Applicable Drugs: Orserdu (elacestrant)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/23/2023

Date Last Reviewed / Revised: 10/28/2026

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following FDA-approved 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).

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 9.2026. Updated October 22, 2026. Accessed October 28, 2026. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Orserdu. Prescribing information. Stemline Therapeutics, Inc.; 2026. Accessed October 28, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/217639s007lbl.pdf
3. Bardia A, Cortés J, Bidard FC, et al. Elacestrant in ER+, HER2- Metastatic Breast Cancer with ESR1-Mutated Tumors: Subgroup Analyses from the Phase III EMERALD Trial by Prior Duration of Endocrine Therapy plus CDK4/6 Inhibitor and in Clinical Subgroups. *Clin Cancer Res*. 2024;30(19):4299-4309. doi:10.1158/1078-0432.CCR-24-1073
4. 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

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.