

Pharmacy Medical Necessity Guidelines: Medications for the Treatment of Hypoactive Sexual Desire Disorder (HSDD)

Effective: July 1, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 			<p>Fax Numbers: RXUM: 617.673.0988</p>

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

FDA-APPROVED INDICATIONS

Addyi (flibanserin) and Vyleesi (bremelanotide) are indicated for the treatment of premenopausal women with acquired, generalized 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.

Both medications are not indicated for the treatment of HSDD in postmenopausal women or in men, or to enhance sexual performance.

COVERAGE GUIDELINES

The plan may authorize coverage of Addyi (flibanserin) or Vyleesi (bremelanotide) for Members, when the following criteria are met:

1. Documented diagnosis of acquired, generalized hypoactive sexual desire disorder characterized by low sexual desire that causes marked distress or interpersonal difficulty

AND

2. Documentation the 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

AND

3. Documentation the member is premenopausal

Reauthorization Criteria:

The plan may authorize subsequent approvals of Addyi (flibanserin) or Vyleesi (bremelanotide) for Members when the following criteria are met:

1. Documentation is provided that the member 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. Medications will not be authorized for postmenopausal women or men.
3. Medications will not be authorized to enhance sexual performance.
4. Vyleesi will be limited to a quantity of 8 syringes per month

CODES

None

REFERENCES

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13. 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.
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15. 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.
16. Vyleesi prescribing information. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2019 June.

APPROVAL HISTORY

April 1, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
- May 8, 2018: No changes
- April 9, 2019: No changes
- December 10, 2019: Updated the name of MNG from "Addyi™ (flibanserin)" to "Medications for the Treatment of Hypoactive Sexual Desire Disorder (HSDD)" and added coverage criteria for Vyleesi (bremelanotide).

- February 11, 2020: Effective July 1, 2020 added reauthorization criteria for both Addyi and Vyleesi and clarified approval duration for reauthorizations will be for one year.

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.

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