

# Faslodex® (fulvestrant) (Intramuscular)

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## I. Length of Authorization

Coverage will be provided for six months and may be renewed.

## II. Dosing Limits

### A. Quantity Limit (max daily dose) [NDC Unit]:

- Faslodex 250 mg/5 mL prefilled injection: 6 syringes first 29 days initially (loading doses), then 2 syringes per 28 days thereafter as maintenance

### B. Max Units (per dose and over time) [HCPCS Unit]:

#### Ovarian Cancer

##### **Loading Dosing:**

- 20 units on day 1 and 10 units on days 15 and 29

##### **Maintenance Dosing:**

- 10 units every 28 days

#### Endometrial Cancer

- 10 units every 28 days

#### Breast Cancer/Uterine Sarcoma

##### **Loading Dosing:**

- 20 units every 14 days for 3 doses

##### **Maintenance Dosing:**

- 20 units every 28 days

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Breast Cancer †** <sup>1,2,5,8-11</sup>

- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
- Disease is advanced, metastatic, or recurrent; **AND**
  - Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
    - Used as initial therapy; **AND**
      - Used as a single agent †; **OR**
      - Used in combination with ribociclib †; **OR**
      - Used in combination with palbociclib or abemaciclib in patients without visceral crisis; **OR**
      - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) in patients without visceral crisis; **OR**
    - Used as subsequent therapy; **AND**
      - Used as a single agent †; **OR**
      - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) †; **OR**
      - Used in combination with everolimus in patients without visceral crisis; **OR**
      - Used in combination with alpelisib in patients without visceral crisis and patient has PIK3CA mutation positive disease; **OR**
  - Patient has HR-positive, HER2-positive disease ‡; **AND**
    - Used as a single agent or in combination with trastuzumab

#### **Ovarian Cancer (epithelial, fallopian tube, or primary peritoneal cancer) ‡<sup>2,7,12</sup>**

- Used as single agent therapy; **AND**
- Patient has recurrent or persistent low-grade serous carcinoma; **AND**
- Will not be used for immediate treatment of biochemical relapse (i.e., rising CA-125 and no radiographic evidence of disease)

#### **Endometrial Adenocarcinoma (Uterine Neoplasms) ‡<sup>2,6,13</sup>**

- Used as single agent therapy; **AND**
- Patient has grade 1 or 2 endometrioid histology; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used as ONE of the following:
  - Primary treatment in patients undergoing both brachytherapy and external beam radiation therapy (EBRT) with cervical involvement that is not suitable for surgery; **OR**

- Primary treatment in patients with disease limited to the uterus or extrauterine disease that is not suitable for primary surgery; **OR**
- Primary treatment in patients with distant metastatic disease; **OR**
- Adjuvant treatment for locally advanced or metastatic (stage III-IV) disease; **OR**
- Treatment for disseminated metastases or locoregional recurrence

**Uterine Sarcoma (Uterine Neoplasms) ‡<sup>2,13</sup>**

- Used as single agent therapy; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used for low-grade endometrial stromal sarcoma (ESS) OR for ER/PR positive uterine leiomyosarcoma (uLMS); **AND**
  - Used following total hysterectomy for stage II-IV disease; **OR**
  - Used for metastatic or recurrent disease; **OR**
  - Used for disease that is not suitable for primary surgery

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

#### IV. Renewal Criteria <sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: bleeding abnormalities, severe injection site reactions, etc.

#### V. Dosage/Administration <sup>1,6,7</sup>

| Indication                      | Dose  |
|---------------------------------|---|
| Breast Cancer & Uterine Sarcoma | <p><b>Loading Dose:</b></p> <ul style="list-style-type: none"> <li>● 500 mg intramuscularly (IM) on Days 1, 15, 29</li> </ul> <p><b>Maintenance Dose:</b></p> <ul style="list-style-type: none"> <li>● 500 mg IM every 28 days</li> </ul> |
| Ovarian Cancer                  | <p><b>Loading Dose:</b></p> <ul style="list-style-type: none"> <li>● 500 mg intramuscularly (IM) on Day 1 and 250 mg IM on Days 15 and 29</li> </ul> <p><b>Maintenance Dose:</b></p>  |

|                    |  |
|--------------------|--|
|                    | <ul style="list-style-type: none"> <li>• 250 mg IM every 28 days</li> </ul>  |
| Endometrial Cancer | 250 mg by IM injection every 4 weeks for at least 8 weeks. Therapy should be continued until evidence of progressive disease or adverse effects prevent further treatment. |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9395 – Injection, fulvestrant, 25 mg; 1 billable unit = 25 mg

### NDC:

- Faslodex\* 250 mg/5 mL single-dose prefilled injections: 00310-0720-xx  
\*Available generically

