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. 148338-001**

Blue Cross Blue Shield of Michigan

Respondent

Issued and entered
this 13th day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 11, 2015, (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*. As originally filed, the Petitioner's request for review was incomplete. Additional information was provided on June 16, 2015 and, at that time, the Director accepted the case for review.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The prescription drug benefits are defined in BCBSM's *Preferred RX Program Certificate SG.* The drugs covered under the *Preferred RX* certificate are listed in BCBSM's *Custom Select Drug List*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on June 30, 2015.

The Director assigned an independent medical review organization to address the medical issues in the case. The review organization's report was submitted to the Director on July 7, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of leg and knee pain which he has treated with non-steroidal anti-inflammatory drugs (NSAIDs). He also has a history of gastroesophageal reflux disease (GERD). His physician told him that NSAIDs make his GERD worse. The Petitioner and his

physician submitted to BCBSM a request for coverage for Celebrex (celecoxib) to treat his leg pain. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM affirmed its denial in a final adverse determination dated May 27, 2015. The Petitioner now seeks a review of that adverse determination from the Director.

III. Issue

Did BCBSM correctly deny coverage for the prescription drug Celebrex?

IV. Analysis

Petitioner's Argument

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

> The patient has GERD that requires treatment. He can't take NSAIDS…it makes the symptoms worse. Celebrex works better for him with no GI issues.

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

> You are covered under the *Preferred Rx Program Certificate for Small Groups (SG)*. As indicated in **Section 3: Prescription Drugs Not Covered** (Pages 17 through 20) of the *Certificate*, your plan does not cover anything other than drugs and services listed as covered. The covered drugs for your group's plan are listed in the BCBSM *Custom Select Drug List* (available on www.bcbsm.com). As Celecoxib is not listed in the *Drug List*, it is not covered by your plan.
>
> To ensure all possible consideration was given, a Clinical Pharmacist, RPh reviewed the submitted documentation and determined the following:
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>> The requested medication is excluded from coverage under your Custom Select drug plan. Oral covered alternatives include: generic Naprosyn (naproxen), generic Lodine (etodolac), generic Relafen (Nabumetone), generic Indocin (indomethacin), and generic Cataflam (diclofenac). For a complete list of covered alternatives please refer to your Custom Select drug list.

> Please Note: Celecoxib prescribing information has the same black box warning about GI risk as traditional oral nonsteroidal anti-inflammatory drugs (NSAIDs). Acetaminophen, opioids or tramadol are other options for treating pain.

Director's Review

A Michigan statute, the Uniform Disability Insurance Policy Provisions Law (MCL 500.3401, *et seq.*) includes the following provision:

> 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.... [MCL 500.3406o]

The *Preferred RX* certificate also allows for exceptions to the drug list limitation:

> **Request for Drugs Not on BCBSM Drug List**
>
> If your prescription drug coverage is limited to an approved drug list, BCBSM must approve coverage of a prescription drug not on the list before it is dispensed. If approval is not obtained before the drug is dispensed, the drug will not be covered.
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> You, your designee, or the provider who prescribes a drug that is not on BCBSM's drug list should contact BCBSM and follow BCBSM's exception request process. We will notify you or your designee, the prescribing provider or the provider's designee whether the request has been granted within 24 hours after receiving all of the information needed to decide whether your request should be granted.

The question of whether Celebrex is a medically necessary and appropriate alternative for treatment of the Petitioner's condition was presented to an independent review organization (IRO) 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 clinical practice for more than 20 years who is board certified in internal medicine and is familiar with the medical management of the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

> According to the documentation provided for review, the member tried therapy with traditional NSAIDs, such as ibuprofen, but had continued bilateral knee pain, the record from a 4/30/15 visit to his treating physician indicates that the member reported that he was experiencing worsening gastroesophageal reflux disease, over the prior 3 weeks, as well as pain in both knees for 6 months....[T]he information submitted for review shows that the member has significant bilateral degenerative joint disease of the knees and has had increased gastroesophageal-related issues with Meloxicam. Meloxicam offers similar efficacy to recommended doses of well-established NSAIDs, including diclofenac, piroxicam and naproxen, but has reduced risk of certain gastrointestinal adverse effects, as demonstrated by randomized clinical trials, large scale clinical outcome studies, pooled analyses and meta-analyses. The member's physician discontinued Meloxicam due to gastroesophageal reflux disease.
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> [O]steoarthritis is the most common form of arthritis and that the goal of pharmacologic treatments for this diagnosis is to decrease associated pain and inflammation, which can improve function. The Osteoarthritis Research Society International expert consensus guidelines recommend either a COX-2 selective agent or nonselective NSAID, dependent on the presence of cardiovascular or gastrointestinal risk factors for the management of osteoarthritis of the hip and knee....[I]n some patients, intolerability to NSAIDs can limit options for treatment of osteoarthritis symptoms....[A]ll NSAIDs carry a risk of serious gastrointestinal side effects, such as bleeding, but more common gastrointestinal tolerability-related side effects include abdominal pain, nausea and dyspepsia. Celebrex (celecoxib) is a COX-2 selective NSAID with demonstrated comparable efficacy in osteoarthritis of the knee versus both naproxen and ibuprofen.
>
> Pursuant to the information set forth above and available documentation... Celebrex is 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. In addition, the IRO recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director can discern no reason why the IRO's recommendation should be rejected in the present case and, therefore, finds that Celebrex is medically necessary for the Petitioner.

V. ORDER

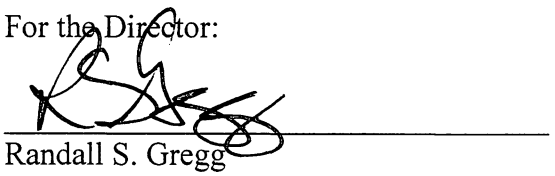
The Director reverses BCBSM's final adverse determination of May 27, 2015. BCBSM shall immediately provide prescription drug coverage for Celebrex, and shall, within seven days, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals 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 60 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:



Randall S. Gregg
Special Deputy Director