Clinical Policy: Fulvestrant (Faslodex Injection)

Reference Number: CP.PHAR.424
Effective Date: 05.14.19
Last Review Date: 08.19
Line of Business: Commercial, Medicaid, HIM

Coding Implications
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.

It is the policy of health plans affiliated with Centene Corporation® 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:

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. 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:
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. 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:
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 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*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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 Faslodex 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*).

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or to the member's renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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
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 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; March 2019. Available at https://www.azpicentral.com/faslodex/faslodex.pdf#page=1. Accessed March 26, 2019.
2. Afinitor/Afinitor Disperz Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. April 2018. Available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/afinitor.pdf. Accessed March 27, 2019.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed March 26, 2019.
4. National Comprehensive Cancer Network. Breast Cancer Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 26, 2019.
5. National Comprehensive Cancer Network. Ovarian Cancer Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed March 26, 2019.
6. National Comprehensive Cancer Network. Uterine Neoplasms Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed March 26, 2019.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/.

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.	05.14.19	08.19

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.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.