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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 17, 2023
Subject:	Orserdu	**Page:**	1 of 4

Last Review Date: March 7, 2025

Orserdu

Description

Orserdu (elacestrant)

Background
Orserdu (elacestrant) is an estrogen receptor antagonist that binds to the estrogen receptor-alpha (ERα). In ER-positive (ER+) HER2-negative (HER2-) breast cancer cells, Orserdu inhibited 17β-estradiol mediated cell proliferation at concentrations inducing degradation of ERα protein mediated through proteasomal pathway. Orserdu demonstrated in vitro and in vivo antitumor activity including in ER+ HER2- breast cancer models resistant to fulvestrant and cyclin-dependent kinase 4/6 inhibitors and those harboring estrogen receptor 1 gene (*ESR1*) mutations (1).

Regulatory Status
FDA-approved indication: Orserdu is an estrogen receptor antagonist indicated for: (1)

- Treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Orserdu may cause hypercholesterolemia and hypertriglyceridemia. Lipid profiles should be monitored prior to starting and periodically while taking Orserdu (1).

Orserdu can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with

Orserdu and for 1 week after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Orserdu and for 1 week after the last dose (1).

The safety and effectiveness of Orserdu in pediatric patients less than 18 years of age have not been established (1).

Related policies
Faslodex

Policy

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

Orserdu may be considered **medically necessary** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 18 years of age or older
Female patients **MUST** be postmenopausal

Diagnosis

Patient must have the following:

1. Advanced or metastatic breast cancer
    a. ER-positive, HER2-negative
    b. Presence of *ESR1* mutation in plasma specimen using an FDA-approved test
    c. Patient has had disease progression following at least one line of endocrine therapy

AND ALL of the following:

a. Prescriber agrees to monitor the patient's lipids

b. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Orserdu and for 1 week after the last dose

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Prior – Approval *Renewal* Requirements

Age 18 years of age or older
Female patients **MUST** be postmenopausal

Diagnosis

Patient must have the following:

1. Advanced or metastatic breast cancer
    a. ER-positive, HER2-negative
    b. Presence of *ESR1* mutation in plasma specimen using an FDA-approved test

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor the patient's lipids
c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Orserdu and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Daily Dosing Limits
86 mg	345 mg per day

345 mg	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Orserdu (elacestrant) is an estrogen receptor antagonist indicated for the treatment of ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer. Orserdu contains warnings regarding dyslipidemia and embryo-fetal toxicity. The safety and effectiveness of Orserdu in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Orserdu [package insert]. New York, NY: Stemline Therapeutics, Inc.; November 2023.
2. NCCN Drugs & Biologics Compendium® Elacestrant 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.

Policy History

Date	Action
February 2023	Addition to PA
June 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.