Vyvanse® (lisdexamfetamine dimesylate) — New Indication

- On January 30, 2015, Shire announced the FDA approval of Vyvanse (lisdexamfetamine dimesylate) capsules, a Schedule II controlled substance, for moderate to severe binge eating disorder (BED). Vyvanse is the first FDA-approved medication for BED.
  - Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.
  - Vyvanse is also indicated for the treatment of attention deficit disorder (ADHD) in patients ages 6 and older.
- BED is the most common eating disorder in the U.S., affecting an estimated 2.8 million adults. BED can occur in normal, overweight, and obese adults and is seen across racial and ethnic groups.
  - BED, is defined as recurring episodes (≥ once weekly, for at least 3 months) of consuming a large amount of food in a short time. Patients feel a lack of control during a binge eating episode and marked distress over their eating.
- The new indication for Vyvanse is based on results from two 12 week randomized, double-blind, placebo-controlled trials involving adults aged 18 to 55 years with moderate to severe BED. The primary endpoint was the change from baseline at week 12 in the number of binge days per week.
  - At week 12, there was a statistically significant greater reduction from baseline in mean number of binge days per week in subjects on Vyvanse compared to placebo. In the first study, the placebo-subtracted difference was -1.35 (95% CI, -1.70 to -1.01) and -1.66 (95% CI, -2.04 to -1.28) in the second study.
  - Subjects treated with Vyvanse also demonstrated improvements in the Clinical Global Impressions-Improvement (CGI-I) rating scale, the proportion of subjects with 4-week binge cessation, and the Yale-Brown Obsessive Compulsive Score Modified for Binge Eating (Y-BOCS-BE) total score.
- Vyvanse carries a boxed warning for abuse and dependence.
- Vyvanse is contraindicated in patients with a known hypersensitivity to amphetamine products and when coadministered with a monoamine oxidase inhibitor (MAOI), or within 14 days of the last MAOI dose.
- The most common adverse reactions (≥ 5% and at a rate at least twice placebo) in adults with BED were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety.
- Similar to the treatment of ADHD, the recommended initial dose of Vyvanse for the treatment of BED is 30 mg once every morning without regard to food. However, the titration schedule and recommended dose range differ between the two indications.

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— Afternoon doses of Vyvanse should be avoided because of the potential for insomnia.

Table 1: Vyvanse Dosing and Administration

Indication	Recommended Initial Dose	Titration Schedule	Recommended Dose	Maximum Dose
ADHD	30 mg every morning	10 mg or 20 mg weekly	30 mg to 70 mg per day	70 mg per day
BED		20 mg weekly	50 mg to 70 mg per day	