

Vyleesi (bremelanotide) Effective 03/01/2025

Plan	☐ MassHealth UPPL☒ Commercial/Exchange		⊠ Prior Authorization	
Benefit	☑ Pharmacy Benefit☐ Medical Benefit	•	☐ Quantity Limit☐ Step Therapy	
Specialty Limitations	N/A			
Contact Information	Medical and Specialty Medications			
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693	
	Non-Specialty Medications			
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

Overview

Vyleesi (bremelanotide injection) is a melanocortin receptor agonist 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

Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men. It is also not indicated to enhance sexual performance.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted all of the following criteria are met:

- 1. Member is premenopausal
- 2. Member has a documented diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty
- 3. Member's diagnosis is not due to a coexisting medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted demonstrating member has had a positive response to therapy

Limitations

- 1. Initial approvals will be for 8 weeks
- 2. Reauthorizations will be for 12 months
- 3. The following quantity limits apply:

Drug Name	Quantity Limit
Vyleesi 1.75mg/0.3mL pens	8 pens per 30 days

References

1. Vyleesi (bremelanotide) [prescribing information]. Waltham, MA; AMAG Pharmaceuticals Inc; March 2024.

Review History

01/22/2020 – Drug reviewed P&T Mtg

03/18/2020 – Created PA criteria and approved following DCC and P&T Mtg. Effective 8/1/20.

12/11/2024 – Reviewed and updated at December P&T. Updated verbiage for members who are new to the plan. Updated reauthorization criteria to remove requirement that initial criteria are met. Effective 3/1/2025.

