Clinical Policy: Fulvestrant (Faslodex Injection)

Reference Number: ERX.SPA.328
Effective Date: 09.01.19
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

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

Description
Fulvestrant (Faslodex® Injection) is an estrogen receptor antagonist.

FDA Approved Indication(s)
Faslodex is indicated for the treatment of:
Monotherapy
- 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.

Combination 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.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Faslodex Injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**
1. Diagnosis of advanced breast cancer (i.e., recurrent, stage III, or stage IV [metastatic]);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is HR-positive (i.e., estrogen or progesterone receptor [ER/PR]-positive);
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 500 mg three times for the first month then once monthly;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (off-label) (must meet all)**:**
1. Diagnosis of ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Disease is classified as low-grade serous carcinoma;

4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Endometrial Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of endometrial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Disease is classified as grade 1 or 2 endometrioid carcinoma;
4. Faslodex is prescribed in one of the following ways (a, b, c, or d):
   a. For recurrent or metastatic disease;
   b. For stage II disease, in combination with sequential external beam radiation therapy
   c. For stage IIIA or higher disease;
   d. For disease not suitable for primary surgery;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Uterine Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of uterine sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Disease is classified in one of the following ways (a or b):
   a. Low-grade endometrial stromal sarcoma;
   b. HR-positive (i.e., ER/PR-positive) uterine leiomyosarcoma;
4. Faslodex is prescribed in one of the following ways (a, b, c, or d):
   a. Following total hysterectomy;
   b. For vaginal or pelvic recurrence;
   c. For metastatic disease;
   d. For disease not suitable for primary surgery;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

E. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Faslodex Injection for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 500 mg once monthly;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ER: estrogen receptor
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
PR: progesterone receptor

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Monotherapy • HR-positive, 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.	Faslodex: 500 mg IM into buttocks (gluteal area) slowly (1 - 2 minutes per injection) as two 5 mL injections, one in each buttock, on Days 1, 15, 29 and once monthly thereafter.	Faslodex: 500 mg three times for first month then once monthly
Combination 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	Faslodex: 500 mg IM into buttocks (gluteal area) slowly (1 - 2 minutes per injection) as two 5 mL injections, one in each buttock, on Days 1, 15, 29 and once monthly thereafter. Ribociclib: 600 mg PO QD for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. Palbociclib: 125 mg PO QD for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. Abemaciclib: 150 mg PO BID. *Pre/perimenopausal women treated with the combination of Faslodex plus palbociclib, abemaciclib, or ribociclib, should be treated with luteinizing hormone-releasing hormone (LHRH)*	Faslodex: 500 mg three times for first month then once monthly Ribociclib: 600 mg/day Palbociclib: 125 mg/day

Indication	Dosing Regimen	Maximum Dose
disease progression after endocrine therapy.	*agonists according to current clinical practice standards.*	Abemaciclib: 300 mg/day

VI. Product Availability

Two 5 mL glass barrels (syringes), each containing 250 mg/5 mL of Faslodex solution for IM injection. The syringes are presented in a tray with polystyrene plunger rod and safety needles (SafetyGlide™) for connection to the barrel.

VII. References

1. Faslodex Prescribing Information. Wilmington, DE: AstraZeneca; September 2020. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=83d7a440-e904-4e36-afb5-cb02b1c919f7. Accessed May 6, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 6, 2021.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed May 6, 2021.
4. National Comprehensive Cancer Network. Ovarian Cancer Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 6, 2021.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed May 6, 2021.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	05.14.19	08.19
3Q 2020 annual review: modified continued therapy approval duration from 6 to 12 months; for endometrial carcinoma, added option for use in stage II disease, in combination with sequential external beam radiation therapy; references reviewed and updated.	04.30.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.06.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.