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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2021
Subject:	Faslodex	**Page:**	1 of 3

Last Review Date: March 8, 2024

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
Orserdu

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** if the conditions indicated below are met.

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

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.
2. NCCN Drugs & Biologics Compendium® Fulvestrant 2024. National Comprehensive Cancer Network, Inc. Accessed on January 11, 2024.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
March 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update
June 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.