

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

In the matter of:

[REDACTED]

Petitioner

v

File No. 149183-001-SF

[REDACTED]

Plan Sponsor

and

MedImpact Healthcare Systems, Inc.

Plan Administrator

Respondents

Issued and entered
this 8th day of September 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On August 6, 2015, [REDACTED] authorized representative of [REDACTED] (Petitioner), filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by MedImpact Healthcare Systems, the administrator of the Petitioner's prescription drug benefit plan which is sponsored by the [REDACTED] [REDACTED]

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 prescription drug benefit plan is such a governmental self-funded plan.

The Director notified MedImpact of the appeal and asked it to provide the information used to make its final adverse determination. MedImpact furnished its response on August 12, 2015. The Director accepted the Petitioner's request on August 13, 2015.

This case involves medical issues so the Director assigned it to an independent review organization which provided its recommendation to the Director on August 27, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of coronary artery disease, hypertension, diabetes mellitus, and atrial fibrillation. She takes multiple medications including Coumadin but blood clotting tests have been unstable, putting her at risk for bleeding or thrombosis. Her physician recommended the prescription drug Xarelto, a blood thinner, to reduce her risk of major stroke associated with atrial fibrillation. The Petitioner requested that MedImpact authorize coverage for Xarelto 15mg, a drug that is on MedImpact's formulary.

MedImpact denied the request on the basis that it is not medically necessary. The Petitioner appealed MedImpact's decision through its internal grievance process. At the conclusion of that process, MedImpact maintained its denial and issued its final adverse determination May 28, 2015. The Petitioner now seeks a review of this adverse determination from the Director.

III. ISSUE

Is the prescription drug Xarelto medically necessary for the Petitioner's treatment?

IV. ANALYSIS

Respondent's Argument

In its May 28, 2015 final adverse determination MedImpact wrote:

A [physician] Board certified in Internal Medicine [and] Cardiovascular Disease reviewed the case and made the following determination:

The request for Xarelto is not medically necessary.

As noted in the medical records provided, the patient does not have any of the risk factors noted. As such, the use of Xarelto therapy would not be medically necessary.

Petitioner's Argument

In the request for external review, the Petitioner's authorized representative wrote:

Due to [Petitioner's] complex medical history, immunocompromised state, history of chronic infections and multiple medications, her INR is unstable posing a high risk for bleeding or thrombotic events. Therefore it is in

[Petitioner's] best interest to have a novel anticoagulant such as Xarelto to reduce risk of major stroke associated with her atrial fibrillation.

Director's Review

The question of whether the prescription drug Xarelto is medically necessary for treatment of Petitioner's condition 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 reviewer is a physician certified by the American Board of Internal Medicine with a subspecialty in cardiovascular disease. The reviewer is published in peer reviewed medical literature and is in active clinical practice. The IRO reviewer's report included the following analysis and conclusion:

It is the determination of this reviewer that the enrollee does not meet the health plan's criteria for the coverage of the prescription drug Xarelto.

The health plan's criteria require either a previous history of stroke, a low ejection fraction (EF), symptomatic heart failure, an age greater than seventy five (75) years, or an age of sixty five (65) and higher AND risk factors to allow for use of novel oral anticoagulant (NOAC) drugs.

However, [these criteria are] not in line with the current medical literature. Presently the standard of care dictates the use of the CHA2DS2-VASc score to determine the risk of future stroke. [Citation omitted.] With a history of [hypertension, diabetes mellitus] and female sex, the enrollee has a CHA2DS2-VASc score of 3. This makes use of Xarelto consistent with the medical literature and the standard of care.

* * *

It is the determination of this reviewer that the medication Xarelto is medically necessary for the treatment of the enrollee's condition.

* * *

Xarelto has United States Food and Drug Administration (FDA) indication for stroke prophylaxis in setting of non-valvular atrial fibrillation.

The enrollee's potential stroke risk demonstrates the need for an anticoagulant. The enrollee's fluctuating oral intake makes Coumadin a poor choice for anticoagulation. Efficacy of Xarelto is not affected by oral intake and as such is a more appropriate therapy in this case. Therefore, Xarelto is medically necessary for the treatment of this enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by MedImpact Healthcare Systems, Inc. for the prescription drug Xarelto be overturned.

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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 in this case is based on extensive experience, expertise, and professional judgment.

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

V. ORDER

The Director reverses MedImpact's May 28, 2015 final adverse determination. MedImpact shall immediately provide coverage for the prescription drug Xarelto, 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, toll free at 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 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