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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2021
Subject:	Faslodex	**Page:**	1 of 3

Last Review Date: March 12, 2021

Faslodex

Description

Faslodex (fulvestrant)

Background
Faslodex (fulvestrant) is an estrogen receptor antagonist that binds to the estrogen receptor (ER) in a competitive manner with affinity comparable to that of estradiol and downregulates the ER protein in human breast cancer cells. Faslodex has been demonstrated to be a reversible inhibitor of the growth of tamoxifen-resistant, as well as estrogen-sensitive human breast cancer (MCF-7) cell lines (1).

Regulatory Status
FDA-approved indication: Faslodex is an estrogen receptor antagonist indicated for the treatment of breast cancer (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Faslodex may be considered **medically necessary** for patients with breast cancer who have had an inadequate response, intolerance, or contraindication to the generic.

Faslodex may be considered **investigational** for all other diagnoses.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Breast cancer

a. Patient **MUST** have tried the preferred product (generic Faslodex: fulvestrant) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Faslodex (fulvestrant) is an estrogen receptor antagonist that binds to the estrogen receptor (ER) in a competitive manner with affinity comparable to that of estradiol and downregulates the ER protein in human breast cancer cells. Faslodex has been demonstrated to be a reversible inhibitor of the growth of tamoxifen-resistant, as well as estrogen-sensitive human breast cancer (MCF-7) cell lines (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Faslodex while maintaining optimal therapeutic outcomes.

References

1. Faslodex [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2020.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
March 2021	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.