

Clinical Policy Title:	elacestrant
Policy Number:	RxA.793
Drug(s) Applied:	Orserdu™
Original Policy Date:	04/13/2023
Last Review Date:	12/11/2025
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 advanced or metastatic breast cancer;
2. Disease is ER+, HER2-, ESR1-mutated;
3. Disease has progressed following at least one line of endocrine therapy

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Breast cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 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 24, 2025.
2. National Comprehensive Cancer Network Guidelines. Breast Cancer. Version 3.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 24, 2025.
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 24, 2025.
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 24, 2025.

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
Policy was reviewed:	03/24/2025	04/10/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<ol style="list-style-type: none"> 1. Removed age criteria. 2. Removed dosing criteria. 3. Updated approval duration verbiage. 4. Removed reauthorization requirement for positive response to therapy. 5. Updated continuation of therapy language. 		
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>