UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1407-2
Program	Prior Authorization/Notification
Medication	Orserdu™ (elacestrant)
P&T Approval Date	3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Orserdu (elacestrant) is an estrogen receptor antagonist indicated for 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. NCCN also recommends for premenopausal women treated with ovarian ablation/suppression.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Orserdu** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Breast Cancer

1. **Initial Authorization**

   a. **Orserdu** will be approved based on **all** of the following criteria:

      (1) Diagnosis of breast cancer

      -AND-

      (2) **One** of the following:

         (a) Advanced
         (b) Metastatic

-AND-

(3) Disease is estrogen receptor (ER)-positive

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Presence of an *ESR1* gene mutation

-AND-

(6) Patient is **one** of the following:

(a) Postmenopausal woman
(b) Male
(c) Premenopausal woman treated with ovarian ablation/suppression

-AND-

(7) Disease has progressed following at least one line of endocrine therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Orserdu** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Orserdu** therapy.

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Orserdu [package insert]. New York, NY: Stemline Therapeutics, Inc.; November 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium®). Available at www.nccn.org. Accessed February 2, 2024.

Program	Prior Authorization/Notification – Orserdu (elacestrant)
Change Control	
3/2023	New program.
3/2024	Annual review. Added premenopausal women treated with ovarian ablation/suppression to coverage criteria per NCCN. Updated background and references.