Clinical Policy: Fulvestrant (Faslodex Injection)

Reference Number: CP.PHAR.424
Effective Date: 05.14.19
Last Review Date: 08.25 Coding Implications
Line of Business: Commercial, HIM, 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 Injection 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 health plans affiliated with Centene Corporation® that fulvestrant and Faslodex Injection are **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. One of the following (a or b):
   a. Disease is HR-positive (i.e., estrogen or progesterone receptor [ER/PR]-positive);
   b. Disease is triple negative (i.e., ER-negative, PR-negative, and HER2-negative);
5. For Faslodex requests, member must use fulvestrant, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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. Prescribed as single-agent therapy;
5. For Faslodex requests, member must use fulvestrant, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 or b):
   a. For recurrent or metastatic disease;
   b. For disease not suitable for primary surgery;
5. Prescribed as single-agent therapy;
6. For Faslodex requests, member must use fulvestrant, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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, or c):
   a. Low-grade endometrial stromal sarcoma;
   b. Adenosarcoma without sarcomatous overgrowth;

c. HR-positive (i.e., ER/PR-positive) uterine sarcoma;

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 recurrent or metastatic disease;
   d. For disease not suitable for primary surgery;
   e. For extrauterine disease;
5. Prescribed as single-agent therapy;
6. For Faslodex requests, member must use fulvestrant, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving fulvestrant for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Faslodex requests, member must use fulvestrant, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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
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 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 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 27, 2025.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 19, 2025.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed May 19, 2025.
4. National Comprehensive Cancer Network. Ovarian Cancer Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 19, 2025.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed May 19, 2025.

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
J9393	Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg
J9394	Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg
J9395	Injection, fulvestrant, 25 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	05.06.21	08.21
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); continued approval duration for commercial line of business changed from 12 months to 6 months or to the member's renewal date, whichever is longer; references reviewed and updated.	04.08.22	08.22
Template changes applied to other diagnoses/indications.	09.23.22	
Added HPCPS codes [J9394, J9393].	01.06.23	
3Q 2023 annual review: no significant changes; 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.	04.13.23	08.23
3Q 2024 annual review: revised policy/criteria section to also include generic fulvestrant; added redirection to generic fulvestrant for all indications; removed stage II and IIIA disease references from endometrial carcinoma criteria per NCCN; removed adjuvant therapy	05.23.24	08.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
for stage IV disease from endometrial carcinoma criteria for consolidation as this may be captured by metastatic disease option; added additional criteria options for recurrent and extrauterine disease for uterine carcinoma criteria per NCCN; references reviewed and updated.		
3Q 2025 annual review: for breast cancer, added triple negative disease option per NCCN; for ovarian, fallopian tube, and primary peritoneal cancer, endometrial carcinoma, and uterine cancer, added requirement for monotherapy per NCCN; references reviewed and updated.	04.09.25	08.25

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.