

Clinical Policy: Bremelanotide (Vyleesi)

Reference Number: ERX.SPA.347

Effective Date: 12.01.19

Last Review Date: 11.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Bremelanotide (Vyleesi[™]) is a melanocortin receptor agonist.

FDA Approved Indication(s)

Vyleesi 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 NOT due to:

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

Limitation(s) of use:

- Not indicated for treatment of HSDD in postmenopausal women or in men.
- Not indicated to enhance sexual performance.

Policy/Criteria

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Vyleesi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of HSDD in premenopausal women;
2. Age \geq 18 years;
3. Failure of a 3-month trial of bupropion at up to maximally studied effective doses (see *Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
4. Vyleesi is not prescribed concurrently with Addyi;
5. Dose does not exceed 1.75 mg (1 injection) per day and no more than 8 doses per month.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1.75 mg (1 injection) per day and no more than 8 doses per month.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

- B. Other diagnoses/indications** (must meet 1 or 2):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
 2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
bupropion (Aplenzin [®] , Budeprion SR [®] , Budeprion XL [®] , Forfivo XL [®] , Wellbutrin [®] , Wellbutrin SR [®] , Wellbutrin XL [®])	Varies	Immediate-release: 450 mg/day (300 mg/day if pediatric) Sustained-release: 400 mg/day Extended-release (HCl): 450 mg/day Extended-release (HBr): 522 mg/day

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

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): uncontrolled hypertension or known cardiovascular disease
- Boxed warning(s): none reported

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 Vyleesi 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.
- Two randomized trials (Segraves RT, et al. and Safarinejad MR, et al.) of premenopausal women with HSDD and without underlying depression reported increased sexual pleasure, desire, arousal, and orgasm with bupropion compared with placebo.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HSDD	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)

VI. Product Availability

Single-dose prefilled autoinjector: 1.75 mg/0.3 mL

VII. References

1. Vyleesi Prescribing Information. Waltham MA: AMAG Pharmaceuticals, Inc.; June 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/210557s000lbl.pdf. Accessed July 29, 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_Changes_from_DSM-IV-TR_to_DSM-5.pdf. Accessed July 29, 2020.
3. Segraves RT, Clayton A, Croft H, et al. Bupropion sustained release for the treatment of hypoactive sexual desire disorder in premenopausal women. J Clin Psychopharmacol. 2004;24(3):339.
4. 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 Sep;106(6):832-9.
5. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins - Gynecology. Female Sexual Dysfunction: ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists, Number 213. Obstet Gynecol. 2019;134 (1):e1-e18.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.06.19	11.19
Added 3-month trial and failure of bupropion; added Vyleesi is not prescribed concurrently with Addyi; references reviewed and updated.	11.19.19	02.20
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.29.20	11.20
Clarified language of bupropion trial requirement from “up to maximally indicated doses” to “up to maximally studied effective doses.”	03.18.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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