

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. 152365-001

Alliance Health and Life Insurance Company,

Respondent.

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Issued and entered  
this 12<sup>th</sup> day of April 2016  
by Sarah Wohlford  
Special Deputy Director

**ORDER**

**I. BACKGROUND**

██████████ (Petitioner) was denied coverage for a prescription drug by his health insurer, Alliance Health and Life Insurance Company (Alliance).

On February 26, 2016, ██████████, 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 group health care benefits, including prescription drug coverage, through Alliance. The Director immediately notified Alliance of the external review request and asked for the information it used to make its final adverse determination. Alliance responded on March 1, 2016. On March 4, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization, which provided its analysis and recommendation to the Director on March 18, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has onychomycosis (fungal infection of the toenails) as well as diabetes mellitus, hypertension, and chronic kidney disease. His podiatrist, who has been treating him for

mycotic toenails since 2012 without success, prescribed the drug Jublia 10% topical solution and asked Alliance to approve it. Alliance denied the request.

The Petitioner appealed the denial through Alliance's internal grievance process. At the conclusion of that process, Alliance issued a final adverse determination dated January 14, 2016, upholding its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did Alliance properly deny coverage for Jublia 10% topical solution?

### IV. ANALYSIS

#### Petitioner's Argument

On the external review request form, the Petitioner's authorized representative said:

I am trying to get the medicine Jublia 10% sol. approved. The patient has tried & failed on all other topicals & he cannot take the oral medication because he has chronic kidney disease.

#### Respondent's Argument

In its final adverse determination to the Petitioner, Alliance stated:

... After considering all available evidence, previous decisions and the member's medication history, the recommendation is to uphold the denial for Jublia (efinaconazole).

Jublia is a medication used to treat nail infections and is not included on the Formulary (nonformulary medication). The Formulary provides coverage for the following medications to treat nail infections: itraconazole, terbinafine and ciclopirox topical solution.

Medical exception for Jublia must show documentation of trial and failure of each of the formulary options available to treat your medical condition. Based on the additional information included with the physician's appeal, it is stated that you have tried and failed itraconazole, terbinafine and ciclopirox. However, medical records to support these claims, maximum doses of each medication tried, and the date ranges for when each medication was tried were not provided. Additionally, your prescription claims records could not help to substantiate that you have completed an adequate trial of each of these agents (there are no pharmacy claims for itraconazole, terbinafine or ciclopirox). Due to the lack of

documentation to support the trial and failure of each of the formulary options available to treat your medical condition, medical necessity for a formulary exception for Jublia has not been demonstrated.

### Director's Review

Alliance declined to authorize Jublia because it is not on its formulary ("Commercial Formulary," January 1, 2016). Alliance does have a "medical exception process" in its medical policy number CPCM-PDF, "Prescription Drug Formulary," which says in part (pp. 7-8):

Physicians and member may apply for Coverage for non-formulary drugs when there is medical necessity. The physician can submit a medical exception request using the exception process and must submit documentation to support request, including but not limited to: medical records, office visit notes, and supporting clinical literature. HAP Clinical pharmacist evaluates the patient's past drug history and physician supporting statement to determine if there is a legitimate medical need for the requested drug. To request coverage of a non-formulary drug, a prescriber or member may:

\* \* \*

- Supporting statement from prescribing provider must be included with the request. The statement must address the following:
  - The patient has failed HAP formulary drug product(s)
  - The choices available in the HAP Formulary are not suited for the present or patient care need, and the drug selected is required for patient safety.
  - The use of a Formulary Drug may provoke an underlying condition, which would be detrimental to patient care.

Each request is reviewed on an individual per patient basis. Approval is given if medical necessity is established. Non formulary drug when approved for coverage by the Plan defaults to the highest brand copay. Specialty drug when approved for coverage by the Plan defaults to the highest Specialty copay. . . . If the request does not meet medical necessity criteria, the request is denied and alternative therapy is recommended.

The Petitioner asked for an exception but Alliance determined that he did not meet medical necessity criteria. Therefore, the question of whether Jublia is a medically necessary 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 a podiatrist who has been in active practice more than 15 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The Health Plan indicated that [Jublia] is a non-formulary medication. The Health Plan noted that the member's formulary provides coverage for itraconazole, terbinafine and ciclopirox topical solution for treatment of nail infections. The Health Plan explained that the member has not had an adequate trial and failure with all formulary treatment options, including oral antifungal medications. . . .

**Recommended Decision:**

The MAXIMUS podiatrist consultant determined that Jublia is medically necessary for treatment of the member's condition.

**Rationale:**

\* \* \*

The member has been followed by his podiatrist for evaluation of thick, painful mycotic toenails which he is unable to care for by himself. Numerous visits have taken place between 2013 through 2015. The medical records from these visits demonstrate that member has a diagnosis of onychomycosis and has been treated with topical medications and toenail debridement, but this treatment has not alleviated his pain nor has it cured his onychomycosis.

A medication request form dated 12/20/15 from the member's podiatrist stated that he has tried terbinafine oral antifungal for 90 days, which did not "do anything" for him. This document also advises that member has used Pen Lac nail lacquer without success in treating the onychomycosis. Finally, the document advises that this member has tried itraconazole which also did not help with the onychomycosis.

The Health Plan's criteria for Jublia require that a patient must first fail two different topical antifungal medications and must also fail oral terbinafine for onychomycosis. The MAXIMUS podiatrist consultant explained that according to the prior authorization request form, it appears that the member has met these guidelines for the coverage of Jublia. The podiatrist consultant indicated that while it is reasonable to require the member to try and fail the formulary medications before taking Jublia, according to the documentation provided for review, he has met this requirement.

Pursuant to the information set forth above and available documentation, the MAXIMUS podiatrist consultant determined that Jublia is medically necessary for treatment of the member's condition. [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's recommendation should be rejected in this case, finds that the prescription drug Jublia 10% topical solution is medically necessary to treat the Petitioner's condition and is therefore a covered benefit under his policy.

#### V. ORDER

The Director reverses Alliance's January 14, 2016, final adverse determination.

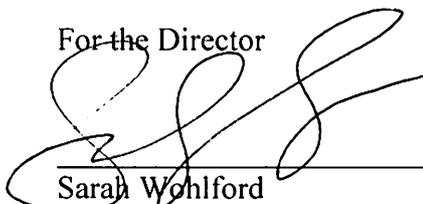
Alliance shall immediately cover the prescription drug Jublia 10% Solution. Alliance shall, within seven days of providing coverage, furnish the Director with proof it has complied with this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone 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 sixty 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



Sarah Wohlford  
Special Deputy Director