Reference number(s)
2903-A

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.

A. FDA-Approved Indications
Faslodex is indicated for the treatment of:
a. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
b. HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
c. 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.
d. HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy

B. Compendial Uses
a. Breast cancer: therapy for recurrent or stage IV hormone receptor-positive disease
b. Low grade serous ovarian carcinoma
c. Endometrial carcinoma
d. 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. Low Grade Serous Ovarian Carcinoma
Authorization of 12 months may be granted for treatment of persistent disease or recurrence of low-grade serous ovarian carcinoma.

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 an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Faslodex [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 24, 2020.