Fulvestrant:
Faslodex®; Fulvestrant Ψ
(Intramuscular)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

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

Ovarian Cancer

- **Loading Dosing:** 20 billable units on day 1 and 10 billable units on days 15 and 29
- **Maintenance Dosing:** 10 billable units every 28 days

Endometrial Cancer

- 10 billable units every 28 days

Breast Cancer/Uterine Sarcoma

- **Loading Dosing:** 20 billable units every 14 days for 3 doses
- **Maintenance Dosing:** 20 billable units every 28 days

III. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

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

Breast Cancer † ‡ [1-3,4,7,10-13,16,17]

- Patient is postmenopausal, premenopausal with ovarian ablation/suppression**,** or male (sex assigned at birth); **AND**

- Patient has advanced, metastatic, or recurrent unresectable invasive disease; **AND**
  - Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease with no visceral crisis; **AND**
    - Used as initial 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 a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) **¥ ‡**; **OR**
      - Used in combination with inavolisib and palbociclib in patients with PIK3CA activating mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
        - Used after disease progression on adjuvant endocrine therapy; **OR**
        - Used after disease relapse within 12 months of adjuvant endocrine therapy completion; **OR**
    - Used as subsequent therapy; **AND**
      - Used as a single agent; **OR**
      - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) **¥ ‡**; **OR**
      - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if a CDK 4/6 inhibitor was not previously used; **OR**
      - Used in combination with everolimus **‡**; **OR**
      - Used in combination with alpelisib in patients who have PIK3CA activating mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖ **‡**; **OR**
      - Used in combination with capivasertib in patients with PIK3CA or AKT1 activating mutations or PTEN loss of function alterations, as determined by an FDA-approved or CLIA-compliant test❖; **AND**
        - Used for disease that has progressed on at least one endocrine-based regimen in the metastatic setting; **OR**
        - Used for disease recurrence on or within 12 months of completing adjuvant therapy; **OR**
        - Used after disease progression or recurrence after one or more prior lines of endocrine therapy (ET), including one line containing a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib); **OR**

- Patient has HR-positive, HER2-positive* disease as determined by an FDA-approved or CLIA-compliant test❖‡; **AND**
  - Used as a single agent or in combination with trastuzumab; **OR**

- Patient has recurrent unresectable or metastatic inflammatory disease ‡; **AND**
  - Patient has HR-positive, HER2-negative disease with no visceral crisis; **AND**
    - Used as first line therapy; **AND**
      - Used as a single agent; **OR**
      - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) ¥; **OR**
      - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if disease progression on adjuvant ET or with early disease relapse within 12 months of adjuvant ET completion; **AND**
        - Used after disease progression on adjuvant endocrine therapy; **OR**
        - Used after disease relapse within 12 months of adjuvant endocrine therapy completion; **OR**
      - Used in combination with inavolisib and palbociclib in patients with PIK3CA activating mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
        - Used after disease progression on adjuvant endocrine therapy; **OR**
        - Used after disease relapse within 12 months of adjuvant endocrine therapy completion; **OR**
    - Used as subsequent therapy; **AND**
      - Used as a single agent; **OR**
      - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) ¥; **OR**
      - Used in combination with everolimus; **OR**
      - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if a CDK 4/6 inhibitor was not previously used; **OR**
      - Used in combination with alpelisib in patients who have PIK3CA activating mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
      - Used in combination with capivasertib in patients with PIK3CA or AKT1 activating mutations or PTEN loss of function alterations, as determined by an FDA-approved or CLIA-compliant test❖; **AND**

- Used after disease progression or recurrence after one or more prior lines of ET, including one line containing a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib); **OR**

- Patient has HR-positive, HER2-positive* disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used as a single agent or in combination with trastuzumab

¥ *When an aromatase inhibitor is used in males, suppression of testicular steroidogenesis with a gonadotropin releasing hormone (GnRH) analog is required.*

Ovarian Cancer (Epithelial, Fallopian Tube, or Primary Peritoneal Cancer) ‡ [4,9,14]

- Used as single agent therapy; **AND**
- Patient has recurrent low-grade serous carcinoma; **AND**
- Patient has previously received treatment with an aromatase inhibitor (i.e., letrozole, anastrozole, exemestane)

Endometrial Carcinoma (Uterine Neoplasms) ‡ [4,8,15]

- Used as single agent therapy; **AND**
- Patient has grade 1 or 2 endometrioid adenocarcinoma histology; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used as ONE of the following**:**
  - Adjuvant treatment for stage IV disease; **OR**
  - Treatment for disseminated metastases or locoregional recurrence; **OR**
  - Primary treatment in patients with locoregional extrauterine disease that is not suitable for primary surgery; **OR**
  - Primary treatment in patients with distant metastatic disease

Uterine Sarcoma (Uterine Neoplasms) ‡ [4,15]

- 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), adenosarcoma without sarcomatous overgrowth, or ER/PR positive uterine sarcoma; **AND**
  - Used following total hysterectomy for stage II-IV disease; **OR**
  - Used for metastatic or recurrent disease; **OR**
  - Used as primary treatment; **AND**
    - Disease is not suitable for primary surgery (disease is not amenable to resection or patient is not suitable for surgery based on comorbidities); **OR**

- Patient has extrauterine disease diagnosed by biopsy or myomectomy

*HER2-positive overexpression criteria [16]
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following: ○ HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR** ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR** ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-3]

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 (including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy), etc.

V. Dosage/Administration [1-3,8,9,17]

Indication	Dose
Breast Cancer	**Loading Dose:** • Administer 500 mg intramuscularly (IM) on Days 1, 15, 29 **Maintenance Dose:** • Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity ******Note:** For premenopausal and perimenopausal women, administer a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. For men, consider administering a LHRH agonist according to current clinical practice standards.*

Uterine Sarcoma	**Loading Dose:** • Administer 500 mg intramuscularly (IM) on Days 1 15, 29 **Maintenance Dose:** • Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity
Ovarian Cancer	**Loading Dose:** • Administer 500 mg intramuscularly (IM) on Day 1 and 250 mg IM on Days 15 and 29 **Maintenance Dose:** • Administer 250 mg IM every 28 days until disease progression or unacceptable toxicity
Endometrial Carcinoma	Administer 250 mg intramuscularly (IM) every 4 weeks for at least 8 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9395 – Injection, fulvestrant, 25 mg; 1 billable unit = 25 mg
- J9393 – Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg
- J9394 – Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg

NDC(s):

- Faslodex 250 mg/5 mL single-dose prefilled syringe: 00310-0720-xx*****
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Teva): 00591-5019-xx **Ψ**
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Fresenius Kabi): 63323-0715-xx **Ψ**

– ****** Available as a multi-sourced generic.*

– ***Ψ** Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book:*

Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA

VII. References

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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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C56.3	Malignant neoplasm of bilateral ovaries
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
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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