Clinical Policy Title:	elacestrant
Policy Number:	RxA.793
Drug(s) Applied:	Orserdu™
Original Policy Date:	04/13/2023
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast cancer (must meet all);

1. Diagnosis of unresectable, advanced or metastatic breast cancer;
2. Age ≥ 18 years;
3. Member must have ER+, HER2−, ESR1-mutated advanced or metastatic breast cancer;
4. Member must have disease progression following at least one line of endocrine therapy, which must include a CDK 4/6 inhibitor;
5. Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 ;
6. Orserdu™ will be prescribed as single agent therapy;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 345 mg once daily;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Breast cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Orserdu™ will be prescribed as single agent therapy;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 345 mg once daily;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. ECOG performance status scale. ECOG-ACRIN Cancer Research Group. 2022. Available at: https://ecog-acrin.org/resources/ecog-performance-status/. Accessed March 20, 2023.
2. National Comprehensive Cancer Network Guidelines. Breast Cancer. Version 3.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 20, 2023.
3. Stemline Therapeutics, Inc. Elacestrant Monotherapy vs. Standard of Care for the Treatment of Patients with Er+/Her2- Advanced Breast Cancer Following Cdk4/6 Inhibitor Therapy: A Phase 3 Randomized, Open-Label, Active-Controlled, Multicenter Trial. clinicaltrials.gov; 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT03778931. Accessed March 20, 2023.
4. Burstein HJ, Lacchetti C, Anderson H, et al. Adjuvant endocrine therapy for women with hormone receptor–positive breast cancer: asco clinical practice guideline focused update. JCO. 2019;37(5):423-438. Available at: https://ascopubs.org/doi/10.1200/JCO.18.01160. Accessed March 20, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/20/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023