Faslodex® (fulvestrant)
(Intramuscular)

Document Number: IC-0043

Last Review Date: 09/01/2020

Date of Origin: 01/01/2012

Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 09/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 04/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020

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 [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; AND

Breast Cancer † [1,2,5,8-11]

- 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) ‡ [2,7,12]

- 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) ‡ [2,6,13]

- 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) ‡ [2,13]

- 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 [1]

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 [1,6,7]

Indication	Dose
Breast Cancer & Uterine Sarcoma	**Loading Dose:** • 500 mg intramuscularly (IM) on Days 1, 15, 29 **Maintenance Dose:** • 500 mg IM every 28 days
Ovarian Cancer	**Loading Dose:** • 500 mg intramuscularly (IM) on Day 1 and 250 mg IM on Days 15 and 29 **Maintenance Dose:** • 250 mg IM every 28 days
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 August 2020.
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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.
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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.

11. Sledge GW Jr, Toi M, Neven P, et al. MONARCH 2: Abemaciclib in Combination With Fulvestrant in Women With HR+/HER2- Advanced Breast Cancer Who Had Progressed While Receiving Endocrine Therapy. J Clin Oncol. 2017;35(25):2875-2884. doi:10.1200/JCO.2017.73.7585.
12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2020. National Comprehensive Cancer Network, 2020. 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 Guidelines, go online to NCCN.org. Accessed August 2020.
13. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms Version 2.2020. National Comprehensive Cancer Network, 2020. 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 Guidelines, go online to NCCN.org. Accessed 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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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