Utilization Management Policy Name: Vyvanse - Essential Formulary

Restricted Product(s):

- Vyvanse (lisdexamfetamine)

FDA Approved Use:

- For the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients ≥6 years of age.
- For the treatment of moderate to severe binge eating disorder in adults.

Criteria for Approval of Restricted Product(s):

1. The patient has been diagnosed with moderate to severe binge eating disorder; **OR**
2. ONE of the following:
    a. The requested medication is currently being used to treat a refractory psychiatric disorder and the patient must be stabilized on current regimen or the provider states that the patients condition is too critical to try other medications **(medical record documentation required); OR**
    b. The requested medication is prescribed by a psychiatrist or in consult with a psychiatrist (defined as a healthcare practitioner with a supervising psychiatrist or a collaborative care arrangement with a psychiatrist); **AND**
        i. The provider attests that the patient cannot be effectively treated with a formulary generic alternative product, **OR**
    c. ONE of the following:
        i. The patient has tried and failed THREE of the following formulary generic products:
            1. Amphetamine/Dextroamphetamine ER (generic Adderall XR)
            2. Dexmethylphenidate ER (generic Focalin XR)
            3. Methylphenidate ER (ex. Generic Concerta)
            4. Dextroamphetamine ER (generic Dexedrine); **OR**
        ii. The patient has a clinical contraindication/intolerance/clinical rationale in regard to those not tried and failed by the patient **(documentation or written, clinical rationale required).**

Duration of Approval: 365 days (1 year)

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity per Day (unless specified)	Max Daily Dose/Maximum Dose Studied Per FDA Label
Vyvanse (lisdexamfetamine) capsule or chew 10mg	1	

Vyvanse (lisdexamfetamine) capsule or chew 20mg	1	Per the FDA label, doses >70mg/day were not studied in clinical trials. Only once daily doses were studied.
Vyvanse (lisdexamfetamine) capsule or chew 30mg	1	
Vyvanse (lisdexamfetamine) capsule or chew 40mg	1	
Vyvanse (lisdexamfetamine) capsule or chew 50mg	1	
Vyvanse (lisdexamfetamine) capsule or chew 60mg	1	
Vyvanse (lisdexamfetamine) capsule 70mg	1	

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

Duration of Approval: 365 days (1 year)

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

October 2023: Criteria update: Removed restriction from Vyvanse generics.
September 2023: Criteria update: Added new Vyvanse generic as a restricted product to the policy.
June 2022: Original utilization management policy issued.