



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BREMELANOTIDE

| Generic | Brand | HICL | GCN | Exception/Other |
|---------------|---------|-------|-----|-----------------|
| BREMELANOTIDE | VYLEESI | 45878 | | |

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Vyleesi (bremelanotide) a covered benefit?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom causes marked distress or interpersonal difficulty

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?

- The patient is a premenopausal female
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to bupropion
- The patient is **NOT** currently using Addyi (flibanserin)

If yes, **approve for 8 weeks by HICL with a quantity limit of #2.4mL per month.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **BREMELANOTIDE (Vyleesi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom causes marked distress or interpersonal difficulty

The following criteria must also be met for approval:

- The patient is a premenopausal female
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to bupropion
- The patient is **NOT** currently using Addyi (flibanserin)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
 - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
 - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
 - HSDD symptom causes marked distress or interpersonal difficulty

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - The patient is a premenopausal female
 - The patient is **NOT** currently using Addyi (flibanserin)
 - Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

If yes, **approve for 6 months by HICL with a quantity limit of #2.4mL per month.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BREMELANOTIDE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **BREMELANOTIDE (Vyleesi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom causes marked distress or interpersonal difficulty

The following criteria must also be met for approval:

- The patient is a premenopausal female
- The patient is **NOT** currently using Addyi (flibanserin)
- Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

- Vyleesi [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2019.

| Library | Commercial | NSA |
|---------|------------|-----|
| Yes | Yes | No |

Part D Effective: N/A

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