MEDICAL MUTUAL®

Drug Policy

Policy:	**201927**	**Initial Effective Date: 08/19/2019**
Code(s):	**HCPCS J3490**	**Annual Review Date: 07/20/2023**
SUBJECT:	**Vyleesi (bremelanotide)**	**Last Revised Date: 07/20/2023**

☐Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Vyleesi is a melanocortin receptor agonist indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD). Vyleesi is not indicated for the treatment of HSDD in postmenopausal women or in men or to enhance sexual performance.

POLICY STATEMENT

This policy involves the use of Vyleesi*. Prior authorization is recommended for pharmacy and medical benefit coverage of Vyleesi. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

*Note**:** The treatment of sexual dysfunction, including hypoactive sexual desire disorder (HSDD), is specifically excluded under many benefit plans, regardless of underlying condition; therefore, use of Vyleesi for HSDD where the primary reason for treatment is sexual dysfunction is generally not covered. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions, and limitations of coverage.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Hypoactive Sexual Desire Disorder (HSDD), initial therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient is a premenopausal woman 18 years of age or older; AND
B. The patient has acquired, generalized HSDD as characterized by low sexual desire that causes marked distress or interpersonal difficulty; AND
C. The patient has had normal sexual desire in the past, prior to the diagnosis of HSDD; AND
D. The condition is NOT due to any of the following:
  a. A co-existing medical or psychiatric condition; AND
  b. Problems with the relationship; AND
  c. The effects of a medication or drug substance; AND
E. The prescribing physician has determined the average pre-treatment (that is, prior to the use of any therapy for HSDD) number of satisfying sexual events for the patient over a specific time frame (example: two satisfying sexual events over 1 month) in order to evaluate Vyleesi treatment efficacy after therapy initiation; AND
F. The patient does NOT have uncontrolled hypertension or known cardiovascular disease; AND
G. The patient will not be using more than 8 doses per month or more than one dose within a 24-hour time-frame

2. <u>Hypoactive Sexual Desire Disorder (HSDD), continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient meets all above criteria for new starts; AND
B. The prescribing physician confirms that since initiating Vyleesi therapy, the patient reports an increase in the number of satisfying sexual events as compared to pre-treatment (that is, prior to the use of any therapy for HSDD)

Dosing in Vyleesi. *<u>Dosing must meet the following:</u>* ***(medical benefit requests only)***
1.75 mg administered subcutaneously at least 45 minutes before anticipated sexual activity

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 months
B) *Extended Approval:* 6 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Vyleesi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Enhancement of Sexual Performance. Vyleesi is not indicated to enhance sexual performance.

2. Use in Men or Postmenopausal Women. Vyleesi is only indicated for use in premenopausal women.

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

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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vyleesi [prescribing information]. AMAG Pharmaceutials Inc.; Waltham, MA. June 2019.
2. Bremelanotide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 25 June 2019. Accessed on 18 July 2019.
3. Bremelanotide. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 2 July 2019. Accessed on 18 July 2019.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3490

†When *unclassified drugs* (J3490) is determined to be Vyleesi