

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 106346-001

v

Blue Cross and Blue Shield of Michigan
Respondent

Issued and entered
this 4th day of January 2011
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On July 22, 2009, XXXXX, on behalf of her infant son XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Petitioner is an eligible dependent under his mother's health care coverage through the Michigan Education Special Services Association (MESSA). The plan is underwritten and administered by BCBSM. His benefits are defined in the MESSA *Choices II Group Insurance for School Employees* certificate of coverage.

After an assessment of the material submitted, the Commissioner accepted the request for external review on July 30, 2009. The Commissioner notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on August 11, 2009.

Initially, it was thought the issue in this matter could be resolved by analyzing the contract alone. Later, an analysis of the medical issues was ordered from an independent review organization. The results were received on December 29, 2009.

II FACTUAL BACKGROUND

The Petitioner was born XXXXX, and was soon diagnosed with severe cow's milk and soy-allergic colitis. A number of food substitutes were tried under the supervision of his pediatrician. None appeared to work and Petitioner continued to have severe stomach pain. After several months of trials, the pediatrician prescribed Neocate, an amino acid-based food substitute available only by prescription. With the Neocate diet, Petitioner's symptoms ended. Petitioner's parents requested BCBSM provide coverage for the cost of the Neocate. BCBSM denied the request.

The Petitioner appealed BCBSM's denial. BCBSM held a managerial-level conference on June 26, 2009, and issued its final adverse determination on July 13, 2009, maintaining its denial.

III ISSUE

Did BCBSM properly deny coverage for the Petitioner's Neocate formula?

IV ANALYSIS

Petitioner's Argument

Petitioner's parents say he was in severe pain and agony following every feeding and displayed extreme discomfort at all hours of the day or night. After repeated doctor and specialist visits and use of various formulas and medications, the Petitioner was prescribed Neocate on April 23, 2009. Using Neocate, the Petitioner was no longer in distress after his feedings.

Petitioner's mother says that the decision to put the Petitioner on Neocate was a proactive approach. Waiting for serious complications and severe health problems to occur before feeding him Neocate was not something they were comfortable with.

The Petitioner's mother argues that the Neocate is medically necessary for her son for

the first year of his life. It was prescribed by Petitioner's pediatrician who provided the following reasons why Neocate is essential for Petitioner:

I feel that Neocate is a medical necessity and will provide the proper dietary management for this patient, who has been diagnosed with Esophageal Reflux and Milk Protein Allergy. Without the use of Neocate, my patient may experience complications of the condition, which may result in increased medical costs.

Neocate is specifically designed to meet the nutritional needs of infants with severe cow milk protein allergy or multiple food protein allergies who are unable to digest a normal diet or other hypoallergenic products. Its unique formulation (100% free amino acids, milk free, gluten free, and soy protein free) provides complete nutrition and can be the sole source of nutrition for the first year of life. Neocate's elemental composition requires minimal digestion, thus is ideally suited for patients with compromised gastrointestinal function.

Clinical trials have shown that the use of Neocate ensures a normal growth pattern for infants who would otherwise experience failure to thrive. The FDA classified Neocate as an "Exempt Infant Formula" which must be used under medical supervision and is not sold over the counter or at retail level.

BCBSM's Argument

In its final adverse determination, BCBSM stated the reasons why coverage was denied:

MESSA/BCBSM considers special formulas to be medically necessary when a baby or child has a severe underlying medical condition. In [Petitioner's] case, there is evidence of milk allergy and GERD with colic. However, he maintains his growth and weight. His condition is not a severe disabling gastrointestinal disorder. As a result, the criteria for payment of Neocate is not met, and no benefits can be approved.

The final adverse determination cites two policy provisions from the *Choices II* certificate of coverage: section 10 excludes coverage for services and supplies that are not medically necessary and section 1 defines medical necessity for physician and hospital services. The definition of medical necessity for physician services is:

Determination by physicians acting for BCBSM, based on criteria and guidelines developed by physicians for BCBSM who are acting for their respective provider type and/or medical specialty, that:

- the covered services is accepted as necessary and appropriate for the patient's condition. It is not mainly for the convenience of the member or physician.
- in the case of diagnostic testing, the results are essential to and are

used in the diagnosis or management of the patient's condition.

