Pharmacy Policy Bulletin: J-0943 Vyleesi (bremelanotide injection) – Commercial and Healthcare Reform	
Number: J-0943	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0943-009	**Original Date:** 08/07/2019
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Vyleesi (bremelanotide injection)
FDA-Approved Indication(s):	• 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.

Background:	• Vyleesi is a melanocortin receptor (MCR) agonist that non-selectively activates several receptor subtypes. Although the mechanism of action is not known, it is assumed to activate selected brain pathways that are involved in normal sexual responses.
	• HSDD is a lack of, or significantly reduced, sexual drive, interest, and arousal leading to personal distress or difficulties. It can be manifested by no or reduced interest in sexual activity, thoughts, excitement, cues, and sensations. It also includes lack of response to a partner's attempts to initiate sexual activity.
	• HSDD may be lifelong or acquired, and generalized or situational.
	• The treatment of HSDD may engage both psychosocial and biological strategies because psychosocial/interpersonal and biological factors impact each other.
	• Prescribing Considerations
	  ○ Vyleesi is contraindicated in patients with uncontrolled hypertension or known cardiovascular disease.
	  ○ Vyleesi is not indicated for use in men or post-menopausal women.
	  ○ Vyleesi is not indicated to enhance sexual performance.
	  ○ Patients should not use more than one dose within 24 hours. More than 8 doses per month is not recommended.
	  ○ Treatment should be discontinued after 8 weeks if an improvement in sexual desire and associated distress is not reported.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Vyleesi may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.
B. The member is a premenopausal female.
C. The member has a diagnosis of HSDD (ICD-10: F52.0), classified as acquired and generalized.
D. The provider attests that the HSDD is unrelated to all of the following **(1., 2., and 3.)**:
  1. Co-existing medical or psychiatric condition
  2. Problems with the relationship
  3. Effects of a medication or drug substance
E. The member meets one (1) of the following criteria **(1., 2., or 3.)**:
  1. The member is currently enrolled in behavioral therapy for HSDD.
  2. The member has experienced therapeutic failure in behavioral therapy for HSDD.
  3. The member is not a candidate for behavioral therapy for HSDD.

II. Reauthorization

When a benefit, reauthorization of Vyleesi may be approved when all of the following criteria are met **(A. and B.)**:

A. The member is a premenopausal female.
B. The prescriber attests that the member has experienced improved sexual desire from baseline.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 2 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Vyleesi [package insert]. Cranbury, NJ: Palatin Technologies, Inc.; October 2020.
2. U.S. Food & Drug Administration. FDA approves new treatment for hypoactive sexual desire disorder in premenopausal women. Available at: https://www.fda.gov/news-events/press-

announcements/fda-approves-new-treatment-hypoactive-sexual-desire-disorder-premenopausal-women. Accessed October 7, 2024.
3. Diagnostic and Statistical Manual of Mental Disorders. Sexual Dysfunctions. 5th edition. *American Psychiatric Association*. 2013.
4. Clayton AH, Goldstein I, Kim NN, et al. The International Society for the Study of Women's Sexual Health Process of Care for Management of Hypoactive Sexual Desire Disorder in Women. *Mayo Clin Proc*. 2018;93(4):467-487.