Drug Coverage Policy

Effective Date.....08/01/2024
Coverage Policy Number.....IP0117
Policy Title.....Vyleesi

Hypoactive Sexual Desire Disorder – Vyleesi

- Vyleesi™ (bremelanotide subcutaneous injection - Palatin)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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.

Medical Necessity Criteria

Note: Sexual dysfunction therapy is specifically excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Vyleesi is considered medically necessary when the following is met:

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 with or treated for 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD):** **Added** IFP to the policy. **Removed** criterion requiring the patient to be female at birth. **Updated** the criterion related to depression to the patient has not been diagnosed or treated with depression within the previous 6 months. **Updated** the continuation of therapy approach by requiring the patient to be premenopausal.	08/01/2024

The policy effective date is in force until updated or retired.