UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2178-6
Program	Prior Authorization/Medical Necessity
Medication	Vyleesi™ (bremelanotide)
P&T Approval Date	11/2019, 8/2021, 9/2022, 11/2023, 11/2024, 11/2025
Effective Date	2/15/2026

1. Background:

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 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. Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner. Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men and is not indicated to enhance sexual performance.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Vyleesi** will be approved based on **all** of the following criteria:

   a. Diagnosis of one of the following:

      (1) Acquired, generalized hypoactive sexual desire disorder (HSDD)

      -OR-

      (2) Female sexual interest/arousal disorder

      -AND-

   b. Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months

      -AND-

   c. Low sexual desire is NOT due to any of the following:

      (1) A co-existing medical or psychiatric condition
      (2) Problems within the relationship
      (3) The effects of a medication or other drug substance

      -AND-

   d. Patient was female at birth

-AND-

e. Patient is premenopausal

-AND-

f. Patient does not have uncontrolled hypertension

-AND-

g. Patient does not have known cardiovascular disease

Initial authorization will be issued for 2 months

B. Reauthorization

1. **Vyleesi** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to Vyleesi therapy

-AND-

b. Patient continues to be premenopausal

Reauthorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Vyleesi [package insert]. Cranbury, NJ: Palatin Technologies; February 2021.
2. Sexual dysfunctions. In: Diagnostic and Statistical Manual of Mental Disorders, 5th ed., American Psychiatric Association, Arlington, Virginia 2013.
3. Overview of Sexual dysfunction in females: Management. UpToDate. Updated June 24, 2025. Last accessed October 10, 2025.

Program	Prior Authorization/Medical Necessity – Vyleesi
Change Control	
Date	Change
11/2019	New program.

8/2021	Updated references.
9/2022	Updated references.
11/2023	Updated references.
11/2024	Annual review. Updated references.
11/2025	Annual review. Updated references.