



Commercial/Healthcare Exchange PA Criteria

Effective: March 30, 2023

Prior Authorization: Orserdu (elacestrant)

Products Affected: Orserdu (elacestrant) oral tablets

Medication Description: ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Covered Uses: Treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Previous Therapies Tried/Failed
3. Medical History

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an oncologist

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Breast Cancer in Postmenopausal Women or Men***. Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, **and** F):
 - A. Patient is \geq 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.

March 2023



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* 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.

References:

1. Product Information: ORSERDU™ oral tablets, elacestrant oral tablets. Stemline Therapeutics (per FDA), New York, NY, 2023.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|--------------|-----------------------|--------------------------|--------------------------|-------------|
| 1 | New Policy | New Policy | All | 03/30/2023 |