MEDICATION POLICY:
Orserdu (elacestrant)

Generic Name: elacestrant

Applicable Drugs: Orserdu

Preferred: anastrozole, exemestane, letrozole, fulvestrant

Non-preferred: Orserdu (elacestrant)

Date of Origin: 10/23/2023

Date Last Reviewed / Revised: 10/23/2023

Prior Authorization Criteria

(May be considered medically necessary when criteria I through VIII are met)

I. Documented diagnosis of advanced or metastatic breast cancer.

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

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

IV. Disease progression following at least one line of endocrine therapy [e.g., Arimidex (anastrozole), Aromasin (exemestane), Femara (letrozole), Faslodex (fulvestrant)].

V. Postmenopausal woman or adult man (≥ 18 years).

VI. Prescribed by or in consultation with an oncologist.

VII. Medication dose, plan for appropriate monitoring, and/or dose adjustment(s) consistent with FDA labeling (table 1).

VIII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a 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 86mg tablets per 30 days.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with documentation of the absence of disease progression or unacceptable toxicity.

Appendix

Table 1. FDA-labeled initial dosage recommendations and dosage reductions

Initial dose	First dose reduction	Second dose reduction
345 mg orally twice daily	258 mg orally twice daily	172 mg once daily

References

1. Orserdu. Prescribing information. Stemline Therapeutics, Inc: 2023. Accessed September 10, 2023.https://rxmenarinistemline.com/ORSERDU_(elacestrant)_Full_Prescribing_Information.pdf
2. 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
3. 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.
4. 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.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer. V.4.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed June 25, 2023.

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.