

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. 145618-001-SF

████████████████████

Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,
Respondents.

Issued and entered
this 20th day of February 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 5, 2015, ██████████ on behalf of her minor daughter ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* The Petitioner seeks a review of an adverse health care determination made by Blue Cross Blue Shield of Michigan (BCBSM). On January 12, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

The Petitioner receives health care benefits through a group plan sponsored by ██████████ (the plan), a local unit of government self-funded health plan subject to Act 495. The plan is administered by BCBSM. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on January 22, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

Initially, this case appeared not to involve medical issues so it was not assigned to an independent review organization (IRO). However, upon further evaluation it was determined that it would benefit from a medical review and it was assigned to an IRO, which provided its report and recommendation on February 5, 2015.

II. FACTUAL BACKGROUND

The plan's benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC²* (the certificate).

The Petitioner is developmentally disabled. From June 3 to July 29, 2014, she had hyperbaric oxygen therapy (HBOT) to improve her condition (40 sessions). The Petitioner's mother paid for the HBOT at the time it was performed and then sought reimbursement from the plan for the \$5,400.00 charge.

When BCBSM denied coverage for the HBOT, the Petitioner appealed through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated December 1, 2014, in which its representative said:

... After review, the denial of payment is maintained. We need more information about the service to consider payment for it. Without the additional information, no payment can be made, and you remain responsible for the non-covered charge.

The service indicated on the billing statement was "unlisted special service, procedure or report" (procedure code 99199). If a service is reported as an unlisted procedure, BCBSM needs supporting documentation about the procedure. When we initially denied the claim, we advised you that additional information was needed. . . .

... At this time, I must base my decision on the information already received. If we receive the records at a later date, we will conduct a review.

Absent receipt of the medical records, this is our final determination regarding your grievance. . . .

The Petitioner then filed her request with the Director seeking a review of that adverse determination.

² BCBSM form no. 457F, effective 01/14.

III. ISSUE

Is BCBSM required to cover the Petitioner's hyperbaric oxygen therapy?

IV. ANALYSIS

BCBSM's Argument

On January 23, 2015, BCBSM furnished additional information as part of its response to the external review request:

At the time of the [managerial-level conference], BCBSM did not have the medical records for the services. Since that time, BCBSM has received and reviewed the records by a board-certified D.O. in Internal Medicine, who determined as follows:

All documentation was reviewed. Member is appealing non-payment of Hyperbaric Oxygen Therapy (HBO) performed from 6/3/14 - 7/29/14 for her daughter with developmental delay. This therapy was not ordered by a physician, there is no diagnosis code used and the therapy is billed with an unlisted special service procedure code. The mother heard about the therapy on the radio. According to BCBSM Policy: "Hyperbaric Oxygen Therapy" this therapy is approved for members meeting specific inclusion criteria and this policy [specifically] excludes autism spectrum disorders or developmental delay as HBO is considered investigational for treating these conditions. Member does not meet inclusion criteria for HBO therapy. Therefore, we are unable to approve this Hyperbaric Oxygen Therapy as described under 99199.

Petitioner's Argument

On the external review request form the Petitioner's mother said:

The claim was denied because of the facility's code. When talking to the facility that is the only code they can charge for hyperbaric oxygen therapy. Licensing issues. The service was given to my daughter regardless of the code used. I want to be reimbursed for the \$5,400.00 spent on this therapy.

Director's Review

The certificate explains that HBOT is covered when it is rendered as an inpatient hospital service at a participating hospital or as an outpatient hospital service, which is not the case here. In "Section 3: What BCBSM Pays For" (pp. 45, 46), the certificate says:

Hospital Services

* * *

The services in this section are in addition to all other services listed in this certificate that are payable in a participating hospital, including surgery beginning on Page 94.

Locations: The following services are payable in a participating hospital or an approved outpatient location as listed below.

We pay for:

- Inpatient hospital services:

* * *

- Hyperbaric oxygenation (therapy given in a pressure chamber)

- Outpatient hospital services:

Services that are payable in an inpatient hospital are also payable as outpatient services (except for those related to inpatient room, board, and inhalation therapy). In addition, the following services are payable:

- Services to treat chronic conditions are payable when they require repeated visits to the hospital.

The certificate (p. 126) also excludes coverage for “experimental treatment,” which is defined (p. 145) as

[t]reatment 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.”

BCBSM initially denied coverage for the Petitioner’s HBOT because of a lack of supporting documentation. Subsequently, after receiving medical records, BCBSM determined that the HBOT was experimental for the treatment of the Petitioner’s condition. BCBSM’s medical policy title “Hyperbaric Oxygen Therapy - Systemic,” does not include developmental delay as one of the conditions or diagnoses for which HBOT is appropriate.

The question of whether HBOT is experimental treatment for the Petitioner’s condition 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 physician reviewer is board certified in pediatrics with subspecialty certification neonatal-perinatal medicine; an assistant clinical professor at a university-based college of medicine; a member of American Academy of Pediatrics, the Society for Pediatric Research, and the American College of Osteopathic Pediatricians; published in peer reviewed medical literature; and in active clinical practice. The IRO report included the following analysis and

recommendation:

Reviewer's Decision:

It is the determination of this reviewer that the hyperbaric oxygen therapy is experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The enrollee is noted to be a six (6) year old female child who functions at the level of a one (1) year old child with severe cognitive delays. Standard of care for treatment of a child with developmental delays would include speech therapy, occupational therapy and physical therapy.

HBOT has not been studied adequately in randomized clinical trials to support its use for the treatment of children with cognitive delays or developmental delays. Since HBOT has not been adequately studied as to the benefits or adverse effects as a result of its use in children with developmental delays, it is considered experimental/investigational and therefore, it cannot be considered medically necessary in the treatment of developmental delay.

A review of the current literature related to the use of HBOT for children with autism/developmental delays published within the past five (5) years is very limited. The medical or scientific evidence does not demonstrate that the expected benefits of the requested health care services are more likely to be beneficial to the enrollee than any available standard health care service. Limited clinical information in the form of randomized clinical studies is currently available to support the recommendation for HBOT for children with autism or developmental delays. However, there is no existing documentation to support that the use of HBOT is superior or even equal to standard health care services including occupational therapy, speech therapy and physical therapy for children with cognitive delays/developmental delays.

* * *

HBOT is approved by the Federal Food and Drug Administration (FDA) for 14 conditions, however, HBOT has not been approved by [FDA] for the enrollee's stated condition of developmental delays or Autism. The use of HBOT as a treatment for children with developmental delays cannot be recommended at this time. Since HBOT has had limited study in children, and there are no large randomized clinical trials to support or refute its use, at this time the use of HBOT would be considered experimental/investigational when used for the treatment of children with autism or developmental delays.

In summary, in the small clinical studies that have evaluated the use of HBOT in children with autism or cerebral palsy, no clinically significant benefit was reported. The use of HBOT cannot be supported as the standard of care for

children with autism or developmental delays. At this time, the use of HBOT would be viewed as experimental/investigational at best since none of the reported studies have documented a clinically significant benefit attributed to HBOT.
[Citations 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 experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that hyperbaric oxygen therapy is investigational treatment for the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

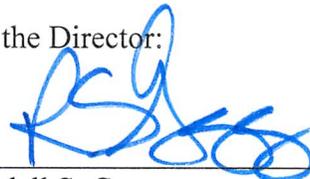
V. ORDER

The Director upholds BCBSM's denial in its final adverse determination of December 1, 2014, for the reasons stated above.

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 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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director