

## Faslodex® (fulvestrant)

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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]:

– N/A

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

##### Loading Dosing

<b>Male</b>	20 units every 14 days for 3 doses
<b>Female</b>	20 units every 14 days for 3 doses

##### Maintenance Dosing

<b>Male</b>	20 units every 28 days
<b>Female</b>	20 units every 28 days

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

#### Breast Cancer †

- Disease is metastatic or recurrent; **AND**
- Patient is postmenopausal; premenopausal with ovarian ablation/suppression; or male with suppression of testicular steroidogenesis; **AND**
  - Patient has asymptomatic visceral disease or involvement of bone or soft tissue only; **AND**
    - Disease is hormone receptor-positive; **OR**
    - hormone receptor-negative with clinical characteristics predicting a hormone receptor-positive tumor; **OR**

- Patient has ER positive, HER-2 negative disease; **AND**
  - Patient has progressed on endocrine therapy; **AND**
  - Must be used in combination with palbociclib (Ibrance)

†FDA Approved Indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug

#### V. Dosage/Administration

Indication	Dose
Breast Cancer	<p><b>Loading Dose:</b></p> <ul style="list-style-type: none"> <li>• 500 mg IM on Days 0, 14, 28 (250 mg with hepatic impairment)</li> </ul> <p><b>Maintenance Dose:</b></p> <ul style="list-style-type: none"> <li>• 500 mg IM every 28 days (250 mg with hepatic impairment)</li> </ul> <p>When used in combination with palbociclib, the recommended dose of palbociclib is 125 mg once daily for 21 consecutive days in a 28 day cycle.</p>

#### VI. Billing Code/Availability Information

Jcode:

J9395 – Faslodex (AstraZeneca 250 mg Injection: 1 billable unit = 25 mg

NDC:

- Faslodex 50mg/ml injection 00310-0720-xx (AstraZeneca)

#### VII. References

1. Faslodex [package insert]. Cheshire, England; AstraZeneca; March 2016. Accessed March 2016.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Fulvestrant. National Comprehensive Cancer Network, 2016. 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 2016.

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, Petruzella 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. First Coast Service Options, Inc. Local Coverage Determination (LCD): Fulvestrant (Faslodex®) (L33998). Centers for Medicare & Medicaid Services, Inc. Updated on 7/1/2014 with effective date 10/1/2015. Accessed March 2016.
7. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD) for Chemotherapy Drugs and their Adjuncts (L35033). Centers for Medicare & Medicaid Services, Inc. Updated on 2/16/2016 with effective date 3/1/2016. Accessed March 2016.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
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

### FASLODEX® (fulvestrant) Prior Auth Criteria

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ICD-10	ICD-10 Description
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
Z85.3	Personal history of malignant neoplasm of breast

## 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):

<b>Jurisdiction(s):</b> J-N	<b>NCD/LCD Document (s):</b> L33998
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33998&amp;ver=3&amp;SearchType=Advanced&amp;CoverageSelection=Both&amp;NCSelection=NCD&amp;ArticleType=Ed&amp;PolicyType=Final&amp;s=All&amp;Keyword=j9395&amp;KeywordLookUp=Doc&amp;KeywordSearchType=Exact&amp;kq=true&amp;bc=IAAABAAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33998&amp;ver=3&amp;SearchType=Advanced&amp;CoverageSelection=Both&amp;NCSelection=NCD&amp;ArticleType=Ed&amp;PolicyType=Final&amp;s=All&amp;Keyword=j9395&amp;KeywordLookUp=Doc&amp;KeywordSearchType=Exact&amp;kq=true&amp;bc=IAAABAAAAAAAAA%3d%3d&amp;</a>	

<b>Jurisdiction(s):</b> 5, 8	<b>NCD/LCD Document (s):</b> L35053
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35053&amp;ver=50&amp;SearchType=Advanced&amp;CoverageSelection=Both&amp;NCSelection=NCD&amp;ArticleType=Ed&amp;PolicyType=Final&amp;s=All&amp;Keyword=j9395&amp;KeywordLookUp=Doc&amp;KeywordSearchType=Exact&amp;kq=true&amp;bc=IAAABAAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35053&amp;ver=50&amp;SearchType=Advanced&amp;CoverageSelection=Both&amp;NCSelection=NCD&amp;ArticleType=Ed&amp;PolicyType=Final&amp;s=All&amp;Keyword=j9395&amp;KeywordLookUp=Doc&amp;KeywordSearchType=Exact&amp;kq=true&amp;bc=IAAABAAAAAAAAA%3d%3d&amp;</a>	

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E	CA, HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC