Clinical Policy Title:	flibanserin
Policy Number:	RxA.340
Drug(s) Applied:	Addyi®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Flibanserin (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 orally once daily 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Member is 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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Vyleesi™ (bremelanotide acetate)	1.75 mg SC in abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity	1.75 mg/day (max 8 doses/month)

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Moderate or strong CYP450 3A4 inhibitors;
  - Hepatic impairment.

- Boxed warning(s):
  - Hypotension and syncope due to interaction with alcohol. Taking flibanserin within two hours after consuming alcohol increases the risk of severe hypotension and syncope.
    Severe hypotension can occur when flibanserin is used with moderate or strong CYP450 3A4 inhibitors or in patients with hepatic impairment.

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 May 28, 2021.
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 May 28, 2021.
3. Flibanserin, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed May 28, 2021.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Elsevier; Gold standard.; 2021. Available at: http://www.clinicalkey.com . Accessed May 28, 2021.

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
Policy was reviewed: 1. Background was updated to remove “is a serotonin 5 HT1A receptor agonist and a 5 HT2A receptor antagonist…”. 2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 3. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 5. Appendix B: Therapeutic Alternatives was updated to include drug “Vyleesi” and its dosing	05/28/2021	09/14/2021

regimen, “1.75 mg SC in abdomen or thigh, as needed…”. 6. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 7. Appendix C was updated to include boxed warning, “due to interaction with alcohol. Taking flibanserin within two hours after…”. 8. References were reviewed and updated.		