Clinical Policy: Bremelanotide (Vyleesi)
Reference Number: CP.PHAR.434
Effective Date: 08.07.19
Last Review Date: 02.20
Line of Business: Commercial, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Bremelanotide (Vyleesi™) is a melanocortin receptor agonist.

FDA Approved Indication(s)
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 NOT due to:

- A co-existing medical or psychiatric condition,
- Problems with the relationship, or
- The effects of a medication or drug substance.

Limitation(s) of use:
- Not indicated for treatment of HSDD in postmenopausal women or in men.
- Not indicated to enhance sexual performance.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Vyleesi is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Hypoactive Sexual Desire Disorder (must meet all):
   1. Diagnosis of HSDD in premenopausal women;
   2. Age ≥ 18 years;
   3. Failure of a 3-month trial of bupropion at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   4. Vyleesi is not prescribed concurrently with Addyi;
   5. Dose does not exceed 1.75 mg (1 injection) per day and no more than 8 doses per month.

Approval duration: 3 months

B. Other diagnoses/indications
   1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.
II. Continued Therapy

A. Hypoactive Sexual Desire Disorder (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Member is responding positively to therapy;
   3. If request is for a dose increase, new dose does not exceed 1.75 mg (1 injection) per day and no more than 8 doses per month.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DSM: Diagnostic and Statistical Manual of Mental Disorders
FDA: Food and Drug Administration
HSDD: hypoactive sexual desire disorder

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>bupropion</td>
<td>Varies</td>
<td>Immediate-release: 450 mg/day (300 mg/day if pediatric)</td>
</tr>
<tr>
<td>(Aplenzin®, Budeprion SR®, Budeprion XL®, Forfivo XL®, Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®)</td>
<td></td>
<td>Sustained-release: 400 mg/day</td>
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<tr>
<td></td>
<td></td>
<td>Extended-release (HCl): 450 mg/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Extended-release (HBr): 522 mg/day</td>
</tr>
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</table>
Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): uncontrolled hypertension or known cardiovascular disease
- Boxed warning(s): none reported

Appendix D: General Information
- HSDD is characterized by a deficiency or absence of sexual fantasies and desire for sexual activity which causes marked distress or interpersonal difficulty, and is not better accounted for by another psychiatric disorder or due exclusively to the direct physiological effects of a substance or to the direct physiological effects of another medical condition. HSDD does not encompass normal (e.g., daily or weekly) fluctuations in levels of desire.
- There is currently no published data demonstrating the efficacy of Vyleesi in the treatment of HSDD in postmenopausal women or in men.
- Treatment should be discontinued after 8 weeks if there is no improvement in symptoms.
- In the DSM-5, female hypoactive sexual desire disorder was merged with female arousal dysfunction and is now reclassified as one disorder: female sexual interest/arousal disorder.
- Two randomized trials (Segraves RT, et al. and Safarinejad MR, et al.) of premenopausal women with HSDD and without underlying depression reported increased sexual pleasure, desire, arousal, and orgasm with bupropion compared with placebo.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSDD</td>
<td>1.75 mg SC in abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity</td>
<td>1.75 mg/day (max 8 doses/month)</td>
</tr>
</tbody>
</table>

VI. Product Availability
Single-dose prefilled autoinjector: 1.75 mg/0.3 mL

VII. References
Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>08.06.19</td>
<td>11.19</td>
</tr>
<tr>
<td>Removed TBD HIM* line of business; added 3-month trial and failure of bupropion;</td>
<td>11.19.19</td>
<td>02.20</td>
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<tr>
<td>added Vyleesi is not prescribed concurrently with Addyi; references reviewed and</td>
<td></td>
<td></td>
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<tr>
<td>updated.</td>
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</table>

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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