

Elacestrant (ORSERDU)

Criteria for Use

June 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive elacestrant.

- Hypersensitivity to elacestrant or any of its components
- Severe hepatic impairment (Child-Pugh C)

Inclusion Criteria

All of the following criteria must be met.

- Men or postmenopausal women with advanced or metastatic breast cancer
- Hormone receptor (HR)-positive, HER2-negative breast cancer
- ESR1*-mutation positive as detected by an approved test
- Progressive disease on or after an endocrine-based regimen that included a CDK4/6 inhibitor [including adjuvant regimens if progress within 12 months]

Additional Inclusion Criteria

All of the following criteria must be met.

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0 – 1
- Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria *Select if applicable*

- For patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 1 week after treatment.

Other Indications
