Generic Name: imlunestrant

Therapeutic Class or Brand Name: Inluriyo

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/9/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast cancer

i. Documentation of estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic disease

ii. Documentation of estrogen receptor-1 (ESR1) mutated disease

iii. Documentation of disease progression following at least one line of endocrine therapy (ex: anastrozole, exemestane, fulvestrant, letrozole, tamoxifen, etc.) and at least one cyclin-dependent kinase 4/6 inhibitor (CDK4/6) (ex: Ibrance [palbociclib], Kisqali [ribociclib], or Verzenio (abemaciclib])

iv. Inluriyo will be given as a single agent.

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Pre/peri-menopausal women and men should be treated with a gonadotropin-releasing hormone agonist (GnRH) (e.g., Zoladex [goserelin], Lupron [leuprolide], etc.).

Quantity / Days Supply Restrictions

- Maximum 60 tablets per 30 days. Quantities limited to a 30-day supply.

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 5.2025. Updated October 16, 2025. Accessed January 2, 2026. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Inluriyo. Prescribing Information. Eli Lilly and Company. 2025. Accessed January 2, 2025. uspl.lilly.com/inluriyo/inluriyo.html#pi
3. Jhaveri KL, Neven P, Casalnuovo ML, et al. Imlunestrant with or without abemaciclib in advanced breast cancer. N Engl J Med. 2025;392:1189-1202. doi:10.1056/NEJMoa2410858