

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
Before the Director of the Department of Insurance and Financial Services

In the matter of:

██████████ ██████████  
Petitioner

v

File No. 240511-001

Blue Care Network of Michigan  
Respondent

---

Issued and entered  
this 16<sup>th</sup> day of October 2025  
by Joseph Stoddard  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On October 14, 2025, ██████████ M.D., authorized representative of the minor child ██████████ (Petitioner), filed with the Director of the Department of Insurance and Financial Services a request for an expedited external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The request for review concerns the denial of authorization for the off-label use of a prescription drug.

The Petitioner receives health care benefits through Blue Care Network of Michigan (BCN), a health maintenance organization. The benefits are described in BCN's *Blue Elect Plug High Deductible Health Plan POS for Large Groups Certificate of Coverage* (the certificate). The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN responded on October 14, 2025.

On October 14, 2025, the Director agreed to review BCN's denial on an expedited basis because the Petitioner's physician attested that the Petitioner's life or well-being would be jeopardized by the length of time required to perform an expedited internal review. See MCL 550.1913. The Director assigned an independent review organization (IRO) to analyze the medical issues in this appeal. The IRO submitted its report to the Director on October 15, 2025.

**II. FACTUAL BACKGROUND**

The Petitioner is ██████████ years old and has generalized idiopathic epilepsy and epileptic syndrome, not intractable, without status epilepticus. The Petitioner has tried and failed ethosuximide, Lamictal,

Keppra, amantadine, methsuximide, and zonisamide. Due to their resistant epilepsy, the Petitioner's physician recommended the off-label use of the prescription drug Epidiolex (cannabidiol) and asked BCN to authorize an exception for off-label use of the drug. BCN denied the request on the basis that the drug is not approved by the Food and Drug Administration (FDA) for the Petitioner's diagnosis.

The Petitioner appealed BCN's decision through its internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated October 8, 2025, affirming its coverage denial. The Petitioner now seeks the Director's review of that determination.

### III. ANALYSIS

#### Respondent's Argument

In its final adverse determination, BCN wrote:

Our grievance panel, which consisted of the Director for Customer Support and Servicing and our Medical Director, an MD, who is Board Certified in Internal Medicine, reviewed your request for authorization for Epidiolex 100 MG/ML Solution for [the Petitioner] to treat Resistant Epilepsy (a condition where seizures persist despite attempts to control them with two or more anti-seizure medications at appropriate doses) and upheld the original denial.

The decision is based on the information reviewed through the grievance process, which has been determined to not meet the medical necessity criteria in the enclosed Blue Care Network Prior Authorization and Step Therapy Coverage Criteria for Epidiolex, page 58.

We cover the requested medication when we have documentation (chart notes) that it is being used for the treatment of seizures (a condition when your brain activity causes uncontrollable shaking, muscle movement, loss of awareness, staring spells or other symptoms) due to one of the following diagnoses: (1) Dravet syndrome (DS, a severe form of childhood epilepsy which causes seizures) or (2) Lennox-Gastaut syndrome (LGS, a severe form of childhood epilepsy which causes multiple types of seizures) or (3) tuberous sclerosis complex (TSC, a genetic disorder characterized by noncancerous tumors that develop in different parts of the body, including the brain). Because the member is not being treated for seizures due to one of these diagnoses, clinical indications have not been met, and your request remains denied.

#### Petitioner's Argument

In a letter accompanying the request for external review, the Petitioner's physician wrote:

I am writing this Letter of Medical Necessity on behalf of [the Petitioner] to support the coverage of cannabidiol (Epidiolex) for the preventative treatment in

resistant epilepsy including non-convulsive seizures.

I acknowledge that your policy excludes cannabidiol (Epidiolex) coverage because she does not have one of the following diagnoses: 1) Dravet Syndrome, 2) Lennox-Gastaut Syndrome, or 3) Tuberous Sclerosis Complex. This letter serves to document that cannabidiol (Epidiolex) is medically necessary for [the Petitioner]. On behalf of [the Petitioner], I am requesting an exception for use in this case.

Below you will find a description of the patient's medical history, including prior therapies, and her current co-morbidities and diagnoses.

Please reference the following article by: Flamini et al (2023) which supports the prescribing of this medication.

#### Medical History, Diagnosis and Rationale

[The Petitioner] has been a patient in the Neurology Clinic since July 2018 for Childhood absence epilepsy, refractory and generalized non-convulsive epilepsy as well.

[The Petitioner] has tried and failed the following medications: Keppra, Lamictal, Amantadine, Ethosuximide, Zonisamide (hallucinations), Methsuximide.

- Ethosuximide: 6/29/18-9/21/18, was discontinued due to ineffectiveness
- Lamictal: 11/12/18-10/11/19, was discontinued due to ineffectiveness
- Keppra: 1/14/19-4/22/19, was discontinued due to ineffectiveness
- Amantadine: 10/1/21-1/7/22, was discontinued due to ineffectiveness
- Methsuximide, 10/28/21 and was discontinued due to ineffectiveness
- Zonisamide: 1/7/22-3/4/22, was discontinued due to hallucinations.

Based on my patient's treatment history and in accordance with the FDA labeling, it is my medical opinion that this patient would benefit from cannabidiol (Epidiolex) to reduce seizure severity and frequency. It is my clinic [sic] assessment that a reduction in seizures will have positive effect on [the Petitioner's] ability to participate in activities of daily living and improve daily functioning.

Based on the above facts, I am confident you will agree that cannabidiol (Epidiolex) is indicated and medically necessary for this patient.

