

# Addyi (flibanserin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Addyi (flibanserin)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Addyi (flibanserin) may be approved when the following criteria are met:

- I. Individual is female; **AND**
- II. Individual is premenopausal; **AND**
- III. Individual is 18 years of age or older; **AND**
- IV. Individual has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) or acquired Female Sexual Interest Arousal Disorder (FSIAD) for at least 24 weeks characterized by low sexual desire that causes marked distress or interpersonal difficulty; **AND**
- V. It is confirmed that the diagnosis of HSDD or FSIAD is not attributed to any of the following:
  - A. A co-existing psychiatric condition<sup>1</sup>; **OR**
  - B. A co-existing medical condition<sup>2</sup> that could contribute to sexual dysfunction; **OR**
  - C. Problems within a relationship; **OR**
  - D. Major life stressor (such as, loss of income or bereavement) (DeRogatis 2012, APA 2013); **OR**
  - E. Effects of a medication or other drug substance.

Addyi (flibanserin) may **not** be approved for the following:

- I. Treatment of HSDD in postmenopausal women; **OR**
- II. Treatment of HSDD in men; **OR**
- III. Enhancement of sexual performance in the absence of HSDD or FSIAD; **OR**
- IV. In individuals utilizing moderate (including but not limited to, atazanavir, ciprofloxacin, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, grapefruit juice) or strong CYP3A4 inhibitors (examples include but not limited to ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, telithromycin, conivaptan); **OR**
- V. Concomitant use with CYP3A4 inducers (including but not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, St. John's Wort); **OR**
- VI. In individuals with any degree of hepatic impairment (mild, moderate, or severe); **OR**
- VII. Individuals who will be using Addyi (flibanserin) in combination with Vyleesi (bremelanotide).

1. **Notes:** Examples of co-existing psychiatric conditions include a history of major depressive disorder within the previous six months, a current diagnosis of mild to severe depression using a validated depression scale.
2. Examples of a co-existing medical condition that could contribute to sexual dysfunction include pelvic inflammatory disease (PID), cervicitis, interstitial cystitis, vulvodynia, significant vaginal atrophy, sexual pain.
3. Addyi (flibanserin) has a black box warning regarding the risk of severe hypotension and syncope when used in close timing (less than 2 hours) with alcohol. Skipping the Addyi dose altogether is recommended if three or more alcoholic beverages have been consumed that evening. Additionally, the box warning also notes that concomitant use of Addyi with moderate or strong CYP3A4 inhibitors and use in individuals with hepatic impairment is contraindicated due to the same risks of severe hypotension and syncope.

#### **Key References:**

1. American College of Obstetricians and Gynecologists, Committee on Practice Bulletins-Gynecology. Female Sexual Dysfunction: Practice Bulletin 213. Obstetrics Gynecology July 2019; 134(1). Accessed December 2, 2021.
2. American Psychiatric Association (APA). Diagnostic and statistical manual of mental disorders. 5th ed. Arlington (VA): APA; 2013. (Level III). Accessed December 2, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
4. Clayton AH, Lucas J, DeRogatis LR, et al. Phase I Randomized Placebo-controlled, Double-blind Study of the Safety and Tolerability of Bremelanotide Coadministered With Ethanol in Healthy Male and Female Participants. Clin Ther. 2017 Mar;39(3):514-526.e14. doi: 10.1016/j.clinthera. 2017.01.018.
5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 2, 2021.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
8. DeRogatis L, Komer L, Katz M, et al. Treatment of Hypoactive Sexual Desire Disorder in Premenopausal Women: Efficacy of Flibanserin in the VIOLET Study. J Sex Med. 2012; 9 (4):1074-1085.
9. NCT02333071. ClinicalTrials.gov. U.S. National Library of Medicine. Available at <https://clinicaltrials.gov/ct2/show/NCT02333071?term=nct02333071&rank=1>.
10. Thorp J, Simon J, Dattani, et al. Treatment of Hypoactive Sexual Desire Disorder in Premenopausal Women: Efficacy of Flibanserin in the DAISY Study. J Sex Med. 2012; 9 (3):793-804.
11. World Health Organization (WHO). Cardiovascular Disease. 2021. Available at <https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-cvds>. Accessed on December 2, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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