

Applicable Drugs: Inluriyo (imlunestrant)

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

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.