

**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. 154601-001

Humana Insurance Company,

Respondent.

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

**ORDER**

**I. PROCEDURAL BACKGROUND**

████████████████████ (Petitioner) was denied coverage for a laboratory test by her health insurer, Humana Insurance Company (Humana).

On July 18, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of Humana's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits from Humana. The Director immediately notified Humana of the external review request and asked for the information it used to make its final adverse determination. Humana responded on July 22, 2016. After a preliminary review of the material submitted, the Director accepted the request on July 25, 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 8, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in a *Certificate of Insurance* issued by Humana (the certificate).

The Petitioner has a large cyst on her left ovary and a history of pelvic pain. On March 17, 2016, her physician performed the OVA1 test (CPT code 81503), a blood test used to evaluate the risk of ovarian cancer. The test was processed by Aspira Labs and the charge was \$1,495.00.

Humana denied coverage for the test, saying the Petitioner did not meet its medical necessity criteria. The Petitioner appealed the denial through Humana's internal grievance process. At the conclusion of that process Humana issued a final adverse determination dated June 24, 2016, affirming its denial. The Petitioner now seeks a review of Humana's final adverse determination from the Director.

### III. ISSUE

Did Humana correctly deny coverage for the OVA1 test as not medically necessary for the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### Humana's Argument

In its final adverse determination, Humana told the Petitioner:

Thank you for your patience while we investigated your appeal regarding the denial of the laboratory Services rendered by Aspira Labs, Inc. on March 17, 2016. A private review agent, who is board certified in obstetrics & gynecology, thoroughly reviewed the following information:

- Your appeal request
- Your medical records
- Humana's Medical Coverage Policy for Tumor Markers for Diagnosis and Monitoring of Cancer
- Your Benefit Plan Document (BPD)

Unfortunately, we're unable to approve your appeal on the denial of the laboratory services rendered by Aspira Labs, Inc. on March 17, 2016.

Why we were unable to approve your appeal

We were unable to approve your appeal because based on a review of the clinical documentation, the appeal information, and the Humana Pharmacy Coverage Policy, the OVA1 testing (service code 81503) does not meet the medical necessity criteria for coverage.

The private review agent stated that "Based on a review of the clinical documentation, the appeal information, and Humana coverage policy, CPT code 81503 does not meet the criteria to be considered medically necessary. Specifically, the supplied medical policy states that the OVA1 testing is 'not covered.'

At this time, there are no screening tools for ovarian cancer. Biomarkers such as CA125, HEP4, and OVA1 are imprecise and are not specific enough to be accurately used for ovarian cancer screening. Because of this, their utility in a clinical setting is limited. Furthermore, the American Congress of Obstetricians and Gynecologists Committee Opinion on the role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer noted that the clinical utility of the OVA1 Test 'is not yet established.'

The Society of Gynecologic Oncology states that:

As physicians who are expert in the care of women with gynecologic cancers, members of the SGO are supportive of scientific advances such as OVA1 that may help healthcare providers better detect when referral to a gynecologic oncologist is indicated. However, this test has not been approved for use as an ovarian cancer screening tool, nor has it been proven to result in early detection or reduce the risk of death from this disease.

Therefore, based on the submitted guidelines and clinical information provided, medical necessity has not been established for the CPT code 81503 in this patient's case."

### Petitioner's Argument

In an undated letter accompanying the external review request, the Petitioner said:

I went to great lengths to insure I was meeting with an in-network doctor for my issues.

The in-network doctor recommended and ordered blood work done along with other things during my exam. It never crossed my mind to review all procedures being done, and supplies used with the insurance company while in the doctor's office with my clothes off.

Since it was an in-network doctor and in-network hospital one would think they know all of the rules for services better than me.

The anesthesia service doctors were not in-network I came to find out after my surgery and they billed me full price. Humana ended up treating

them as in-network since they were working with in-network doctors and in-network hospitals. Which is how I would expect it to work being treated by an in-network doctor.

What is the point of having in-network doctors and contracts with them if I have to read the manual and determine medically which procedure, test, or supplies are approved and necessary and [accepted] by Humana.

Requested resolution is the Aspira Labs bill be covered as it was ordered by in-network Dr ... We had no control over where it was sent.

### Director's Review

The certificate (p. 54) excludes coverage for treatments, services, supplies or surgeries that are medically necessary. The certificate (p. 106) defines "medically necessary" as

health care services that a health care practitioner exercising prudent clinical judgment would provide to his or her patient for the purpose of preventing, evaluating, diagnosing or treating a sickness or bodily injury or its symptoms. Such health care service must be:

- In accordance with nationally recognized standards of medical practice;
- Clinically appropriate in terms of type, frequency, extent, site, and duration, and considered effective for the patient's sickness or bodily injury;
- Not primarily for the convenience of the patient, physician or other health care provider; and
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the patient's sickness or bodily injury.

For the purpose of medically necessary, generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations, the views of physicians practicing in relevant clinical areas and any other relevant factors.

Humana denied coverage for the OVA1 test because the Petitioner did not meet the criteria of its medical policy titled "Tumor Markers for Diagnosis and Monitoring of Cancer."

Therefore, the question of whether the OVA1 test was medically necessary for the medical management 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 physician reviewer is board certified in obstetrics and gynecology and gynecologic oncology, is familiar with the medical management of patients with the member's condition, and is in active practice. The IRO report included the following analysis and recommendation:

The OVA1 test is a biomarker assay consisting of serum proteins, including CA125. A risk assessment prediction for ovarian cancer is provided using an algorithm based on these five proteins. The MAXIMUS physician consultant indicated that this testing has provided an increase in sensitivity, but decrease in specificity sometimes by threefold. The physician consultant explained that while poor specificity (false positives) for the CA125 tumor marker alone has been well described in reproductive aged women who are still having menstrual cycles, the specificity and sensitivity is much improved in post-menopausal women with adnexal/ovarian masses. The consultant noted that in addition, this member's ultrasound showed benign features, such as simple appearance of the cyst with no free fluid and normal Doppler flow. These findings are predictive of a benign pathology.

The physician consultant explained that standard of care would allow for use of ultrasound and CA125 alone in predicting the member's risk of ovarian cancer and subsequent need for referral to a subspecialist. The physician consultant explained that OVA1, while it contains CA125, is not prerequisite to this preclinical decision making process. The physician consultant indicated that the Health Plan's medical criteria regarding the OVA1 test are therefore consistent with standards of care.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the OVA1 testing performed on 3/17/16 was not medically necessary for diagnosis and treatment of the member's condition. [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 OVA1 test is not medically necessary for the treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

**V. ORDER**

The Director upholds Humana'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:

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

Randall S. Gregg  
Special Deputy Director