

Clinical Policy Title:	fulvestrant
Policy Number:	RxA.118
Drug(s) Applied:	Faslodex®, fulvestrant
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

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. Disease is HR-positive, human epidermal growth factor receptor 2 (HER2)- negative, and the requested medication is prescribed in one of the following ways (a, b, c, d, e or f):
 - a. As first line therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole) in patients without visceral crisis;
 - b. As first line therapy in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib or ribociclib) for HER2- negative disease with no visceral crisis;
 - c. As second line and subsequent therapy in combination with everolimus for HER-2 negative disease with no visceral crisis;
 - d. As a second line or subsequent-line therapy in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) for HER-2 negative disease with no visceral crisis if a CDK4/6 inhibitor was not previously used;
 - e. As a second or subsequent line therapy in combination with alpelisib for HER2- negative disease with no visceral crisis if PIK3CA activating mutation positive;
 - f. As a first line or subsequent-line therapy as a single agent for HER2- negative disease with no visceral crisis;
3. If disease is HR-positive and HER2-positive, the requested medication is used as a single agent or in combination with Herceptin®.

Approval Duration

All Lines of Business (except Medicare): 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. Disease is classified as low-grade serous carcinoma;
3. Request is for one of the following: (a, 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).

Approval Duration

All Lines of Business (except Medicare): 6 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

C. Endometrial carcinoma (off-label) (must meet all):

1. Diagnosis of endometrial carcinoma;
2. Disease is classified as grade 1 or 2 endometrioid carcinoma;
3. The requested medication is prescribed in one of the following ways (a, b, c, d or e):
 - a. Primary treatment in patients undergoing both brachytherapy and external beam radiation therapy (EBRT) with cervical involvement that is not suitable for surgery;
 - b. Primary treatment in patients with disease limited to the uterus or extrauterine disease that is not suitable for primary surgery;
 - c. Primary treatment in patients with distant metastatic disease;
 - d. Adjuvant treatment for locally advanced or metastatic (stage III-IV) disease;
 - e. Treatment for disseminated metastases or locoregional recurrence.

Approval Duration

All Lines of Business (except Medicare): 6 months

D. Uterine sarcoma (off -label) (must meet all):

1. Diagnosis of uterine sarcoma;
2. Disease is classified in one of the following ways (a, b, or c):
 - a. Low-grade endometrial stromal sarcoma;
 - b. Adenosarcoma without sarcomatous overgrowth;
 - c. HR-positive (i.e., ER/PR-positive) uterine leiomyosarcoma;
3. The requested medication 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.
 - e.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All indication in Section I (must meet all):

1. Auto-approval is based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Breast Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Ovarian Cancer Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical policy title was updated. 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. 	<p>01/20/2021</p>	<p>03/09/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A..4 a, b, c, d, e, f was included; 2. Initial Approval Criteria I.A.5 was updated to include, Used as a single agent or in combination with Herceptin® if disease is HR-Positive, HER2- positive; 3. Initial approval criteria I.C.4 updated to remove: <ol style="list-style-type: none"> a. For recurrent or metastatic disease; b. For stage IIIA or higher disease; c. For disease not suitable for primary surgery; 3. Initial approval criteria I.C.4 updated to include: <ol style="list-style-type: none"> a. Primary treatment in patients undergoing both brachytherapy and external beam radiation therapy (EBRT) with cervical involvement that is not suitable for surgery; b. Primary treatment in patients with disease limited to the uterus or extrauterine disease that is not suitable for primary surgery; c. Primary treatment in patients with distant metastatic disease; d. Adjuvant treatment for locally advanced or metastatic (stage III-IV) disease; e. Treatment for disseminated metastases or locoregional recurrence; 2. References were reviewed and updated. 	<p>11/24/2021</p>	<p>01/17/2022</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.D.3: Updated to include new diagnostic criteria Disease is classified in one of the following ways (a, b, or 	<p>10/12/2022</p>	<p>01/17/2023</p>

<p>c):</p> <ol style="list-style-type: none"> a. Low-grade endometrial stromal sarcoma; b. Adenosarcoma without sarcomatous overgrowth; c. HR-positive (i.e., ER/PR-positive) uterine leiomyosarcoma. <p>2. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Added generic fulvestrant to Drug(s) Applied. 2. Removed age restrictions. 3. Removed prescriber restrictions. 4. Removed dose restrictions. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed reauthorization requirement for positive response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated. 	<p>08/28/2024</p>	<p>09/13/2024</p>