Reference number(s)
3115-C

Initial Prior Authorization with Quantity Limit Vyleesi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vyleesi	bremelanotide

Indications

FDA-approved Indications

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
- The effects of a medication or 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.

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.

Reference number(s)
3115-C

Coverage Criteria

Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)

Authorization may be granted when the patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) when ALL the following criteria are met:

- The patient is premenopausal.
- HSDD is NOT caused by a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.
- The diagnosis has been appropriately documented (i.e., evaluated by a complete clinical assessment, using Diagnostic and Statistical Manual of Mental Disorders (DSM) and interviews/questionnaires).

Continuation of Therapy

Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)

Authorization may be granted when the patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) when ALL the following criteria are met:

- The patient is premenopausal.
- HSDD is NOT caused by a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.
- The patient has received at least an 8-week supply of the requested drug as a paid claim through a pharmacy benefit (excluding the use of samples or vouchers/coupons).
- The patient has experienced an improvement in the symptoms of HSDD since staring this therapy.

Quantity Limits Apply

8 autoinjectors (2.4 mL) per 25 days or 24 autoinjectors (7.2 mL) per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3115-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Vyleesi [package insert]. Cranbury, NJ: Palatin Technologies, Inc.; February 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 29, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/29/2024).
4. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, Text Revision. Washington, District of Columbia: American Psychiatric Association; 2000.
5. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition, Text Revison. Arlington, Virgina: American Psychiatric Association; 2022.