

Fulvestrant (Faslodex®)

Place of Service

Home infusion

Office Administration

Outpatient Facility Administration

HCPCS

- J9393 per 25 mg (Teva only)
- J9394 per 25 mg (Fresenius Kabi only)
- J9395 per 25 mg

Condition(s) listed in policy (see criteria for details)

- [Breast cancer, locally advanced, recurrent or metastatic](#)
- [Endometrial carcinoma](#)
- [Epithelial ovarian cancer](#)
- [Fallopian tube cancer](#)
- [Primary peritoneal cancer](#)
- [Uterine sarcoma](#)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Fulvestrant is an estrogen antagonist without known agonist effects

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Faslodex® (fulvestrant) NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer, advanced or recurrent unresectable (local or regional), or metastatic

Covered Doses

Up to 500 mg (20 units) per dose divided into two intramuscular injections, every 2 weeks for 3 doses, then 20 units per month all other doses

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

Endometrial carcinoma

1. Being used as a single agent therapy, **AND**

2. Patient is unable to take oral hormone therapies supported by the National Comprehensive Cancer Network (NCCN) to treat endometrial carcinoma

Covered Doses

Up to 500 mg (20 units) per dose divided into two intramuscular injections, every 2 weeks for 3 doses, then 20 units per month all other doses

Coverage Period

Indefinite

ICD-10:

C54.0-C54.3, C54.8, C54.9, C55

Epithelial ovarian cancer/ Fallopian tube cancer/ Primary peritoneal cancer

1. Disease is persistent or recurrent low-grade serous carcinoma, **AND**
2. Being used as a single agent, **AND**
3. Patient has had prior chemotherapy with a platinum regimen

Covered Doses

Up to 500 mg (20 units) per dose divided into two intramuscular injections, every 2 weeks for 3 doses, then 20 units per month all other doses

Coverage Period

Indefinite

ICD 10:

C48.1, C48.2, C48.8, C56.1, C56.2, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9, Z85.43

Uterine sarcoma

1. Disease is low-grade endometrial stromal sarcoma (ESS) or hormone receptor positive uterine leiomyosarcoma (uLMS)

Covered Doses

Up to 500 mg (20 units) per dose divided into two intramuscular injections, every 2 weeks for 3 doses, then 20 units per month all other doses

Coverage Period

Indefinite

ICD 10:

C53.0, C54.0-C54.3, C54.8, C54.9, C55

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Faslodex® (fulvestrant) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

250 mg per syringe (Intramuscular injection -500 mg dose administered as two IM injections into buttock)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com>
- Faslodex® (fulvestrant) [Prescribing information]. Wilmington, DE: Astra Zeneca; 11/2020.
- National Comprehensive Cancer Network. Breast cancer (Version 3.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer (Version 1.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Uterine Neoplasms (Version 1.2022). Available at www.nccn.org.

(7) Policy Update

Date of last revision: 4Q2022

Date of next review: 3Q2023

Changes from previous policy version:

No clinical change to policy following revision.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*