## VII. References

1. Faslodex [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; July 2020. Accessed August 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for fulvestrant. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed by Magellan Rx August 2020.
3. Chia S, Gradishar W, Mauriac L, et al. Double-blind, randomized placebo-controlled trial of fulvestrant compared with exemestane after prior nonsteroidal aromatase inhibitor therapy in postmenopausal women with hormone-receptor positive, advanced breast cancer: results from EFECT. *J Clin Oncol* 2008; 26:1664-1670.
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10. Cristofanilli M, Turner NC, Bondarenko I, et al. Fulvestrant plus palbociclib versus fulvestrant plus placebo for treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer that progressed on previous endocrine therapy (PALOMA-3): final analysis of the multicentre, double-blind, phase 3 randomised controlled trial [published correction appears in *Lancet Oncol*. 2016 Apr;17 (4):e136] [published correction appears in *Lancet Oncol*. 2016 Jul;17 (7):e270]. *Lancet Oncol*. 2016;17(4):425-439. doi:10.1016/S1470-2045(15)00613-0.
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12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2020. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed by Magellan Rx August 2020.
13. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) for Uterine Neoplasms Version 2.2020. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed by Magellan Rx August 2020.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10  | ICD-10 Description  |
|---------|---|
| C48.1   | Malignant neoplasm of specified parts of peritoneum                       |
| C48.2   | Malignant neoplasm of peritoneum, unspecified                             |
| C48.8   | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C50.011 | Malignant neoplasm of nipple and areola, right female breast              |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast               |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast        |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast                |

| ICD-10  | ICD-10 Description  |
|---------|---|
| C50.022 | Malignant neoplasm of nipple and areola, left male breast               |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast        |
| C50.111 | Malignant neoplasm of central portion of right female breast            |
| C50.112 | Malignant neoplasm of central portion of left female breast             |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast      |
| C50.121 | Malignant neoplasm of central portion of right male breast              |
| C50.122 | Malignant neoplasm of central portion of left male breast               |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast        |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast       |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast        |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast         |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast          |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast   |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast       |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast        |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast         |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast          |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast   |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast       |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast        |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast         |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast          |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast   |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast       |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast        |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast         |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast          |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast   |
| C50.611 | Malignant neoplasm of axillary tail of right female breast              |
| C50.612 | Malignant neoplasm of axillary tail of left female breast               |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast        |
| C50.621 | Malignant neoplasm of axillary tail of right male breast                |
| C50.622 | Malignant neoplasm of axillary tail of left male breast                 |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast          |

| ICD-10  | ICD-10 Description   |
|---------|--|
| C50.811 | Malignant neoplasm of overlapping sites of right female breast       |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast        |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast         |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast          |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast   |
| C50.911 | Malignant neoplasm of unspecified site of right female breast        |
| C50.912 | Malignant neoplasm of unspecified site of left female breast         |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast  |
| C50.921 | Malignant neoplasm of unspecified site of right male breast          |
| C50.922 | Malignant neoplasm of unspecified site of left male breast           |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast    |
| C53.0   | Malignant neoplasm of endocervix                                     |
| C54.0   | Malignant neoplasm of isthmus uteri                                  |
| C54.1   | Malignant neoplasm of endometrium                                    |
| C54.2   | Malignant neoplasm of myometrium                                     |
| C54.3   | Malignant neoplasm of fundus uteri                                   |
| C54.8   | Malignant neoplasm of overlapping sites of corpus uteri              |
| C54.9   | Malignant neoplasm of corpus uteri, unspecified                      |
| C55     | Malignant neoplasm of uterus, part unspecified                       |
| C56.1   | Malignant neoplasm of right ovary                                    |
| C56.2   | Malignant neoplasm of left ovary                                     |
| C56.9   | Malignant neoplasm of unspecified ovary                              |
| C57.00  | Malignant neoplasm of unspecified fallopian tube                     |
| C57.01  | Malignant neoplasm of right fallopian tube                           |
| C57.02  | Malignant neoplasm of left fallopian tube                            |
| C57.10  | Malignant neoplasm of unspecified broad ligament                     |
| C57.11  | Malignant neoplasm of right broad ligament                           |
| C57.12  | Malignant neoplasm of left broad ligament                            |
| C57.20  | Malignant neoplasm of unspecified round ligament                     |
| C57.21  | Malignant neoplasm of right round ligament                           |
| C57.22  | Malignant neoplasm of left round ligament                            |
| C57.3   | Malignant neoplasm of parametrium                                    |
| C57.4   | Malignant neoplasm of uterine adnexa, unspecified                    |
| C57.7   | Malignant neoplasm of other specified female genital organs          |
| C57.8   | Malignant neoplasm of overlapping sites of female genital organs     |
| C57.9   | Malignant neoplasm of female genital organ, unspecified              |
| Z85.3   | Personal history of malignant neoplasm of breast                     |

| ICD-10 | ICD-10 Description                              |
|--------|---|
| Z85.43 | Personal history of malignant neoplasm of ovary |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15  | KY, OH  | CGS Administrators, LLC                           |