Reference number(s)
2903-A

Specialty Guideline Management fulvestrant products

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
Cligavyx	fulvestrant
Faslodex	fulvestrant

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1-3]

Cligavyx and Faslodex are indicated for the treatment of:

- Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy as monotherapy.
- HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy as monotherapy.
- HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib as initial endocrine based therapy or following disease progression on endocrine therapy.
- HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy.

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Compendial Uses[4]

- Breast cancer
- Low grade serous ovarian carcinoma
- Endometrial carcinoma
- Uterine sarcoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review, where applicable:

- Hormone receptor (HR) status
- HER2 activating mutation status

Coverage Criteria

Breast Cancer[1-5]

Authorization of 12 months may be granted for treatment of breast cancer when either of the following criteria is met:

- The disease is recurrent unresectable, advanced, or metastatic HR-positive.
- The requested medication will be used in combination with neratinib and trastuzumab or tucatinib and trastuzumab as third-line or later, for triple negative metastatic disease with HER2 activating mutation.

Low Grade Serous Ovarian Carcinoma[4]

Authorization of 12 months may be granted for treatment of recurrence of low-grade serous ovarian carcinoma as a single agent for members who previously received an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane).

Endometrial Carcinoma[4]

Authorization of 12 months may be granted for treatment of endometrial carcinoma when either of the following criteria are met:

- Medication will be used as a single agent.

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- Medication will be used in combination with abemaciclib for estrogen receptor (ER) positive disease.

Uterine Sarcoma[4]

Authorization of 12 months may be granted for treatment of low-grade stage II-IV endometrial stromal sarcoma (ESS), adenosarcoma without sarcomatous overgrowth, or estrogen receptor/progesterone receptor positive (ER/PR+) uterine sarcomas, as a single agent.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Cligavyx [package insert]. Parsippany, NJ: Avyxa Pharma, LLC; November 2025.
2. Faslodex [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2021.
3. Fulvestrant [package insert]. Bedminster, NJ: Alembic Pharmaceuticals Inc.; August 2025.
4. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 23, 2025.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 23, 2026.

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