Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

# Medications for the Treatment of Hypoactive Sexual Desire Disorder (HSDD)

*Effective: May 1, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

Acquired hypoactive sexual desire disorder (HSDD) refers to HSDD that develops in patients who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation, or partner.

**Food and Drug Administration – Approved Indications**

**Addyi (flibanserin)** is indicated for the treatment of women less than 65 years of age 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.

Addyi is not indicated in men and is not indicated to enhance sexual performance.

**Vyleesi (bremelanotide)** 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 with the relationship, or the effects of a medication or drug substance.

Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men, or to enhance sexual performance.

## Clinical Guideline Coverage Criteria

### Addyi (filbanserin):

### Initial Criteria:

The plan may authorize coverage of **Addyi (filbanserin)** for patients when the following criteria are met:

1. Diagnosis of acquired, generalized hypoactive sexual desire disorder characterized by low sexual desire

**AND**

2. Patient is a woman less than 65 years of age

**AND**

3. Diagnosis is not due to a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or other drug substance

### Reauthorization Criteria:

The plan may authorize subsequent approvals of **Addyi (filbanserin)** for patients when the following criteria are met:

1. Documentation that the patient continues to meet all coverage criteria.

**Vyleesi (bremelanotide):**

**Initial Criteria:**

The plan may authorize coverage of **Vyleesi (bremelanotide)** for patients when the following criteria are met:

1. Diagnosis of acquired, generalized hypoactive sexual desire disorder characterized by low sexual desire

**AND**

2. Diagnosis is not due to a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or other drug substance have been addressed.

**AND**

3. Patient is premenopausal

**Reauthorization Criteria:**

The plan may authorize subsequent approvals of **Vyleesi (bremelanotide)** for patients when the following criteria are met:

1. Documentation that the patient continues to meet all coverage criteria.

## Limitations

1. Initial approval duration of Addyi will be limited to one year. Initial approval duration of Vyleesi will be approved for 8 weeks. Discontinuation is recommended if there is no improvement in symptoms. Subsequent approvals for both medications will be for a duration of one year.
2. Addyi and Vyleesi will not be authorized for men.
3. Vyleesi will not be authorized for postmenopausal women.
4. Medications will not be authorized to enhance sexual performance.

## Codes

None

## References


1. Addyi prescribing information. Raleigh, NC: Sprout Pharmaceuticals, Inc.; December 2025.
2. American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin No. 119: female sexual dysfunction. *Obstet Gynecol.* 2011;117(4):996-1007.
3. American Psychiatric Association. Diagnostic and statistical manual of mental disorders:DSM-5. 5th ed. Washington, DC: American Psychiatric Association; 2013b.
4. American Psychiatric Association. Diagnostic and statistical manual of mental disorders: DSM-IV-TR. 4th ed. Washington, DC: American Psychiatric Association; 2000.
5. American Psychiatric Association. Highlights of changes from DSM-IV-TR to DMS-5. 2013a. URL: http://www.dsm5.org/Documents/changes%20from%20dsm-iv-tr%20to%20dsm-5.pdf. Available from Internet. Accessed 2015 September 29.
6. Basson R. Human sex-response cycles. *J Sex Marital Ther.* 2001;27(1):33-43.
7. DeRogatis LR, 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):1074-85.
8. Food and Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS). 2015c August 18. URL: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=350. Available from Internet. Accessed 2016 March 21.
9. Food and Drug Administration. FDA approves first treatment for sexual desire disorder. 2015a August 18. URL: http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm458734.htm. Available from Internet. Accessed 2016 March 21.
10. Jayne C, Simon JA, Taylor LV, et al. Open-label extension study of flibanserin in women with hypoactive sexual desire disorder. *J Sex Med.* 2012;9(12):3180-8.
11. Katz M, DeRogatis LR, Ackerman R, et al. Efficacy of flibanserin in women with hypoactive sexual desire disorder: results from the BEGONIA trial. *J Sex Med*. 2013;10(7):1807-15.
12. Kingsberg SA, Woodard T. Female sexual dysfunction: focus on low desire. *Obstet Gynecol.* 2015;125(2):477-86.
13. Safarinejad MR, Hosseini SY, Asgari MA, et al. A randomized, double-blind, placebo-controlled study of the efficacy and safety of bupropion for treating hypoactive sexual desire disorder in ovulating women. *BJU Int.* 2010;106:832-9.
14. Simon JA, Kingsberg SA, Shumel B, et al. Efficacy and safety of flibanserin in postmenopausal women with hypoactive sexual desire disorder: results of the SNOWDROP trial. *Menopause.* 2014; 21(6):633-40.
15. Stahl SM. Mechanism of flibanserin, a multifunctional serotonin agonist and antagonist (MSAA), in hypoactive sexual desire disorder. *CNS Spectr.* 2015;20(1):1-6.

16. Thorp J, Simon J, Dattani D, 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.
17. Vyleesi prescribing information. Waltham, MA: AMAG Pharmaceuticals, Inc.; November 2025.

## Approval And Revision History

September 12, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes.
- June 11, 2024: No changes.
- July 8, 2025: No changes.
- April 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template. Updates made to the overview section to indicate Addyi is indicated for the treatment of HSDD in women less than 65 years of age and is no longer limited to premenopausal women. Updated criteria for Addyi to reflect updated diagnosis for women less than 65 years of age (eff 5/1/26).

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.