Attention-Deficit Hyperactivity Disorder (ADHD)  
Stimulant Step Therapy Policy  
March 2017

OVERVIEW
All of the long-acting stimulants are indicated for the treatment of attention-deficit hyperactivity disorder (ADHD). Some products are also indicated for the treatment of narcolepsy. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder (BED). Approval for this indication was based on two 12-week randomized, double-blind, multi-center, parallel-group, placebo-controlled, dose-optimization studies in adults aged 18 to 55 years (n = 374 and n = 350) with moderate to severe BED. Patients from both studies on Vyvanse had a statistically significantly greater reduction from baseline in mean number of binge days/week at Week 12. All of these products have abuse potential and are Schedule II controlled substances.

POLICY STATEMENT
A step therapy program has been developed to encourage use of one Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

**Step 1:**
Generic amphetamine/dextroamphetamine extended-release capsules (generics to Adderall XR), generic dextroamphetamine extended-release capsules (generics to Focalin XR), generic dextroamphetamine extended-release capsules (generics to Dexedrine Spansules), generic methylphenidate extended-release capsules (generics to Metadate CD and Ritalin LA), Metadate ER (generic according to FDB), generic methylphenidate sustained-release tablets (generics to Ritalin SR), generic methylphenidate extended-release tablets (generics to Concerta)

**Step 2:**
Adderall XR, Adzenys XR-ODT , Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Dexedrine Spansules, Dyanavel XR, Focalin XR, Metadate CD, Mydayis, QuilliChew ER, Quillivant XR, Ritalin LA, Ritalin SR, Vyvanse, Vyvanse chewable tablets.

**CRITERIA**
Exceptions for a Step 2 agent can be made for patients with one of the following conditions/situations:

1. If the patient has tried a Step 1 agent, then authorization for a Step 2 agent may be given.

2. Authorization may be given for Daytrana if the patient cannot swallow or has difficulty swallowing solid oral dosage forms.
3. Authorization may be given for Vyvanse (capsule or chewable tablets) for the treatment of binge eating disorder. Vyvanse is the only stimulant indicated for this disorder.

4. No other exceptions are recommended.

References

- Daytrana® transdermal system [prescribing information]. Miami, FL: Noven Pharmaceuticals, Inc.; August 2015.
- Focalin XR® extended-release capsules [prescribing information]. East Hanover, NJ: Novartis; April 2015.
- Ritalin® tablets and Ritalin SR® sustained-release tablets [prescribing information]. East Hanover, NJ: Novartis; December 2013.


