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) [Pharmacy Benefit]:

– Faslodex 250 mg/5 mL injection: 6 vials first 28 days initially, as a load, then 2 vials per 28 days, thereafter as maintenance

B. Max Units (per dose and over time) [Medical Benefit]:

Endometrial Cancer/Uterine Sarcoma
- 10 units every 28 days

Breast Cancer/Ovarian Cancer

Loading Dosing:
- 20 units every 14 days for 3 doses

Maintenance Dosing:
- 20 units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Breast Cancer †

- 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 in combination with ribociclib as initial endocrine based therapy †; OR
    - Used in combination with a CDK 4/6-inhibitor (e.g., ribociclib, palbociclib or abemaciclib) and patient has progressed on endocrine therapy †; OR

        - Used in combination with everolimus and patient has received prior endocrine therapy within the previous 12 months; OR
        - Used as single agent therapy; OR
    - Patient has HR-positive, HER2-negative disease and has not previously received endocrine therapy †; OR
    - Patient has HR-positive disease and progressed on endocrine therapy †; 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 Cancers) ‡

- Used as single agent therapy; AND
- Patient has recurrent, low-grade serous carcinoma; AND

Uterine Adenocarcinoma ‡

- 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 for metastatic or unresectable disease excluding patients with cervical involvement undergoing brachytherapy without external beam radiation therapy (EBRT) that is not suitable for primary surgery; OR
    - Adjuvant treatment for locally advanced or metastatic disease; OR
    - Used as hormonal therapy for recurrent or disseminated metastatic disease; OR
    - Used in patients with limited disease of the uterus that is not suitable for primary surgery

Uterine Sarcoma ‡

- Used as single agent therapy; AND
- Used for low-grade, stages II-IV endometrial stromal sarcoma (ESS) OR for ER/PR positive stages II-IV uterine leiomyosarcoma (uLMS); AND
    - Used following total hysterectomy; OR
    - Patient has resectable isolated metastases or disseminated metastases; OR
    - Patient has radiologically isolated vaginal or pelvic recurrence; OR
    - Used for disease that is not suitable for primary surgery

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria 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 the following: bleeding abnormalities, increased exposure in patients with hepatic impairment, severe injection site reactions, etc.

V. Dosage/Administration

Indication	Dose
Breast Cancer, Ovarian Cancer	Loading Dose: • 500 mg intramuscularly on Days 1, 15, 29 Maintenance Dose: ○ 500 mg IM every 28 days
Endometrial Cancer, Uterine Sarcoma	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

Jcode:

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

NDC:

- Faslodex* 250 mg/5 mL injection: 00310-0720-xx
  *Available generically

VII. References

1. Faslodex [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; March 2019. Accessed March 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for fulvestrant. National Comprehensive Cancer Network, 2018. 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 March 2019.
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.

4. Mauriac L, Romieu G, Bines J. Activity of fulvestrant versus exemestane in advanced breast cancer patients with or without visceral metastases: data from the EFECT trial. Breast Cancer Res Treat 2009; 117:69-75.
5. Di Leo A, Jerusalem G, Petruzelka L, et al. Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor-positive advanced breast cancer. J Clin Oncol 2010; 28:4594-4600.
6. Covens AL, Filiaci V, Gersell D. Phase II study of fulvestrant in recurrent/metastatic endometrial carcinoma: a Gynecologic Oncology Group study. Gynecol Oncol. 2011 Feb;120(2):185-8. doi: 10.1016/j.ygyno.2010.10.015. Epub 2010 Nov 13.
7. Argenta PA, Thomas SG, Judson PL, et al. A phase II study of fulvestrant in the treatment of multiply-recurrent epithelial ovarian cancer. Gynecol Oncol. 2009 May;113(2):205-209.
8. First Coast Service Options, Inc. Local Coverage Determination (LCD): Fulvestrant (Faslodex®) (L33998). Centers for Medicare & Medicaid Services, Inc. Updated on 6/8/2018 with effective date 6/14/2018. Accessed March 2019.

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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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) and Local Coverage Determinations (LCDs) 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):

Jurisdiction(s): N	NCD/LCD Document (s): L33998
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33998&bc=gAAAAAAAAAAAAA==	

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