VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – mTOR and PIK3CA Inhibitor) – Revtorpyk Utilization Management Medical Policy
- Revtorpyk® (gedatolisib intravenous infusion – Celcuity)

REVIEW DATE: 07/29/2026

OVERVIEW

Revtorpyk, a kinase inhibitor, in combination with fulvestrant and with or without Ibrance® (palbociclib capsules and tablets), is indicated for the treatment of hormone receptor **(HR)-positive**, human epidermal growth factor receptor 2 (**HER2)-negative** locally advanced or metastatic **breast cancer** without a phosphatidylinositol-3-kinase (*PIK3CA*) mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.[1]

Dosing

Revtorpyk is dosed as a 180 mg intravenous infusion over 30 minutes once weekly on Days 1, 8, and 15 of every 28-day cycle until disease progression or unacceptable toxicity.[1]

Guidelines

In the National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 6.2026 – July 29, 2026), for HR-positive, HER2-negative breast cancer, the "Preferred" first-line therapies are aromatase inhibitors + cyclin dependent kinase (CDK)4/6 inhibitors.[2] Fulvestrant + CDK4/6 inhibitor is recommended as "Preferred" first-line therapy if disease progression on adjuvant endocrine therapy or relapse within 12 months of adjuvant endocrine therapy. For second-line or subsequent therapy, fulvestrant + CDK4/6 inhibitor is recommended if CDK4/6 inhibitor was not previously used (category 1). For tumors without a *PIK3CA* mutation following progression on or after treatment with at least one line of endocrine therapy: fulvestrant/Revtorpyk ± Ibrance (category 1). Everolimus + endocrine therapy (exemestane, fulvestrant, tamoxifen) is also recommended. For HER2-negative tumors with activating mutations (e.g., *PIK3CA*), biomarker-directed therapy is recommended.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Revtorpyk. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Revtorpyk, as well as the monitoring required for adverse events and long-term efficacy, approval requires Revtorpyk to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Revtorpyk is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Breast Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, G, and H):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Patient has hormone receptor (HR)-positive disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **E)** The tumor is negative for phosphatidylinositol-3-kinase (*PIK3CA*) mutation; AND
   - **F)** The medication will be used in combination with fulvestrant; AND
   - **G)** The patient has tried at least one prior endocrine therapy in the metastatic setting; AND
     Note: Examples include anastrozole, letrozole, exemestane, fulvestrant, tamoxifen.
   - **H)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve Revtorpyk 180 mg administered intravenously not more frequently than once weekly (Days 1, 8, and 15) of every 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Revtorpyk is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Revtorpyk® intravenous infusion [prescribing information]. Minneapolis, MN: Celcuity; July 2026.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 6.2026 – July 29, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 4, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/29/2026