PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/03/2024

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 (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 (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 13, 2023.