

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

In the matter of:

██████████,
Petitioner,

v

McLaren Health Plan,
Respondent.

File No. 150696-001

Issued and entered
this 14th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by McLaren Health Plan (McLaren).

On November 19, 2015, ██████████, RN, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through the Medicaid program. McLaren, a health maintenance organization, administers the benefits. The Director immediately notified McLaren of the external review request and asked for the information it used to make its final adverse determination. The Director received McLaren's response on November 23, 2015. After a preliminary review of the material submitted, the Director accepted the request on November 30, 2015.

The issue in this external review can be decided by a contractual analysis. The Director reviews contractual issues pursuant to MCL 500.1911(7). This matter does not require a medical opinion from an independent review organization.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *McLaren Medicaid Certificate of Coverage*¹ (the certificate).

The Petitioner has cystic fibrosis. Her physician asked McLaren to authorize the prescription drug Orkambi to treat her condition. McLaren denied the request.

The Petitioner appealed the denial through McLaren's internal grievance process. At the conclusion of that process, McLaren affirmed its denial in a final adverse determination dated September 28, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did McLaren correctly deny coverage for Orkambi?

IV. ANALYSIS

A

The Petitioner's physician explained the medical necessity for Orkambi in an August 10, 2015, letter to McLaren:

Until recently, therapies for [cystic fibrosis] have been aimed at treating the symptoms of CF. With the identification of the genetic mutations that cause cystic fibrosis, science has been able to also identify the cystic fibrosis transmembrane conductance regulator (CFTR) gene that encodes for the defective chloride channel in cystic fibrosis patients. There are many genetic mutations that manifest phenotypically as cystic fibrosis, therefore medications aimed at the defective chloride channel must be tailored for the specific genetic mutation causing the defect. Each mutation affects the chloride channel in a slightly different manner, therefore these medications being developed target specifically how the mutation changes the chloride channel.

Orkambi is a CFTR potentiator, indicated solely for CF patients over the age of 12 who are homozygous (two copies) for the F508del mutation in the CFTR gene. It is part of a new generation of medications designed to treat the actual cause of the symptoms related to cystic fibrosis, instead of just the symptoms. Orkambi is the first FDA approved medication designed specifically for patients who are homozygous F508del. There are no generic medications or medications in its class that could be considered an alternative. [The Petitioner] has had genetic

¹ Dated January 2014.

testing which revealed that she does have two copies of the F508del mutation (see attached documentation).

Other appropriate cystic fibrosis therapies for this patient have been maximized, such as mucolytics, mucous hydrators, bronchodilators, airway clearance, and inhaled antibiotics. Despite these standard therapies [she] continues to have exacerbation and is at risk for continued loss of lung function.

Orkambi has been shown to increase FEV1 by 3-5%. More than that, it has been shown to decrease the incidence of cystic fibrosis exacerbations. Each exacerbation may include time off from Work/school, intravenous antibiotic therapy, possible hospitalization, and is marked by a decrease in lung function (measured by FEV1) that may or may not come back up to baseline after the exacerbation.

We are requesting approval for Orkambi 200mg/125mg tablet, 2 tablets by mouth every 12 hours. Orkambi in conjunction with standard CF therapies has the potential to improve lung function (or slow the rate of decline), reduce hospital stays/IV antibiotics, improve quality of life and provide a longer life span. We are asking that you please consider these aspects of care when reviewing this request.

B

McLaren provides prescription drug coverage for its Medicaid members but limits that coverage to drugs on its formulary. Orkambi is not on McLaren's formulary. The certificate (p. 9), in "Section 6. Schedule of Covered Services," says:

Outpatient Prescription Drugs. Prescription must be on our Formulary or Preauthorized. Covered with a generic substitution process and Co-payment. Prescriptions will be dispensed in quantities prescribed by providers up to a 90-day supply, including Coverage for an off-label use of a FDA approved drug when medically necessary.

Health maintenance organizations that offer prescription drugs and limit that benefit to drugs included in a formulary are required to provide for exceptions from the formulary limitation when a nonformulary drug is a medically necessary and appropriate alternative. MCL 500.3406o. However, the requirement does not apply in this case because McLaren is administering benefits for Medicaid, a state-run health program for low income individuals. Section 3571 of the Insurance Code says:

A health maintenance organization is not precluded from meeting the requirements of, receiving money from, and enrolling beneficiaries or recipients of state and federal health programs. . . . A health maintenance organization that partici-

pates in a state or federal health program . . . is not required to offer benefits or services that exceed the requirements of the state or federal health program. MCL 500.3571.

Orkambi is not on the list of drugs that must be covered by health maintenance organizations that administer the Medicaid program's benefits. Therefore, McLaren is not required to provide coverage for Orkambi.

V. ORDER

The Director upholds McLaren's September 28, 2015, 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:



Randall S. Gregg
Special Deputy Director