiac catheterization on 10/10/24 found a long, tubular area of coronary stenosis in the left anterior descending coronary artery. The patient's documented cardiovascular/coronary disease with elevated BMI of 38.6 qualifies for approval of Wegovy medication.

I am confident that this additional information will permit your approval of Wegovy for [the Petitioner].

Respondent's Argument

In its final adverse determination, BCBSM wrote:

As a Grievance and Appeals Coordinator, I reviewed your appeal. You are covered under the [REDACTED] group health care plan. The prescription drug benefits of your plan are summarized in the [REDACTED] ABC with 5-Tier Rx Prescription Coverage Booklet. As indicated on Page 5 of the Booklet, the prior authorization program manages use of certain medications that are used only for certain health conditions.

Page 6 of the Booklet under "Exclusions and Limitations", indicates that [REDACTED] will not pay for weight loss or weight control treatment drugs. In this case, we are unable to provide authorization because the requested medication is not a covered benefit, as explained below.

A Blue Cross Medical Director, a board-certified MD in Family Medicine, also reviewed your appeal. The Medical Consultant used the medical policy or clinical

criteria titled Blue Cross and [REDACTED] Prior Authorization and Step Therapy Coverage Criteria for Wegovy.

“We reviewed your healthcare provider’s appeal for coverage of prescription drug, Wegovy. We did not cover the requested medication because it is excluded from coverage under your drug plan. Your drug plan does not cover most medications used to treat obesity (weight that is higher than what is considered healthy for a given height). Covered alternatives may include: phentermine or diethylpropion. Therefore, our denial must be maintained.”

To clarify, effective January 1, 2025, Blue Cross Blue Shield of Michigan (Blue Cross) changed the way we cover certain GLP-1 medications (Saxenda, Wegovy and Zepbound), used for weight loss. Blue Cross and Blue Care Network made these changes after careful consideration of the GLP-1 weight loss drug’s efficacy, safety and access, and cost. Research has shown that a person’s chance of success in losing weight and maintaining that weight loss is greatly improved when medication is paired with lifestyle changes, including diet and exercise. Data published by the Blue Cross Blue Shield Association in May 2024 shows that most patients are not staying on weight loss GLP-1 drugs consistently enough to see long term benefits. Due to the high cost of these drugs and supply considerations, we want to ensure they are used for the most appropriate patients who can achieve clinical benefit, while long term research is underway.

If you choose to proceed with the treatment or services being appealed, or services have already been performed, you may be liable for the cost.

Director’s Review

The Director assigned an independent review organization (IRO) to evaluate BCBSM’s medical policy criteria and help determine whether the use of the prescription drug Wegovy for cardiovascular disease and elevated BMI is medically necessary for treating the Petitioner’s condition. This review is required by section 11(7) of the Patient’s Right to Independent Review Act, MCL 550.1911(7).

The IRO reviewer is a physician who is board-certified in internal medicine and infectious disease and is in active practice. The IRO reviewer’s report included the following analysis and recommendation:

1. Are the plan’s criteria which denied coverage for the prescription drug Wegovy 0.25 mg/0.5 ml pen consistent with the standard of care?

No. The plan’s criteria, which denied coverage for the prescription drug Wegovy, are not consistent with the standard of care.

The denial was based on exclusion from coverage of Wegovy for patients with obesity. However, the FDA has approved Wegovy for the management of obesity with a body mass index of 30 kg/m² or more or 27 kg/m² and a co-existing condition like hypertension or hyperlipidemia. The denial based on this exclusion is

not consistent with the standard of care. Denial of coverage for cardiovascular disease would be consistent with the standard of care.

2. If they are, does the member meet the criteria for coverage such that the prescription drug WEGOVY 0.25 MG/0.5 ML Pen is medically necessary as indicated for treatment of this patient with established cardiovascular disease and an elevated BMI?

Not applicable.

3. If the plan's criteria are inconsistent with the standard of care criteria, does the member meet standard of care criteria such that an exception for the prescription drug WEGOVY 0.25 MG/0.5 ML Pen is medically necessary for the treatment of this patient with an established history of cardiovascular disease and elevated BMI?

No. The provider is requesting approval of Wegovy for cardiovascular risk reduction. The patient would not qualify for treatment with Wegovy for cardiovascular disease because he does not have established cardiovascular disease as defined in the pivotal clinical trial that led to the approval of Wegovy for the purpose of cardiovascular risk reduction.

Reviewer's Clinical Rationale for the Decision:

The provider is requesting approval of Wegovy for cardiovascular risk reduction. The patient does not qualify for treatment with Wegovy for cardiovascular disease risk reduction since he does not have cardiovascular disease as defined in the clinical trial.

Per the appeal documents, the insurer's denial was based on exclusion from coverage of Wegovy for patients with obesity. The FDA has approved Wegovy for the management of obesity with a body mass index of 30 kg/m² or more or 27 kg/m² and a co-existing condition like hypertension or hyperlipidemia.

Denial of coverage for cardiovascular disease would be consistent with the standard of care. The physician alleges that the patient has coronary artery disease based on a long tubular segment of 40% stenosis of a coronary artery. However, the trial in which cardiovascular outcomes were shown to be improved with semaglutide included patients with established cardiovascular (CV) disease defined by previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease. The patient does not have any of these conditions, and the use of Wegovy for cardiovascular risk reduction does not apply to individuals with asymptomatic coronary artery disease.

The IRO reviewer recommended that the Director uphold BCBSM's denial of coverage.

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(18)(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(17).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the prescription drug Wegovy for the Petitioner's noted cardiovascular disease and obesity is not medically necessary, therefore, it is not covered under the Petitioner's benefit plan.

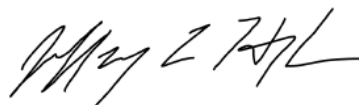
IV. ORDER

The Director upholds Blue Cross Blue Shield of Michigan's January 21, 2025, 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 Appeals, Legal Research, and Market Regulation, Post Office Box 30220, Lansing, MI 48909-7720.

Anita G. Fox
Director

For the Director:



Jeffrey Hayden
Special Deputy Director