

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. 146319-001

Health Alliance Plan of Michigan,
Respondent.

Issued and entered
this 19th day of March 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On February 17, 2015, ██████████, authorized representative of ██████████ (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.*

The Petitioner receives health care benefits, including prescription drug coverage, through Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Director immediately notified HAP of the external review request and asked for the information it used to make its final adverse determination. HAP provided its response on February 20, 2015, and, after a preliminary review of the material submitted, the Director accepted the Petitioner's request on February 24, 2015.

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 10, 2015.

II. FACTUAL BACKGROUND

The Petitioner's benefits are defined in the *HAP HMO Subscriber Contract* (the contract).

The Petitioner was diagnosed with psoriasis and psoriatic arthritis. Her physician prescribed the drug Enbrel to treat her condition and asked HAP to cover it. HAP denied coverage on the basis that Petitioner did not meet its medical criteria for use of the drug.

With Petitioner's authorization, her physician appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated January 23, 2015, upholding its denial. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did HAP properly deny coverage for Enbrel?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's physician explained, in a January 21, 2015, appeal letter to HAP, why Enbrel was prescribed:

I am writing to provide additional information to support my claim for the treatment of [the Petitioner] with Enbrel for Psoriasis (696.1) and Psoriatic Arthritis (696.0). In brief, treatment . . . with Enbrel is medically appropriate and necessary and should be a covered treatment. Below, this letter outlines [the Petitioner's] medical history, prognoses, and treatment rationale.

[The Petitioner] is a 46 year old female with a long history of Psoriasis and Psoriatic Arthritis. Upon examination there are multiple erythematous scaly papules and plaques of the scalp, ears, breasts, axillae, abdomen, buttocks, bilateral arms, elbows, legs and knees affecting 12% of her body surface area. Her Psoriasis has become more scaly, thick, erythematous, and itchy since last summer. Along with her skin worsening she is also experiencing increased joint pain of her hands, feet and lower back. [She] had poor results with phototherapy treatment in the past. [She] has tried and failed multiple topical steroids. She is not a candidate for oral medications due to side effects.

Key factors that Enbrel is medically necessary:

- Patient has a diagnosis of chronic moderate to severe plaque Psoriasis covering 12% of her body surface area
- Patient has a diagnosis of Psoriatic Arthritis
- Patient has tried and failed phototherapy

- Patient is not a candidate for Methotrexate due to her alcohol consumption
- Patient is not a candidate for Acitretin because she is of childbearing potential
- Cyclosporine can only be used for 1 year
- Patient condition continually worsening

Respondent's Argument

In its final adverse determination, HAP explained its denial of coverage to the Petitioner and her physician:

According to the HMO Subscriber Contract, section 5.1 - Non-Covered services, (o) - Drugs, Dietary Drugs, Food and Food Supplements, number (4) Medications may be excluded from coverage by HAP when there is a similar alternative outpatient prescription drug or treatment. . . .

As part of our investigation, your case was forwarded to our Pharmacy Care Management (PCM) Department where it was reviewed by one of our licensed Pharmacists, who was not involved in the initial denial request. The criteria for Enbrel requires a three month trial of at least one disease modifying therapy such as (Methotrexate, Cyclosporine or Acitretin). The information submitted by the physician did not indicate that you had tried and failed these medications. Therefore, a decision has been made to uphold the denied.

Director's Review

HAP determined that Enbrel was not medically necessary for the Petitioner because she did not meet its criteria for coverage. To determine whether Enbrel is medically necessary to treat the Petitioner's condition, the Director presented the issue to an independent review organization (IRO) as required by section 11(6) of the PRIRA, MCL 550.1911(6).

The IRO physician reviewer is board certified in dermatology and has been in active practice for more than twelve years. The IRO report included the following analysis and conclusion:

The Health Plan [i.e., HAP] indicated that the member does not meet its criteria for coverage of this medication. The Health Plan explained that it provides coverage for anti-tumor necrosis factor medications for the treatment of plaque psoriasis for patients who have tried and failed 3 months of at least one disease modifying agent (i.e. methotrexate, cyclosporine or acitretin), unless there is documented contraindication, have greater than 10% of body surface area covered

with plaque psoriasis and have failed to respond to at least one 30 treatment course of phototherapy with psoralen plus ultraviolet A or phototherapy with ultraviolet B. The Health Plan also explained that based on the member's records, she does not meet these criteria because she has not had an adequate trial of at least one disease modifying agent. . . .

* * *

Recommended Decision:

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

Rationale:

* * *

According to the information provided for review, the Health Plan requires 4 things of a patient prior to approving coverage for etanercept (Enbrel) for treatment of psoriasis: the patient must be over 18 years of age, the patient must have tried and failed either a traditional oral medication or have failed phototherapy, the patient must have a negative TB test and the patient must have moderate disease, which is defined as affecting greater than 10% of the body surface area. The MAXIMUS physician consultant explained that in this case, the physician's appeal letter documents that the member meets all of the criteria except the negative TB test. The TB test can be placed and interpreted within 2 days. The physician consultant noted that TB testing is often not initiated until after a patient is approved for Enbrel, because the test would not be necessary if the patient were not actually going to start taking this medication. The consultant also indicated that according to American Academy of Dermatology guidelines, treatment with etanercept is appropriate for the member. There are treatment algorithms in place that show how to treat a woman of childbearing potential with greater than 5% body surface area involvement. . . . The consultant noted that according to these algorithms, etanercept is appropriate first line treatment and is especially recommended after failing UVB therapy, which this member has failed. The physician consultant explained that if the TB test is negative, then the member does meet the Health Plan's criteria for treatment with Enbrel. The consultant also explained that Enbrel is standard of care for treatment of the member's condition.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Enbrel is medically necessary for treatment of the member's condition. [Citation 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 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 certificate of coverage. MCL 550.1911(15).

The Director accepts the IRO's recommendation and finds the prescription drug Enbrel is medically necessary and therefore a covered benefit under the certificate.

V. ORDER

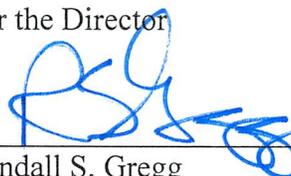
The Director conditionally reverses HAP's January 23, 2015, final adverse determination. Upon receipt of a negative TB test for the Petitioner, HAP shall cover the Petitioner's prescription for Enbrel, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, 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.

Annette E. Flood
Director

For the Director



Randall S. Gregg
Special Deputy Director