Bremelanotide (Vyleesi®)	Place of Service **Self Administration** *May be covered under the pharmacy benefit* **HCPCS**: J3490 **NDCs:** • 64011-0701-01: 1.75 mg in 0.3 mL solution in a single-dose prefilled autoinjector • 64011-0701-04: carton of 4 autoinjectors

Condition(s) listed in policy (*see criteria for details*)

- Hypoactive sexual desire disorder (HSDD)

AHFS therapeutic class: Hypoactive Sexual Desire Disorder (HSDD) Agents

Mechanism of action: Bremelanotide is a melanocortin receptor (MCR) agonist that nonselectively activates several receptor MCR subtypes. Neurons expressing MC4R are present in many areas of the central nervous system (CNS). The mechanism by which Vyleesi® improves HSDD in women is unknown.

(1) Special Instructions and pertinent Information

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. **Please include medical rationale why medication cannot be home self-administered.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Vyleesi® (bremelanotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hypoactive sexual desire disorder (HSDD)

1. Provider attestation that sexual desire disorder is not due to an underlying medical or psychiatric condition, **AND**
2. Provider attestation that sexual desire disorder is not due to an adverse side effect from a medication, **AND**
3. Not being used in a post-menopausal women, **AND**
4. Not being used in a male patient, **AND**
5. Not being used in combination with Addyi

Covered Doses
Up to eight 1.75 mg doses per month

Coverage Period
Initial: 8 weeks

First Reauthorization after 8 Weeks, allow for 1 year if meets below:

1. Attestation that patient has experienced increased sexual desire since initiating Vyleesi therapy, **AND**
2. Not being used in a post-menopausal female patient

Subsequent Reauthorizations (after first reauthorization), allow for 1 year if meets below:

1. Not being used in a post-menopausal female patient

ICD-10:
F52.0, F52.22, F52.31

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Vyleesi® (bremelanotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
1.75 mg in 0.3 mL solution in a single-dose, disposable prefilled autoinjector, provided in a carton of 4 autoinjectors

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Vyleesi ® (bremelanotide injection) [Prescribing information]. Cranbury, NJ: Palatin Technologies, Inc.; 2/2021.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee