Clinical Policy Title:	fulvestrant
Policy Number:	RxA.118
Drug(s) Applied:	Faslodex®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

fulvestrant (Faslodex®) is an estrogen receptor antagonist. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
fulvestrant (Faslodex®)	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	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	Faslodex®: 500 mg three times for first month then once monthly Ribociclib:

	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.	thereafter. Ribociclib: 600 mg PO once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. Palbociclib: 125 mg PO once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. Abemaciclib: 150 mg PO BID.	600 mg/day Palbociclib: 125 mg/day Abemaciclib: 300 mg/day

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.

Dosage Forms

- 5-mL glass barrels (syringes): 250 mg/5 mL solution for IM injection.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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 consultation with an oncologist;
3. Age 18 years of age or older;
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
Commercial: 6 months
Medicaid: 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. Request is for one of the following: (a or b or c);
   a. Used as immediate treatment for serially rising CA-125 in patients that previously received chemotherapy;
   b. For progression on primary, maintenance, or recurrence therapy;
   c. For stable or persistent disease (if not on maintenance therapy);

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
Commercial: 6 months
Medicaid: 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, or c):
   a. For recurrent or metastatic disease;
   b. For stage IIIA or higher disease;
   c. 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).*

Approval Duration
Commercial: 6 months
Medicaid: 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. 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;
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).*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All indication in Section I (must meet all):
1. Member is currently receiving medication that has been authorized by Rxadvance or member has previously met initial approval criteria and 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).*

Approval Duration
Commercial: 12 months

Medicaid: 12 months

III. Appendices

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.

APPENDIX D: General Information

- Risk of Bleeding: Use with caution in patients with bleeding diatheses, thrombocytopenia, or anticoagulant use.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

References

1. Faslodex Prescribing Information. Wilmington, DE: AstraZeneca; August 2020. Available at: https://www.azpicentral.com/faslodex/faslodex.pdf. Accessed January 20, 2021.
2. Afinitor/Afinitor Disperz Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020. Available at: https://www.novartis.us/sites/www.novartis.us/files/afinitor.pdf. Accessed January 20, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 20, 2021.
4. National Comprehensive Cancer Network. Breast Cancer Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 20, 2021.
5. National Comprehensive Cancer Network. Ovarian Cancer Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 20, 2021.
6. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed January 20, 2021.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title was updated.	01/20/2021	03/09/2021

2. Line of business policy applies to was updated to ‘’All lines of business”. 3. Initial criteria I.B.4 added. 4. Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria and received this medication for at least 30 days.” 5. References were reviewed and updated.		