# PRIOR AUTHORIZATION POLICY

**POLICY:** Hypoactive Sexual Desire Disorder – Vyleesi Prior Authorization Policy
- Vyleesi™ (bremelanotide subcutaneous injection – Palatin)

**REVIEW DATE:** 12/14/2022

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## OVERVIEW

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 with the relationship, or effects of a medication or drug substance. Limitations of Use: Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men. Vyleesi is not indicated to enhance sexual performance.[1] In Vyleesi pivotal studies, patients were excluded if they were diagnosed with or being treated for depression, psychosis, bipolar disorder, or substance abuse within 6 months before screening.[2] The prescribing information for Vyleesi notes that it should be discontinued after 8 weeks if the patient does not report an improvement in symptoms.[1]

## Guidelines

The American College of Obstetricians and Gynecologists guideline on Female Sexual Dysfunction (2019) notes the importance of recognizing if the loss of sexual interest is due to a co-morbid or undiagnosed condition, or medication.[3] Consultation with or referral to a mental health specialist with expertise and training in the treatment of female sexual dysfunction (e.g., sex therapists, psychologists, marriage/relationship counselors) should be considered based on the physician's level of expertise and the patient's individual needs. The guideline does not address Vyleesi.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vyleesi. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

**Automation**: None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyleesi is recommended in those who meet the following criteria:

### FDA-Approved Indications

1. **Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 8 weeks if the patient meets the following criteria (i, ii, iii, iv, and v):
     - **i.** Patient is premenopausal; AND
     - **ii.** Patient's symptoms of HSDD/FSIAD have persisted for a minimum of 6 months; AND
     - **iii.** Patient has had normal sexual desire in the past, prior to the diagnosis of HSDD/FSIAD; AND
     - **iv.** Patient has not been diagnosed or treated with depression within the previous 6 months; AND

**v.** Other known causes of HSDD/FSIAD, such as co-existing medical or psychiatric conditions, problems within a relationship, effects of medications (e.g., antidepressants), or drug abuse have been ruled out by the prescriber.

**B)** Patient is Currently Receiving Vyleesi. Approve for 6 months if patient meets the following criteria (i and ii):

**i.** Patient is premenopausal; AND

**ii.** The prescriber confirms that since initiating Vyleesi therapy, the patient reports a significant improvement in sexual desire and/or a decrease in sexual distress.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vyleesi is not recommended in the following situations:

1. **Postmenopausal Patients.** Pivotal trials for Vyleesi included only premenopausal women with acquired, generalized hypoactive sexual desire disorder.[1]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Vyleesi™ subcutaneous injection [prescribing information]. Cranbury, NJ: Palatin; February 2021.
2. Kingsberg SA, Clayton AH, Portman D, et al. Bremelanotide for the treatment of hypoactive sexual desire disorder: Two randomized Phase 3 trials. *Obstet Gynecol.* 2019;134(5):899-908.
3. Female Sexual Dysfunction. *ACOG Practice Bulletin.* Clinical Management Guidelines for Obstetrician-Gynecologist. Number 213; July 2019. Available at: https://www.acog.org/. Accessed on December 6, 2022.