

Drug Policy:

Faslodex™ (fulvestrant)

POLICY NUMBER UM ONC_1039	SUBJECT Faslodex™ (fulvestrant)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE 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, 04/08/20, 02/10/21	APPROVAL DATE February 10, 2021	EFFECTIVE DATE February 26, 2021	COMMITTEE APPROVAL 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, 04/08/20, 02/10/21
PRIMARY BUSINESS OWNER: UM		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 Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines](#) shall follow [NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

B. Metastatic Breast Cancer ER/PR positive

1. **NOTE:** NCH Pathway L1 Preferred Regimens for ER/PR positive metastatic breast cancer, for first line/initial therapy are Kisqali (ribociclib)/Ibrance (Palbociclib) + Aromatase Inhibitor. Verzenio (abemaciclib)/Ibrance (Palbociclib) +/- Faslodex (fulvestrant) is preferred in the subsequent or second line setting.
2. The member is post-menopausal or if the member is pre-menopausal and receiving concomitant ovarian ablation/suppression, Faslodex (fulvestrant) may be used as **ANY** of the following:
 - a. In combination with a CDK4/6 inhibitor e.g. palbociclib, abemaciclib, ribociclib.
 - b. In combination with Piqray (alpelisib), if tumor is PIK3CA mutation positive, as second line therapy.
 - c. In combination with trastuzumab for HER2 positive disease.
 - d. As a single agent.

III. EXCLUSION CRITERIA

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

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Slamon DJ, et al. Phase III Randomized Study of Ribociclib and Fulvestrant in Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: MONALEESA-3. J Clin Oncol. 2018 Aug 20;36(24):2465-2472.

- B. Sledge GW Jr, 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 Sep 1;35(25):2875-2884.
- C. Turner NC, Slamon DJ, Ro J, et al. Overall survival with palbociclib and fulvestrant in advanced breast cancer. N Engl J Med 2018;379:1926-36.
- D. Faslodex prescribing information. AstraZeneca Pharmaceuticals LP, Wilmington, DE. 2020.
- E. Clinical Pharmacology Elsevier Gold Standard. 2021.
- F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2021.
- G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2021.
- H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2021.