PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Orserdu Prior Authorization Policy
- Orserdu™ (elacestrant tablets – Stemline/Menarini)

REVIEW DATE: 02/07/2024

OVERVIEW
Orserdu, an estrogen receptor antagonist, is indicated for the treatment of estrogen receptor-positive (ER+), human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor 1 gene (*ESR1)*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy in postmenopausal women or adult men.[1]

Guidelines
National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 1.2024 – January 25, 2024) recommend Orserdu for ER+, HER2-negative, *ESR1*-mutated recurrent, unresectable or metastatic breast cancer after progression on one or two prior lines of endocrine therapy, including one line containing a cyclin-dependent kinase (CDK) 4/6 inhibitor as "Other Recommended Regimen" (category 2A).

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Orserdu. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Orserdu is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer in Postmenopausal Women or Men***. Approve for 1 year if the patient meets the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has estrogen receptor positive (ER+) disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **E)** Patient has estrogen receptor 1 gene (*ESR1)*-mutated disease; AND
   - **F)** Patient has tried at least one endocrine therapy.
     Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.

***** Refer to the Policy Statement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Orserdu is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Orserdu™ tablets [prescribing information]. New York, NY: Stemline Therapeutics/Menarini Group; November 2023.
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; 40:3246-3256.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 2, 2024.