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Section:	Prescription Drugs	**Effective Date:**	July 31, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 31, 2026
Subject:	Revtorpyk	**Page:**	1 of 4

Last Review Date: December 11, 2026

Revtorpyk

Description

Revtorpyk (gedatolisib)

Background
Revtorpyk (gedatolisib) is a kinase inhibitor of class I phosphatidylinositol-3-kinase (PI3K) isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2, resulting in downstream inhibition of multiple effectors, including AKT. In estrogen receptor (ER)-positive breast cancer cell lines and xenograft models harboring wild-type or mutant *PIK3CA*, Revtorpyk induced apoptosis and anti-proliferative effects in vitro and reduced tumor cell growth in vivo. In a human ER-positive breast cancer xenograft model harboring a *PIK3CA* mutation, the combination of Revtorpyk with palbociclib and fulvestrant increased tumor growth inhibition compared to each treatment alone or the doublet combinations (1).

Regulatory Status
FDA-approved indication: Revtorpyk is a kinase inhibitor 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 (1).

Revtorpyk carries warnings regarding stomatitis, dermatologic adverse reactions, and hyperglycemia. Steroid-containing alcohol-free mouthwash and anti-hyperglycemic medications should be considered as clinically indicated. Interrupt, reduce the dose, or discontinue Revtorpyk based on severity of symptoms (1).

Revtorpyk can cause fetal harm when administered in pregnant women. Females of reproductive potential should be advised to use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose. Male patients with female partners of reproductive potential should use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose (1).

The safety and effectiveness of Revtorpyk in pediatric patients less than 18 years of age have not been established (1).

Related policies
Itovebi, Piqray

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Revtorpyk may be considered **medically necessary** if the conditions indicated below are met.

Revtorpyk may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. Hormone receptor (HR)-positive
2. Human epidermal growth factor receptor 2 (HER2)-negative
3. **NO** PIK3CA mutation
4. Used in combination with fulvestrant (Faslodex)
5. Following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting

6. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose
7. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Used in combination with fulvestrant (Faslodex)
3. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose
4. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Revtorpyk and for 2 weeks after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 9 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Revtorpyk is a kinase inhibitor indicated in combination with fulvestrant with or without palbociclib, for the treatment of adult patients with HR-positive, 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. Revtorpyk may cause stomatitis, dermatologic adverse reactions, hyperglycemia, and embryo-fetal toxicity. The safety and effectiveness of Revtorpyk in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Revtorpyk while maintaining optimal therapeutic outcomes.

References

1. Revtorpyk [package insert]. Minneapolis, MN: Celcuity Inc.; July 2026.
2. NCCN Drugs & Biologics Compendium® Gedatolisib 2026. National Comprehensive Cancer Network, Inc. Accessed on July 16, 2026.

Policy History

Date	Action
July 2026	Addition to PA

Keywords

This policy was effective with interim approval on July 31, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on December 11, 2026.