

**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. 154381-001-SF

Northern Michigan University, Plan Sponsor  
and  
Blue Cross Blue Shield of Michigan, Plan Administrator  
Respondents

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Issued and entered  
this 3<sup>rd</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 29, 2016, ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage for a prescription drug. The denial was issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by Northern Michigan University.

The request for external review was filed under Public Act No. 495 of 2006, MCL 550.1951 *et seq.*, which requires the Director to provide external reviews to persons covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan. The benefits are described in BCBSM's *Preferred Rx Program Certificate ASC* and related rider.

The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. On July 7, 2016, after a preliminary review of the information submitted, the Director accepted the request. BCBSM furnished the requested information on July 14, 2016.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on July 22, 2016.

## II. FACTUAL BACKGROUND

The Petitioner is fifty years old and has attention deficit disorder (ADD) and binge eating disorder (BED). Her doctor prescribed Vyvanse, to treat both conditions. BCBSM denied coverage for this drug, ruling that the Petitioner does not meet its criteria for coverage and it is therefore not medically necessary.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated April 22, 2016. The Petitioner now seeks the Director's review of that adverse determination.

## III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Vyvanse to treat the Petitioner?

## IV. ANALYSIS

### BCBSM's Argument

In its final adverse determination, BCBSM stated that the Petitioner's appeal had been reviewed by a clinical pharmacist who provided the following explanation of the coverage denial:

The coverage guidelines for your Custom Drug List benefit require criteria be met before coverage can be authorized. Our criteria for coverage of this medication, Vyvanse, for attention-deficit/hyperactivity disorder (ADHD), require that you first try a methylphenidate product (options include Concerta, Metadate, Methylin, or Ritalin) and a generic amphetamine product (options include generic Adderall and Adderall XR). We have no record of a trial of a methylphenidate product and a generic amphetamine product.

Further, our criteria for coverage of this medication, Vyvanse, for binge eating disorder require the following as indicated below:

- A record (chart notes) of a diagnosis of moderate to severe binge eating disorder
  - We do not have a record of this diagnosis from your provider.
- A trial of two of the following medications:

- Tricyclic Antidepressant (for example: desipramine and imipramine )
- Selective Serotonin Reuptake Inhibitor (for example: citalopram, fluoxetine, and sertraline ); and
- Topiramate.
  - We have no record (chart notes) of trials with two of these medications from your provider
- A requirement that this medication is prescribed by or in consultation with a psychiatrist.
  - We have no record that this criterion has been met.
- A requirement that this medication be used in conjunction with psychological intervention (such as cognitive behavioral therapy) as supported by documentation of an intervention plan.
  - We have no record (chart notes) that this criterion has been met.
  - Chart notes to support diagnosis, treatment plan and medication trial are required.

### Petitioner's Argument

In a letter dated May 18, 2016 submitted to BCBSM, a physician's assistant treating the Petitioner explained the need for Vyvanse:

I am again asking you to reconsider authorizing Vyvanse for [Petitioner] as this is the only medication that is FDA indicated to treat binge eating as well as attention deficit disorder. She has been on this medication as she has paid for it herself and has had great improvement in her Jasper-Goldberg score, which is a way for us to monitor improvement in ADD. She has also been able to lose weight and has control over binge eating.

### Director's Review

BCBSM's criteria for coverage of Vyvanse and the medical necessity of Vyvanse in treating the Petitioner were analyzed by 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 reviewer is a physician in active practice certified by the American Board of Internal Medicine. The IRO report included the following analysis and recommendation:

BCBSM's criteria for the prescription drug Vyvanse in treating attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED) is consistent with current standard of care.

\* \* \*

With respect to both medical conditions, the enrollee does not meet BCBSM's criteria for coverage of Vyvanse.

\* \* \*

With respect to both medical conditions, Vyvanse is not considered medically necessary for the treatment of the enrollee's condition.

**Clinical Rationale for the Decision:**

**Binge Eating Disorder (BED)**

The following are some generally accepted principles and criteria in treating BED:

1. Consultation with a mental health professional to initiate psychotherapy or cognitive behavioral therapy (CBT), which is the most common treatment and regarded as the most effective.
2. Trial of selective serotonin reuptake inhibitors (SSRIs)/tricyclic antidepressants and duloxetine if behavioral therapy alone is insufficient in treatment of symptoms.
3. Documentation in the medical record of binge eating disorder.

Cognitive Behavioral Therapy (CBT) is considered the treatment of choice for patients with binge eating disorder. With the support of decades worth of research, CBT is a time-limited and focused approach that helps a patient understand how their thinking and negative self-talk and self-image can directly impact their eating and negative behaviors.

With pharmacotherapy for binge eating disorder, SSRIs led to greater rates of reduction in target binge eating, psychiatric, and weight symptoms. Tricyclic antidepressants were inconsistent regarding reductions in binge eating and weight loss. Duloxetine led to decreased binge eating, weight loss, and global improvement in eating disorder and depressive symptoms. A metaanalysis of seven of these studies (one with a tricyclic antidepressant, six with SSRIs) showed significantly higher binge eating remission rates for the antidepressant group compared with the placebo group.

**Attention Deficit Hyperactivity Disorder (ADHD)**

The following are some generally accepted criteria/principles for treating ADHD in adults:

1. Consultation with a mental health professional to determine if the patient meets the Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for adult ADHD.
2. Use of stimulant and non-stimulant medications (i.e. methylphenidate and amphetamine compounds) as first line treatment.

The diagnosis of ADHD for the first time in adulthood is complex. A childhood diagnosis or childhood symptoms compatible with an ADHD diagnosis are required for an adult diagnosis. According to the DSM 5 diagnostic criterion, the symptoms must have started prior to age seven, be age inappropriate, cause impairment in multiple domains and not be caused by other conditions. Consultation with a mental health professional

is imperative prior to instituting treatment for adult ADHD given its complexity and possible overlap with other psychiatric conditions.

Treatment of adults with ADHD consists of medication and psychosocial treatment. ADHD medications are roughly divided into stimulants and non-stimulant medication. Stimulants include methylphenidate and amphetamine compounds. Stimulants are the most effective medications for the treatment of ADHD, with responsiveness rates in the 70%-80% range. A trial of such stimulants (i.e. methylphenidate and amphetamine derivative, i.e. Adderall) is required prior to the use of Vyvanse, in the event of failure of such medications in treatment of a patient's ADHD.

#### Summary

Per the documentation submitted for review, the enrollee does not have a moderate to severe binge eating disorder, and has not had a consultation with a mental health professional or a trial of various first line medications in the treatment of ADHD and/or BED. Therefore, the prescription drug Vyvanse is not medically necessary for the treatment of the enrollee.

#### Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for prescription drug Vyvanse be upheld.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's 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 can discern no reason why that analysis should be rejected in the present case. Therefore, the Director adopts the IRO analysis and finds that treatment with Vyvanse is not medically necessary for the Petitioner.

### **V. ORDER**

The Director upholds BCBSM's April 22, 2016 final adverse determination. BCBSM is not required to provide coverage for Vyvanse to treat the Petitioner.

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 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