Pharmacy Policy Bulletin: J-0441 Addyi (flibanserin) - Commercial and Healthcare Reform	
Number: J-0441	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0441-012	**Original Date:** 09/02/2015
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Addyi (flibanserin)
FDA-Approved Indication(s):	• Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty that is unrelated to a co-existing medical or psychiatric condition, problems within a relationship or the effects of a medication or other drug substance.

Background:	• Addyi is a serotonin 5-HT1A receptor agonist and a serotonin 5-HT2A receptor antagonist. Although the mechanism of action is not known, many neurotransmitters affect sexual response in women, and modulation of some of these neurotransmitters by Addyi may contribute to its mechanism of action and efficacy. • HSDD is a lack of, or significantly reduced, sexual drive, interest, and arousal leading to personal distress or difficulties. It can be manifested by no or reduced interest in sexual activity, thoughts, excitement, cues, and sensations. It also includes lack of response to partner's attempts to initiate sexual activity. • Prescribing Considerations: ○ Use of Addyi and alcohol together close in time increases the risk of severe hypotension and syncope. Counsel patients to wait at least two hours after consuming one or two standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed three or more alcoholic drinks that evening. ○ Severe hypotension and syncope can occur when Addyi is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, Addyi use in these settings is contraindicated. ○ Addyi is not indicated for use in men or in post-menopausal women. ○ Addyi is not intended to enhance sexual performance. ○ Addyi should be dosed at bedtime; administration during waking hours increases risks of hypotension, syncope, accidental injury, and central nervous system (CNS) depression.

	○ The use of Addyi should be discontinued after 8 weeks if the patient does not report an improvement in her symptoms. ○ Addyi is available only through the Addyi REMS program.

Approval Criteria

I. Initial Authorization
When a benefit, coverage of Addyi will be approved when all of the following criteria are met **(A. through G.)**:
- **A.** The member is 18 years of age or older.
- **B.** The member is a premenopausal female.
- **C.** The member has a diagnosis of HSDD. (ICD-10: F52.0)
- **D.** The provider has confirmed that HSDD is unrelated to a co-existing medical or psychiatric condition, substance abuse, or relationship issue.
- **E.** The member meets one (1) of the following criteria **(1., 2., or 3.)**:
  - **1.** The member is currently enrolled in behavioral therapy for HSDD
  - **2.** The member has experienced therapeutic failure of behavioral therapy for HSDD
  - **3.** The member is not a candidate for behavioral therapy for HSDD.
- **F.** The prescriber attests that the member does not have a current issue with alcohol or substance abuse.
- **G.** The prescriber attests that the member has been educated on Addyi administration including the potential adverse effects of alcohol consumption with Addyi.

II. Reauthorization
When a benefit, coverage of Addyi may be approved when the following criteria are met **(A. and B.)**:
- **A.** The prescriber attests that the member is tolerating therapy.
- **B.** The prescriber attests that the member is experiencing improved sexual desire from baseline.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization
- Commercial and HCR Plans: If approved, up to a 2 month authorization may be granted.

Reauthorization
- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Addyi [package insert]. Raleigh, NC: Sprout Pharmaceuticals; September 2021.
2. FDA Orders Important Safety Labeling Changes for Addyi. Available at: https://www.fda.gov/news-events/press-announcements/fda-orders-important-safety-labeling-changes-addyi. Accessed July 9, 2025.
3. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2025. Accessed July 9, 2025.