Note: In the absence of established criteria, medical necessity will be determined by physicians according to accepted standards and practices.

Commissioner's Review

A determination to uphold or reverse an insurer's claim denial is based on the language of the policy or certificate of coverage under which an individual receives health care benefits. In the present case, the certificate of coverage does not specifically address prescribed special foods. The certificate does contain the standard requirement that, in order to be covered, a service must be medically necessary.

For BCBSM benefit plans issued to MESSA members, a written policy statement does exist which describes the circumstances under which prescribed food products will be covered. The policy statement is titled "Formula and Nutritional Supplements." The relevant portions of the policy are reproduced below:

Generally speaking and based on medical review we would only cover formula when it is the sole source of nutrition.

* * *

In all cases, adult, child or infant, if there is no feeding tube, and we are asked to cover the formulas, we need to know the diagnosis, how many calories per day (how much solution is the person to drink/day), what is their regular oral intake of foods/fluids, history, and physical notes, and how long the formula is necessary. . . . In addition to asking if the formula/supplement is necessary, i.e. is there a serious underlying medical condition that necessitates the use of this formula/supplement, we should ask for how long the formula/supplement is being approved before a new review would be necessary.

Infant payable up to age 1, beyond age 1 necessitates review of medical necessity. Adults require periodic review of medical necessity.

Coverage for special foods and formula will be available to patients with severe medical conditions who have had ample trial of over the counter foods and formulas without success. A physician's prescription is required. Severe medical conditions include:

- documented frank, gross gastrointestinal bleeding which includes diarrhea with blood in stools (not just a single episode)
- failure to thrive
- hospitalization resulting from the severe medical condition
- eosinophilic gastroenteritis or eosinophilic esophagitis proven by biopsy
- short bowel syndrome

Coverage for special foods and formulas will not be available for the following isolated symptoms:

- gasey
- colicy
- constipation
- common allergies (milk protein, lactose intolerance)
- otherwise healthy individual

Note: Special formulas are amino acid based formulas such as Neocate, Elecare and Nutrimigin AA. Other baby formulas are not considered "special foods/formulas."

* * *

Candidates' medical documentation must support the diagnosis of a covered condition. Special/medical foods or formulas will be covered when the special food is prescribed and provided under the supervision of a licensed physician and clinical nutritionist. Documentation must support that such foods are recommended to prevent death and serious disability. The cost of special foods must be over and above the cost of usual foods.

It is Respondent's position, stated in their position papers of August 11 and December 21, 2009, that the denial of Neocate is correct based on the MESSA medical policy statement and the findings of MESSA's medical consultants. They concluded that, in spite of milk allergy and GERD with colic, the Petitioner maintained his growth and weight. Therefore, his condition is not a severe disabling gastrointestinal disorder.

The question of whether the Petitioner's Neocate formula was medically necessary 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. The IRO reviewer's report said in part:

[T]he Health Plan's policy provides coverage of special foods and formula, such as Neocate, for patients with severe medical conditions. . . . [P]etitioner] does not have a severe medical condition. . . . [P]etitioner] does not have documented frank, gross gastrointestinal bleeding, failure to thrive, eosinophilic gastroenteritis or eosinophilic esophagitis proven by biopsy or short bowel syndrome. . . . [P]etitioner] has not required hospitalization due to a severe medical condition. . . . [T]he Health Plan's policy regarding elemental infant formulas requires that the use of the formula be recommended by a pediatric allergist, pediatric pulmonologist or pediatric gastroenterologist. . . . [I]n this case, Neocate was not recommended by a pediatric specialist.

Pursuant to the information set forth above and available documentation . . . Neocate is not medically necessary for treatment of the [P]etitioner's] condition.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the conclusion of the IRO and finds that Neocate was not medically necessary and therefore is not a covered benefit under the certificate.

V
ORDER

BCBSM's July 13, 2009, final adverse determination is upheld. BCBSM is not required to provide coverage for the Neocate formula prescribed by Petitioner's physician.

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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.