

**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. 154367-001

Health Alliance Plan of Michigan,

Respondent.

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Issued and entered  
this 3<sup>rd</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. BACKGROUND**

██████████ (Petitioner) was denied coverage for a prescription acute pain patch by her health plan, respondent Health Alliance Plan of Michigan (HAP), a health maintenance organization.

On June 28, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of HAP's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group prescription drug benefits through HAP. The Director immediately notified HAP of the external review request and asked for the information it used to make its final adverse determination. HAP responded on July 6, 2016. On July 7, 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 (IRO). The IRO provided its analysis and recommendation to the Director on July 21, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has a history of knee pain (bursitis). Her doctor prescribed the Flector Patch, a nonsteroidal anti-inflammatory patch for acute pain. HAP denied

coverage for the patch because it is not on its formulary and because other drugs for pain that are on the formulary had not been tried and failed.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated June 7, 2016, upholding the denial. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did HAP properly deny coverage for the Flector Patch?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination, HAP explained its position to the Petitioner:

. . . The first and second level appeal letters submitted state that Flector (diclofenac) is a transdermal patch used in the treatment of short-term pain (acute) associated with soft tissue injuries and is not included on your formulary (non-formulary drug). Your Formulary provides for coverage of diclofenac as immediate-release and delayed-release oral tablets, as well as a topical transdermal gel (Voltaren 1%). Additionally, your Formulary provides coverage for the following non-steroidal anti-inflammatory drugs (NSAIDs) that can be used to treat pain: meloxicam, nabumetone, piroxicam, etodolac, and naproxen. Celecoxib is also available on your Formulary with prior authorization. If NSAIDs cannot be used, alternatives include long- and short-acting opioid pain medications (e.g. morphine sulfate IR and ER, oxycodone IR, oxymorphone IR, tramadol).

Some non-opioid alternatives that may be appropriate for the treatment of your medical condition include: duloxetine, gabapentin, amitriptyline and muscle relaxants. Some of these alternatives may require prior authorization. . . .

Flector is not included on the Formulary as a prescription drug benefit and is called a non-formulary drug. The Formulary is a comprehensive list of medications that was developed with review by physicians and pharmacists from the community and contains other medications for the treatment of your condition. According to Formulary Policy, members must use all formulary medications for an appropriate length of time and demonstrate that these medications have either been ineffective or have caused significant and unacceptable side effects before they may ask for

an exception for coverage of a medication not included on this list. According to the appeal letter and past claims, you have only tried Voltaren and Ibuprofen. Therefore, a medical exception for the non-formulary drug Flector is denied because you have not tried all Formulary options as per the HAP Formulary Policy.

### Petitioner's Argument

On the external review request form, the Petitioner wrote:

I request an external review of the decline of an effective treatment by my HAP HMO. The treatment (Flector patches) was approved around 5 years ago and was effective in treating my knee arthritis pain. Based on this fact, a specialist prescribed Flector patches again for my recent arthritis symptoms. However, Flector patches currently are not on the Formulary list. I claim that the rigid interpretation of HAP's Formulary Policy in my individual case and the consequent decline of the relatively inexpensive Flector treatment are jeopardizing my well-being...

### Director's Review

HAP declined to cover the Flector Patch because it is not on its formulary. HAP will consider exceptions to its formulary limitation if formulary drugs are tried and are ineffective or cause serious side effects and a non-formulary drug is medically appropriate.<sup>1</sup>

The question of whether the Flector Patch is a medically necessary alternative to the drugs on HAP's formulary was presented to an IRO as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in physical medicine and rehabilitation and pain management and has been in active practice for more than 12 years. The IRO reviewer's report included the following analysis and recommendation:

#### **Recommended Decision:**

The MAXIMUS physician consultant determined that Flector patches are not medically necessary for treatment of the member's condition.

#### **Rationale:**

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Flector was requested for the member in January and March 2016. The member reported having tried Voltaren gel for 7 to 8 weeks without im-

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<sup>1</sup> See section 3406o of the Michigan Insurance Code, MCL 500.3406o.

provement. Correspondence from the member references that she occasionally experiences short-term pain in the soft tissue below the left knee. The member had a history of stomach issues in 2009. According to the information provided for review, the member was prescribed 30 Flector patches in 2009, which had lasted until 2016. Episode of knee pain were reported to have occurred 1 to 2 times per year. The member stated that the last such episode occurred after a left ankle injury, which left her with an inability to exercise for two months. A CT scan of the member's abdomen performed in October 2009 due to a clinical indication of abdominal pain and weight loss showed findings of uterine fibroids and resolved right hydrosalpinx.

The MAXIMUS physician consultant explained that the member has not failed formulary alternative medications. The physician consultant indicated that the member had abdominal pain due to fibroids and there is no apparent contraindication to a selective NSAID. There are other formulary non-NSAID medications that could be tried, which identified in the Health Plan's determination letters. The consultant explained that generic and over the counter topical medications including a topical salicylate could be also considered. The consultant noted that the member appears to have recurrent patellar tendinitis and a further assessment for this condition may identify other treatments and preventative measures.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Flector patches are not medically necessary for treatment of the member's condition.

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, discerning no reason why the IRO's recommendation should be rejected, finds that HAP is not required to make an exception to its formulary limitation.

## V. ORDER

The Director upholds HAP's 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 sixty 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

A handwritten signature in black ink, appearing to read 'R. S. Gregg', written over a horizontal line.

Randall S. Gregg  
Special Deputy Director