

Specialty Guideline Management

Revtorpyk

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Revtorpyk	gedatolisib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Revtorpyk is indicated in combination with fulvestrant, with or without palbociclib, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following is necessary to initiate the prior authorization review: documentation of hormone receptor (HR), human epidermal growth factor receptor 2 (HER2), and PIK3CA mutation status.

Reference number(s)
7542-A

Coverage Criteria

Breast Cancer¹

Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer when used in combination with fulvestrant with or without palbociclib and both of the following criteria are met:

- Member does not have a PIK3CA mutation detected.
- Member has experienced progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Revtorpyk [package insert]. Minneapolis, MN: Celcuity Inc.; July 2026.