POLICY NUMBER UM ONC_1039	**SUBJECT** Faslodex™ (fulvestrant)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATE REVIEWED 01/12/11, 03/08/12, 10/30/13, 03/05/15, 04/11/16, 02/06/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**REVISION DATES** (latest version listed last) 01/12/11, 03/08/12, 10/30/13, 03/05/15, 04/11/16, 02/06/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Faslodex (fulvestrant) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **Metastatic Breast Cancer**
   a. The member has recurrent or metastatic estrogen/progesterone receptor positive breast cancer and Faslodex (fulvestrant) is being used as:
      i. A single agent **OR**
      ii. In combination with palbociclib,abemaciclib, ribociclib, or a non-steroidal aromatase inhibitor (anastrozole or letrozole) **OR**
      iii. In combination with alpelisib, if PIK3CA mutation positive, as second line therapy **OR**
      iv. In combination with trastuzumab for HER2-positive disease **AND**
      v. The member is post-menopausal or if the member is pre-menopausal she is receiving concomitant ovarian ablation/suppression.
2. **Ovarian Cancer**
   a. The member has recurrent/metastatic ovarian cancer and Faslodex (fulvestrant) is being used, as a single agent, for low-grade serous carcinoma.
3. **Endometrial Carcinoma**
   a. The member has endometrioid adenocarcinoma and Faslodex (fulvestrant) is being used as a single agent for primary treatment.

III. EXCLUSION CRITERIA

1. The member is a premenopausal female who is not receiving concomitant ovarian ablation/suppression.
2. The member has hormone receptor negative tumor.
3. Dosing exceeds single dose limit of 500 mg.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature..

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Faslodex prescribing information. AstraZeneca Pharmaceuticals LP, Wilmington, DE. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs.. Bethesda, MD. 2020.