Gateway Health℠
Non-Formulary Prior Authorization Criteria

Faslodex® (Fulvestrant)

All requests for Faslodex® (fulvestrant) require prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Faslodex® (fulvestrant) Prior Authorization Criteria:

- Coverage may be provided when the indication is **metastatic breast cancer AND**
  - The prescriber is a hematologist/oncologist **AND**
  - The patient is a postmenopausal woman **AND**
  - The disease is hormone receptor (HR)-positive **AND**
  - The disease has progressed following antiestrogen therapy **AND**
  - The drug is given as monotherapy **AND**
  - 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) **AND**
  - The dose is given on days 1, 15, 29, and monthly thereafter

- Coverage may be provided when the indication is **advanced or metastatic breast cancer AND**
  - The prescriber is a hematologist/oncologist **AND**
  - The patient is age 18 years or older **AND**
  - The patient is female **AND**
  - The patient is not pregnant **AND**
  - The disease is HR-positive, HER2-negative, and has progressed after first-line endocrine therapy **AND**
  - The drug is used in combination with palbociclib **AND**
  - The patient is concurrently taking a LH-RH agonist (applicable to pre/perimenopausal women) **AND**
  - 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) **AND**
  - The dose is given on days 1, 15, 29, and monthly thereafter

- Benefit is approved for 6 months.

- Reauthorization will be granted when there is chart documentation demonstrating clinical benefit and tolerance to fulvestrant.

- 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.

References:
1) Faslodex (fulvestrant) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 07/2016
3) Fulvestrant. In: Micromedex 2.0 online. Ann Arbor, MI. Truven Health Analytics; [2016; accessed 12/14/16]