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. 152710-001**

Alliance Health and Life Insurance Company
Respondent

Issued and entered
this 18th day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 16, 2016, [redacted] (Petitioner) filed a request with the Director of Insurance and Financial Services (DIFS) for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug benefits through group plan underwritten by Alliance Health and Life Insurance Company (AHL). The Director notified AHL of the external review request and asked for the information it used to make its final adverse determination. AHL provided its response on March 23, 2016 and, after a preliminary review of the material submitted, the Director accepted the request for review.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on April 6, 2016.

II. FACTUAL BACKGROUND

The Petitioner is [redacted] years old and has a history of migraine headaches. She has failed to respond to numerous migraine drugs. The Petitioner's neurologist provided her with samples of the drug Midrin which successfully reduced her migraines. The Petitioner requested AHL provide coverage for continued use of Midrin. AHL denied the request for coverage, ruling that Midrin is not part of their formulary.

The Petitioner appealed the denial through AHL's internal grievance process which concluded with a final adverse determination, dated December 3, 2015, affirming the denial of coverage. The Petitioner now seeks the Director's review of that adverse determination.

III. Issue

Did AHL correctly deny the Petitioner coverage for the prescription drug Midrin?

IV. Analysis

BCBSM's Argument

In its December 3, 2015 final adverse determination, AHL wrote to the Petitioner:

> After considering all available evidence, previous decisions and your medication history, the recommendation is to uphold the original denial for Midrin. Midrin is not included on the member's Formulary and is non-formulary drug.
>
> Midrin is a combination product (Acetaminophen-Isometheplene-Dichloralphenazone) used to treat migraine headaches. Formulary options for migraine headaches are Sumatriptan formulations of tablets, nasal spray and injection. Also, Rizatriptan and naratriptan. Tablets of Ergotamine with caffeine are covered. Other medications are covered with prior authorization. These include: Axert, Frova, Relpax and Zolmitriptan. According to the letter of appeal from Dr. Young you have tried Sumatriptan, Naratriptan, Floricet, and Florinal and they have not helped with the headache pain. You have 4 to 6 headaches per month. HAP's Pharmacy Care Management (PCM)[1] recommends upholding the denial of Midrin because you have not tried all the formulary options. You are currently taking Topirimate 100mg daily to prevent migraine headaches, but you still have 4 to 6 headaches per month. The dose of Topirimate could be increased or you could use a different prevention medication. Formulary medications for prevention include Divalproex, Metoprolol, Propranolo, and Verapamil.

Petitioner's Argument

In a March 7, 2016 letter included with the request for external review, the Petitioner's doctor wrote:

> [Petitioner] is having 4-6 migraines per month. The pain is typically in the neck and radiates forward. She admits that the Topamax is controlling most of the headaches and that she has been taking Floricet and that it seems to work well for a little bit but the headaches come right back. [Petitioner] has tried and failed in the past Fiorinal, Fioricet, Imitrex, and Maxalt without any improvement with the pain. I prescribed samples of Midrin to [Petitioner] on 09-09-2015 and informed her to follow up with me if there isn't any improvement. [Petitioner] followed up with me by appointment on 10-12-12015 and informed me that she feels that she

1. AHL and HAP (Health Alliance Plan) are affiliated companies.

> is able to function better during the day when she is on the medication. She notices that when she forgets to take the Midrin the headaches come right back. I am very concerned with the denial due to the fact that my office is unable to provide more samples and she is completely out of the medication. I don't want to take her off as my patient has shown great improvement please reconsider the denial of Midrin.

Director's Review

AHL denied coverage for the drug Midrin because it is not included on its drug formulary and the Petitioner has not tried all the migraine drugs listed on its formulary. AHL's exception criteria are described in HAP's March 1, 2015 Commercial Formulary, which states:

> *What if* my *drug is not on the Formulary?*
>
> When your drug is not listed on the Formulary it is considered non-formulary. You or your doctor can ask us to make an exception and cover your drug. However it is best to first discuss with your doctor or pharmacist if one of the formulary alternatives will work for you.
>
> Exception approvals for standard non-formulary medications will process at the highest non specialty (Tier three) copayment
>
> Exception approvals for non-formulary Specialty medication will process at the highest Specialty (Tier four) copayment. Non-formulary specialty medications when approved for use by the plan can be required to be dispensed by Pharmacy Advantage
>
> *How do I request Prior Authorization or Formulary Exception?*
>
> You or your doctor can ask us to make an exception to our requirements or limits. You may also ask us to cover a medication not included on our formulary or ask us to exempt you from a formulary requirement through the exception process. Your doctor must submit a request to us indicating why formulary requirements should not apply.

The Michigan Insurance Code includes a similar provision which requires health insurers to provide coverage for nonformulary drugs. Section 3406o of the Insurance Code, MCL 500.3406o, provides:

> An insurer that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:
>
> * * *
>
> (c) Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for nonformulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiv-

> ing all information necessary to determine whether the exception should be granted.

The question of whether Midrin is a medically necessary and appropriate alternative 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 in active practice who is certified by the American Board of Psychiatry and Neurology with a subspecialty in clinical neurophysiology and is published in peer reviewed medical literature. The IRO report included the following analysis and recommendation:

> The standard of care in this clinical scenario would include trying alternative abortive migraine medications such as Midrin, other triptans (eletriptan, naratriptan, frovatriptan) or dihydroergotamine (DHE). Midrin is a combination drug including a mild vasoconstrictor, a mild sedative, and acetaminophen. Midrin was used in the past, prior to the availability of triptans, in the management of acute migraine attacks. Midrin is not Food and Drug Administration (FDA) approved.
>
> [Description of cited studies omitted.]
>
> The Michigan Insurance Code of 1956, section 500.3406o, provides details regarding prescription drug coverage and formulary restrictions. According to this, the insurers are required to provide for exceptions from the formulary drug limitations if a nonformulary drug is medically necessary and appropriate. Midrin, a combination drug including isometheptene, dichloralphenazone and acetaminophen qualifies as a medically necessary and appropriate drug for treatment of acute migraine attacks and therefore is considered for a nonformulary drug exception under this rule.
>
> The enrollee has a history of migraine headaches responding partially to Topamax. She currently has four to six migraine headaches per month and has had some difficulties treating these acute migraine attacks. The enrollee has failed to respond to triptans, including sumatriptan and rizatriptan. It is appropriate in her situation to try alternative abortative migraine medications such as Midrin, other Triptans, (eletriptan, naratriptan, frovatriptan) or DHE. Clinically the enrollee has had a good response to Midrin with no significant side effects and this would support continuing this medication. Therefore, for the reasons noted above, the medication Midrin is medically necessary for the treatment of the enrollee's condition.
>
> It is the recommendation of this reviewer that the denial issued by Alliance Health and Life Insurance for Midrin be overturned.

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. The Director can discern no reason why that analysis should be rejected in the present case. Therefore, the Director adopts the IRO analysis and finds that Midrin is a medically necessary alternative to the Respondent's formulary migraine drugs.

V. ORDER

The Director reverses Alliance Health and Life's December 3, 2015 final adverse determination. AHL shall immediately provide coverage for Midrin to treat the Petitioner's migraine headaches. See MCL 550.1911(17).

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 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