RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	flibanserin
Policy Number:	RxA.340
Drug(s) Applied:	Addyi®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Flibanserin (Addyi®) is a serotonin 5-HT1A receptor agonist and a 5-HT2A receptor antagonist. Addyi ® is indicated for the 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 and is NOT due to:

- A co-existing medical or psychiatric condition,
- Problems within the relationship, or
- The effects of a medication or other drug substance.

Limitation(s) of use:

- Addyi® is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi® is not indicated to enhance sexual performance.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
flibanserin (Addyi®)	HSDD	100 mg PO QD at bedtime	100 mg/day

Dosage Forms

- Tablets: 100 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Hypoactive Sexual Desire Disorder (must meet all)**:**

1. Diagnosis of HSDD in premenopausal women;
2. Age 18 years of age or older;
3. Dose does not exceed 100 mg (1 tablet) per day.

Approval duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Hypoactive Sexual Desire Disorder (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 100 mg (1 tablet) per day .

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DSM: Diagnostic and Statistical Manual of Mental Disorders
FDA: Food and Drug Administration
HSDD: hypoactive sexual desire disorder

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Moderate or strong CYP450 3A4 inhibitors
  - Hepatic impairment
- Boxed warning(s):
  - Hypotension and syncope in certain settings

APPENDIX D: General Information

- HSDD is characterized by a deficiency or absence of sexual fantasies and desire for sexual activity which causes marked distress or interpersonal difficulty, and is not better accounted for by another psychiatric disorder or due exclusively to the direct physiological effects of a substance or to the direct physiological effects of another medical condition. HSDD does not encompass normal (e.g., daily or weekly) fluctuations in levels of desire.
- There is currently no published data demonstrating the efficacy of Addyi® in the treatment of HSDD in postmenopausal women or in men.
- Treatment should be discontinued after 8 weeks if there is no improvement in symptoms.
- In the DSM-5, female hypoactive sexual desire disorder was merged with female arousal dysfunction and is now reclassified as one disorder: female sexual interest/arousal disorder.

References

1. Addyi Prescribing Information. Raleigh, NC: Sprout Pharmaceuticals, Inc; October 2019. Available at: www.addyi.com. Accessed July 05, 2020.
2. American Psychiatric Association. Highlights of changes from DSM-IV-TR to DSM-5. Available at: https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM_Change s_from_DSM-IV-TR_-to_DSM-5.pdf. Accessed July 05, 2020.
3. Flibanserin, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed July 05, 2020.

4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed July 05, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated 2. Clinical policy was updated: Updated approval duration verbiage and approval duration for continued therapy. Updated verbiage in line #1 in continued therapy to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy" 3. References were updated	07/05/2020	09/14/2020