Reference number(s)
5770-A

Specialty Guideline Management Orserdu

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Orserdu	elacestrant

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

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.

Compendial Use[2]

Breast cancer – no response to preoperative systemic therapy or recurrent disease

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Estrogen receptor (ER) status, where applicable.

- Human epidermal growth factor receptor 2 (HER2) status, where applicable
- Estrogen receptor 1 (ESR1) mutation status, where applicable

Coverage Criteria

Breast Cancer[1,2]

Authorization of 12 months may be granted for treatment of breast cancer when all of the following criteria are met:

- The disease is ER-positive, HER2-negative, and ESR1-mutated
- Member has received at least one prior line of endocrine therapy including one line containing a cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor (e.g., abemaciclib [Verzenio], palbociclib [Ibrance], ribociclib [Kisqali])
- Member has either:
    - Had no response to preoperative systemic therapy, or
    - Advanced, metastatic or recurrent disease
- The requested medication will be used as a single agent

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Orserdu [package insert]. New York, NY: Stemline Therapeutics, Inc.; November 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 7, 2024.