Clinical Policy: Fulvestrant (Faslodex Injection)

Reference Number: PA.CP.PHAR.424
Effective Date: 01/2020
Last Review Date: 07/2023

Coding Implications
Revision Log

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.

It is the policy of PA Health & Wellness® 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*).

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. 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*).

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. Fulvestrant is prescribed in one of the following ways (a, b, c, d, e or f):
   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. As adjuvant therapy for stage IV disease;
   e. For disease not suitable for primary surgery;
   f. Other category 1, 2A, or 2B NCCN recommended uses;
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*).

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, b, c, d, e or f):
   a. Low-grade endometrial stromal sarcoma;
   b. Adenosarcoma without sarcomatous overgrowth;
   c. HR-positive (i.e., ER/PR-positive) uterine leiomyosarcoma;
   d. HR-positive (i.e., ER/PR-positive) uterine sarcoma;
   e. Undifferentiated uterine sarcoma (UUS);
   f. Perivascular epithelioid cell neoplasms (PEComas);
4. Fulvestrant is prescribed in one of the following ways (a, b, c, d or e):
   a. Following total hysterectomy;
   b. For vaginal or pelvic recurrence;
   c. For metastatic disease;
   d. For disease not suitable for primary surgery;
   e. Other category 1, 2A, or 2B NCCN recommended uses;
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*).

Approval duration: 6 months

E. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 policies – PA.CP.PMN.53

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
LHRH: luteinizing hormone-releasing hormone
NCCN: National Comprehensive Cancer Network
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 disease progression after 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. 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) agonists according to current clinical practice standards.*	Faslodex: 500 mg three times for first month then once monthly Ribociclib: 600 mg/day Palbociclib: 125 mg/day Abemaciclib: 300 mg/day

VI. Product Availability

Two 5 mL glass barrels (syringes), each containing 250 mg/5 mL of fulvestrant solution for IM injection.

VII. References

1. Fulvestrant Prescribing Information. Pennington, NJ: Zydus Pharmaceuticals Inc; December 2022; Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=994edf79-20a5-4e3a-bb35-c4fe3e65acba. Accessed May 23, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 23, 2023.
3. National Comprehensive Cancer Network. Breast Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. May 23, 2023.
4. National Comprehensive Cancer Network. Ovarian Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 23, 2023.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed May 23, 2023.
6. Clinical Pharmacology powered by ClinicalKey. Philadelphia, PA: Elsevier; 2023. Available at: http://www.clinicalkey.com/. Accessed May 23, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9395	Injection, fulvestrant, 25 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	05/2019	
3Q 2020 annual review: for endometrial carcinoma, added option for us in stage II disease, in combination with sequential external beam radiation therapy; references reviewed and updated.	08/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	
3Q 2022 annual review: no significant changes; added "adenosarcoma without sarcomatous overgrowth" to disease classification for the indication of uterine sarcoma per NCCN guideline (2A category); references reviewed and updated.	07/2022	
3Q 2023 annual review: per NCCN guidelines for endometrial carcinoma, added coverage for use as adjuvant therapy for stage IV disease (category 2A); for uterine sarcomas updated coverage language to include HR-positive uterine sarcomas instead of uterine leiomyosarcomas to align with NCCN recommendation language; references reviewed and updated.	07/2023	