Mass General Brigham
Health Plan

Orserdu (elacestrant)
Effective 07/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

FDA-Approved Indication

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

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

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for treatment when all the following criteria are met:

1. Medical charts confirming member has a diagnosis breast cancer that is ER-positive, HER2-negative, and ESR 1-mutated.
2. Provider attests member has received at least one prior line of endocrine therapy (e.g., fulvestrant, anastrozole, letrozole, exemestane)
3. Member has ONE of the following:
    a. No response to preoperative systemic therapy
    b. Advanced, metastatic, or recurrent disease
4. Medication is being used as a single agent.
5. Prescribed by or in consultation with an oncologist

Note: Medication regimens being used in accordance with National Comprehensive Cancer Network (NCCN) guidelines with at least a 2a or 2b level evidence can be reviewed for medical necessity.

Continuation of Therapy

Reauthorization will be granted for a covered indication when there is physician attestation that there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

Orserdu 86mg	90 tablets per 30 days
Orserdu 345mg	30 tablets per 30 days

References

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

Review History

05/10/2023 – Reviewed and Created for May P&T. Effective 7/1/23