## SPECIALTY GUIDELINE MANAGEMENT

# FASLODEX (fulvestrant) fulvestrant

#### **POLICY**

#### I. 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**

Faslodex is 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.
- HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
- 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

## Compendial Indications

- Breast cancer: therapy for recurrent or stage IV hormone receptor-positive disease
- Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer/Epithelial ovarian cancer: recurrence therapy for low grade serous carcinoma
- Endometrial carcinoma
- Uterine sarcoma (low-grade endometrial stromal sarcoma and uterine leiomyosarcoma)

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

## **II. DOCUMENTATION**

Submission of hormone receptor (HR) status is necessary to initiate the prior authorization review, where applicable.

#### III. CRITERIA FOR INITIAL APPROVAL

### A. Breast Cancer

Authorization of 12 months may be granted for treatment recurrent, advanced, or stage IV HR-positive breast cancer.

B. Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer/Epithelial ovarian cancer
Authorization of 12 months may be granted for treatment of recurrent low grade serous carcinoma.

fulvestrant-Faslodex 2903-A SGM P2020

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#### C. Endometrial cancer

Authorization of 12 months may be granted for treatment of endometrial cancer.

#### D. Uterine sarcoma

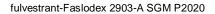
Authorization of 12 months may be granted for treatment of low-grade endometrial stromal sarcoma and uterine leiomyosarcoma.

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for breast cancer, low grade serous carcinoma, endometrial cancer, low-grade endometrial stromal sarcoma or uterine leiomyosarcoma and who have not experienced disease progression or an unacceptable toxicity.

#### V. REFERENCES

- 1. Faslodex [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2019.
- 2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 9, 2020.



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