Applicable Drugs: Orserdu (elacestrant)

Preferred: anastrozole, exemestane, letrozole, fulvestrant.

Non-preferred: Orserdu (elacestrant))

Date of Origin: 10/23/2023

Date Last Reviewed / Revised: 10/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication

A. Advanced or metastatic breast cancer.

i. Lab documentation of ER-positive (ER+) and HER2-negative (HER2-) disease.

ii. FDA-approved test results that document the presence of estrogen receptor 1 gene (ESR1) mutation.

iii. Disease progression following at least one line of endocrine therapy (e.g., Arimidex (anastrozole), Aromasin (exemestane), Femara (letrozole), Faslodex (fulvestrant)] PLUS CDK 4/6 inhibitor therapy (e.g., palbociclib, ribociclib, abemaciclib).

iv. Postmenopausal women or adult men (≥ 18 years).

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

A. EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- 345 mg dose/day: Thirty 345 mg tablets per 30 days.
- 258 mg dose/day: Ninety 86 mg tablets per 30 days.
- 172 mg dose/day: Sixty 86 mg tablets per 30 days.

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

Table 1. FDA Labeled Initial Dosage Recommendations and Dosage Reductions

Initial Dose	First Dose Reduction	Second Dose Reduction
345mg orally once daily	258mg orally once daily	172mg orally once daily

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 5.2025. Updated *October 16, 2025.* Accessed *October 16, 2025.*
2. Orserdu. Prescribing Information. Stemline Therapeutics, Inc; 2023. Accessed October 16, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217639s000lbl.pdf
3. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized Phase III EMERALD Trial. *J Clin Oncol*. 2022;40(28):3246-3256. doi: 10.1200/JCO.22.00338
4. Kaklamani V, Bidard FC, Neven P, et al: EMERALD phase 3 trial of elacestrant versus standard of care endocrine therapy in patients with ER+/HER2– metastatic breast cancer: Updated results by duration of prior CDK4/6 inhibitor in metastatic setting. 2022 San Antonio Breast Cancer Symposium. Abstract GS3-01. Presented December 8, 2022.
5. Kaklamani V, Bardia A, Aftimos P, et al. Subgroup analysis of patients with no prior chemotherapy in EMERALD: a phase 3 trial evaluating elacestrant, an oral selective estrogen receptor degrader (SERD), versus investigator's choice of endocrine monotherapy for ER+/HER2-advanced/metastatic breast cancer (mBC). Abstract presented at the 2022 American Society of Clinical Oncology Annual Meeting. June 3-7,2022; Chicago, Illinois. Abstract 1100.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.