CLINICAL MEDICATION POLICY	
Policy Name:	Faslodex® (fulvestrant)
Policy Number:	MP-009-MC-ALL
Responsible Departments:	Medical Management, Clinical Pharmacy
Provider Notice Date:	04/1/2017
Original Effective Date:	05/01/2017
Annual Approval Date:	03/15/2018
Revision Date:	N/A
Products:	North Carolina Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ may provide coverage under the medical or pharmacy benefits of the Company's Medicaid products for medically necessary intravenous infusion of Faslodex (fulvestrant).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

DEFINITIONS

Faslodex (fulvestrant) – An intramuscular injection used to treat the following:

- A patient with hormone receptor (HR)-positive breast cancer in postmenopausal women whose disease has spread after treatment with antiestrogen medicine
- A patient with HR-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in women whose disease has spread to other parts of the body.

PROCEDURES

1. Faslodex (fulvestrant) is considered medically necessary as an intravenous infusion for:
   a. Treatment of metastatic breast cancer with monotherapy when the patient meets the following criteria:
      1) The patient is aged 18 years or older; AND
      2) The prescribing physician must be a hematologist or oncologist; AND
      3) The patient is not pregnant; AND
      4) The patient is a postmenopausal woman; AND
      5) The disease is hormone receptor (HR)-positive; AND
      6) The disease has progressed following antiestrogen therapy; AND
      7) Dosing is consistent with FDA-approved labeling:
         a. The dose does not exceed 500 mg administered intramuscularly (IM) in patients with normal hepatic function or 250 mg in patients with moderate hepatic impairment (Child-Pugh Class B).
         b. The dose is given on days 1, 15, 29, and monthly thereafter.
   b. Treatment of advanced or metastatic breast cancer with a combination therapy when the patient meets the following criteria:
      1) The patient is aged 18 years or older; AND
      2) The patient is not pregnant; AND
      3) The disease is ER-positive, HER2-negative, and has progressed after first-line endocrine therapy; AND
      4) The drug is used in combination with palbociclib; AND
      5) The patient is concurrently taking a LH-RH agonist (applicable to pre- or postmenopausal women); AND
      6) Dosing is consistent with FDA-approved labeling:
         a. The dose does not exceed 500 mg in patients with normal hepatic function or 250 mg in patients with moderate hepatic impairment (Child-Pugh Class B).
         b. The dose is given on days 1, 15, 29, and monthly thereafter.

2. Contraindications
   There are no known contraindications to Faslodex.

3. When Faslodex is not covered
   Faslodex is not covered for conditions other than those listed above because the scientific evidence has not been established.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case-by-case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Faslodex is outpatient.

6. Coverage Determination
   Gateway Health℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

   There is no specific NCD or North Carolina LCD for Faslodex. For additional information, please see:
   http://www.palmettogba.com/palmetto/providers.nsf/docscat/Providers~JM%20Part%20B~Medical%20Policies~LCDs%20Coverage%20Articles%20NCDs

Governing Bodies Approval
On April 25, 2002, Faslodex was first approved by the FDA for intramuscular (IM) injection, as a single agent in the treatment of HR+ metastatic breast cancer in postmenopausal women with disease progression following anti-estrogen therapy.

On March 6, 2016, the FDA approval expanded use of Faslodex to include treatment of HR+, HER2- advanced or metastatic breast cancer used in combination with palbociclib in women with disease progression after endocrine therapy.

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
J9395	Injection, fulvestrant, 25 mg

Diagnosis Codes

ICD-10 Code	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
C50.111	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
C50.211	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
C50.311	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
C50.411	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
C50.511	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
C50.611	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
C50.811	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
C50.911	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
C79.81	Secondary malignant neoplasm of breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast

D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
Z17.0	Estrogen receptor positive status (ER+)
Z85.3	Personal history of malignant neoplasm of breast

REMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

American Cancer Society. Cancer facts & figures 2016. Atlanta: American Cancer Society; 2016.

Faslodex® (fulvestrant) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 07/2016. Accessed on 01/03/2017 and available at: http://www.azpicentral.com/faslodex/faslodex.pdf#page=1.

National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology™. Accessed on 01/03/2017 and available at: http://www.nccn.org/index.asp.

- Breast cancer (V.2.2016). Revised May 4, 2016.

Zagouri, F., Sergentanis, T.N., Chrysikos, D., Dimopoulos, M., Psaltopoulou, T. Fulvestrant and male breast cancer: a pooled analysis. Breast Cancer Research and Treatment 2015; volume 149, issue 1, pp. 269-275. Accessed on 01/03/2017 and available at: http://link.springer.com/article/10.1007/s10549-014-3240-z?no-access=true.

Policy History:

Date	Activity
N/A	LCD/NCD effective date
03/15/2017	QI/UM Committee approval
05/01/2017	Provider effective date