#### Director's Review

BCN denied coverage for Epidiolex on the basis it is not approved by the FDA to treat the Petitioner's condition of resistant epilepsy including non-convulsive seizures. However, under Michigan law, MCL 500.3406q, insurers that provide pharmaceutical coverage shall provide coverage for an off-label use of federal food and drug administration approved drug for clinical indications other than those stated in the labeling approved by the Food and Drug Administration. Section 3406q of the Insurance Code, MCL 500.3406q, addresses off-label use and states in pertinent part:

- (1) An insurer that delivers, issues for delivery, or renews in this state a health insurance policy that provides pharmaceutical coverage shall provide coverage for an off-label use of a United States Food and Drug Administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.
- (2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:
  - (a) The drug is approved by the United States Food and Drug Administration.
  - (b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:
    - (i) A life-threatening condition if the drug is medically necessary to treat the condition and the drug is on the plan formulary or accessible through the insurer's formulary procedures.
    - (ii) A chronic and seriously debilitating condition if the drug is medically necessary to treat the condition and the drug is on the plan formulary or accessible through the insurer's formulary procedures.
  - (c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:
    - (i) The American Medical Association drug evaluations.
    - (ii) The American Hospital Formulary Service drug information.
    - (iii) The United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional".
    - (iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

The Director assigned an IRO to evaluate BCN's criteria and help determine whether the off-label use of the prescription drug Epidiolex is medically necessary for treating the Petitioner's condition. This review is required by section 11(7) of the Patient's Right to Independent Review Act, MCL 550.1911(7).

The IRO reviewer is a physician who has been board-certified in pediatric neuromuscular neurology since 2014, pediatric neurology since 2013, and is in active practice. The IRO reviewer's report included the following analysis and recommendation:

**1. Are the plan's criteria, which denied coverage for Epidiolex for off-label use, consistent with the standard of care?**

No. Blue Care Network of Michigan plans criteria for coverage of the medication Epidiolex for off-label use, is not consistent with the standard of care. While clinical

trials for Epidiolex were only conducted for patients with Dravet syndrome, Lennox-Gastaut Syndrome (LGS), or Tuberous Sclerosis, there is real-world evidence of it being effective for other patients with generalized epilepsy, as well as documentation of many patients who have been treated with it “off-label”. There is no inherent component of the mechanism of Epidiolex that would preclude it from being effective in other types of refractory epilepsy, as in [the Petitioner’s] clinical scenario.

**2. If they are consistent, does the member meet these criteria for off-label use of Epidiolex?**

Not applicable

**3. If the plan’s criteria are inconsistent with the standard of care criteria, does the member meet criteria such that the off-label use of Epidiolex is medically necessary under standard of care criteria?**

Yes. [The Petitioner] meets the criteria for the off-label use of the medication Epidiolex under the standard of care criteria. She has tried and failed at least five standard anti-seizure medications (ASM) and is currently taking a sixth medication, valproic acid, for which she has side effects as well as ongoing seizures. She therefore has intractable epilepsy and would be similar to patients who have been studied in real-world, expanded-access studies and reports who were found to have up to 50-60% reduction in seizure severity while on the medication Epidiolex.

\*\*\*

**Rationale to support the peer reviewer’s recommendation:**

[The Petitioner] is a ■-year-old female with treatment-resistant epilepsy (TRE)/intractable generalized epilepsy since at least 2018, who has tried and failed five ASM and has ongoing seizures and side effects while taking a sixth ASM. While she does not have a diagnosis of Dravet syndrome, [LGS], or Tuberous Sclerosis, she does have intractable epilepsy.

Clinical trials studying the medication Epidiolex were limited to patients diagnosed with Dravet syndrome, [LGS], or Tuberous Sclerosis; however, there have been numerous large open-label expanded-access studies and real-world reports of many patients without those three diagnoses but with TRE/intractable epilepsy who have been documented to receive benefit from the medication Epidiolex (see references #1 through #4).

Specifically, in an open-label add-on prospective study, the patient has TRE, has failed at least four ASM at adequate doses, and has been on at least two ASM at one time, as noted to be similar to [the Petitioner’s] clinical scenario. In that study, there was a statistically and clinically significant decrease in the Chalfont seizure severity scale, which was sustained from 12-48 weeks, with overall seizure severity improving by approximately 50-60%. The 4-year follow-up study from this

same group documented sustained seizure reduction up to 192 weeks in their cohort of patients (see reference #2).

While the likelihood of complete seizure freedom decreases with each additional ASM after three failed trials, the side effect profile and co-morbid diagnoses that [the Petitioner] has with hallucinations, weight gain, and depression could improve more than just her seizure burden with the addition of the medication Epidiolex (see references #3 & #4),

Therefore, in [the Petitioner's] clinical scenario, the medication Epidiolex is medically necessary. [References omitted]

The IRO reviewer recommended that the Director reverse BCN's denial of coverage.

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(18)(b). The IRO's review is based on extensive 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(17).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the off-label use of the prescription drug Epidiolex is medically necessary, therefore, it is a covered benefit under the Petitioner's benefit plan.

#### **IV. ORDER**

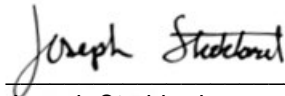
The Director reverses Blue Care Network of Michigan's October 8, 2025, final adverse determination. BCN shall immediately authorize coverage for the prescription drug Epidiolex. See MCL 550.1911(19). BCN shall, within seven days of providing coverage, submit to the Director proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Office of Appeals and Market Regulation, toll free 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 Appeals and Market Regulation, Post Office Box 30220, Lansing, MI 48909-7720.

Anita G. Fox  
Director

For the Director:



---

Joseph Stoddard  
Special Deputy Director