RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	bremelanotide
Policy Number:	RxA.562
Drug(s) Applied:	Vyleesi™
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Bremelanotide (Vyleesi™) is a melanocortin receptor agonist. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
bremelanotide (Vyleesi™)	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)

Dosage Forms

- Single-dose prefilled autoinjector: 1.75 mg/0.3 mL

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;
3. Failure of bupropion at up to maximally indicated doses, 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
Commercial: 2 months
Medicaid: 2 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 1.75 mg (1 injection) per day and no more than 8 doses per month.

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):
  - 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.

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 August 24, 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 August 26, 2020.
3. Bremelanotide, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed August 24, 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 August 24, 2020.
5. Kingsberg SA, Simon JA. Female Hypoactive Sexual Desire Disorder: A Practical Guide to Causes, Clinical Diagnosis, and Treatment. J Womens Health (Larchmt). 2020;29(8):1101-1112. Accessed August 26, 2020.
6. Mayer D, Lynch SE. Bremelanotide: New Drug Approved for Treating Hypoactive Sexual Desire Disorder. Ann Pharmacother. 2020;54(7):684-690. Accessed August 26, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Initial Approval Criteria was updated: Failure of bupropion at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; Vyleesi™ is not prescribed concurrently with Addyi™; 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Initial approval duration was updated to 2 months. 5. Commercial approval duration was updated from Length of benefit to 12 months for continued approval criteria. 6. References were updated.	08/26/2020	12/07/2020