

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. 154225-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 22nd day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 20, 2016, ██████████ (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 request concerned her health insurer's denial of coverage for a medical test. The Director accepted the request for review on June 27, 2016.

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Simply Blue HRA Group Benefits Certificate LG*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on June 28, 2016.

The case involves a medical issue so it was assigned to an independent review organization which submitted its recommendation to the Director on August 11, 2016.

II. FACTUAL BACKGROUND

On March 11, 2016, the Petitioner had a laboratory test performed as part of her annual physical. The test was a lipoprotein analysis by nuclear magnetic resonance, CPT code 83704.¹

1. Medical care is classified according to a numerical coding system compiled by the American Medical

The charge for the test was \$97.00. BCBSM denied coverage, ruling that the test is investigational and, therefore, not a covered benefit under her health plan. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated June 3, 2016, affirming its decision. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Was BCBSM correct to deny coverage for the Petitioner's lipoprotein test?

IV. ANALYSIS

Respondents' Argument

In its final adverse determination, BCBSM explained its decision to the Petitioner:

An associate medical director, board-certified D.O. in Emergency Medicine reviewed your claim, your appeal, and your health care plan benefits for [BCBSM] and determined:

"83704 is investigational – Per the BCBSM medical policy 'Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease' this test is considered investigational. The use of this diagnostic testing has not been scientifically demonstrated to improve patient clinical outcomes better than conventional cholesterol testing."

You are covered under the *Simply Blue HRA Group Benefits Certificate LG (for large, insured group customers)*. As indicated on page 137 of the *Certificate* under **Experimental Treatment**, "we do not pay for experimental treatment. This includes experimental drugs and devices." As a result, the test is not covered under your contract.

Petitioner's Argument

In her external review request, the Petitioner wrote:

Payment of \$97.00 for blood work done in connection with an annual physical. BCBSM has denied payment. Claims I should have called them with the service code to be sure covered — *who*

Association and published in its manual, *Current Procedural Terminology*. The codes in this manual, usually five digit numbers, are commonly referred to as "CPT codes" or "procedure codes" and are used by providers and others to describe medical services when claims are submitted to insurers.

asks or second guesses their doctor when tests are requested? The ACA says physicals and affiliated testing must be done and [paid] 100%. I don't think BCBSM should be second guessing the doctor — My son has a cholesterol problem I suspect this is why the test was requested. Healthcare costs plenty now, this is why we need universal healthcare and the "second guessing, trying to avoid payment" insurance companies should be eliminated.

In a letter dated August 3, 2016, the Petitioner's physician said:

My patient had her normal lab work done at my office and she has a high total cholesterol. Her son is a patient of mine also and he has a very abnormal cholesterol. Many experts in cholesterol would agree that it is important to at least once do the advanced lipoprofile test in order to know what any person's real risk is. [Petitioner] had this done, [BCBSM] has covered this test for quite some time. I was unaware that their coverage was changed. However I do feel this is a mistake as it is so valuable when trying to anticipate someone's risk of heart disease and stroke. I feel you should cover this test as it is so valuable. Please consider covering it for this patient.

Director's Review

The federal Patient Protection and Affordable Care Act (ACA) requires health plans and health insurers offering group or individual health insurance coverage to provide benefits for certain preventive care services without imposing cost sharing requirements. See 42 USC §300gg-13 and regulations at 45 CFR §147.130. The required preventive care benefits are those recommended by the United States Preventive Services Task Force and include "screening for cholesterol." BCBSM's *Simply Blue* certificate (pages 9, 27, and 80-83) covers those services.

The certificate also covers medically necessary diagnostic laboratory and pathology services (pages 19 and 38). However, experimental treatment and services related to experimental treatment are excluded from coverage under Section 6: General Conditions of Your Contract (pp.137-138).

Experimental treatment is defined on page 156 of the certificate as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The lipoprotein test is not a preventive service under the ACA that must be covered with no cost sharing.

The question of whether the lipoprotein test employed in this situation was experimental/investigational 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 was a physician in active practice who is board certified in family medicine and is an assistant professor at a university based school of medicine. The IRO report included the following analysis and recommendation:

Current evidence based literature suggests a standard of care for hyperlipidemia screening based on the risk of cardiovascular disease (CVD). In female patients with a low risk of CVD, screening should start at age 45. However, current literature does not support the use of NMR lipoprotein analysis for routine screening. A prospective study of CVD risk prediction showed NMR lipoprotein analysis to be comparable but not superior to standard lipid or apolipoprotein measurement. The use of NMR lipoprotein analysis has been noted to have no clear benefit over measuring particle number in most studies to date.

Medically and scientifically accepted evidence clearly demonstrates that treatment should meet all of the following:

- The treatment is safe
- The treatment can be expected to produce greater benefits than the standard treatment without posing a greater adverse risk to the insured.

The enrollee does not meet the above as the medical or scientific evidence does not demonstrate that the expected benefits of the requested health care service are more likely to be beneficial to the enrollee than any available standard health care service.

In high cardiometabolic risk patients, the measurement of low-density lipoprotein (LDL) particle size may be of benefit for improving risk stratification and as a guide to titration/adjustment of lipoprotein modifying therapy. As the enrollee is not currently receiving modifying therapy, the measurement of NMR lipoprotein is not supported by evidence based literature. Further, it is not approved by the Federal Food and Drug Administration (FDA).

The enrollee presented for an annual wellness screening which included NMR lipoprotein analysis, which is neither superior to standard lipid testing nor approved by the FDA. Therefore, based on the documentation submitted for review and current evidence based literature, the laboratory and pathology services (procedure

code 83704) performed on March 11, 2016 were experimental/investigational for this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for lab and pathology services (procedure code 83704) performed on March 11, 2016 be upheld. [References 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 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 in this case, finds that the March 11, 2016, laboratory and pathology service was experimental for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

V. ORDER

The Director upholds BCBSM'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 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