Revtorpyk™ (gedatolisib)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 180 mg on Days 1, 8, and 15 of every 28-day cycle

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member will receive prophylactic steroid-containing alcohol-free mouthwash during the first 8 weeks of treatment and thereafter, as clinically indicated; **AND**

Universal Criteria [1]

- Baseline fasting plasma/blood glucose and HbA1c will be obtained and glucose control will be optimized prior to initiation of therapy, with at-home glucose monitoring initiated for members with an HbA1c level >6.4%; **AND**
- Member was instructed to limit sun exposure during treatment; **AND**

Breast Cancer † [1-4]

- Member has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease* with no visceral crisis; **AND**
- Member is postmenopausal, premenopausal with ovarian ablation/suppression**,** or male (sex assigned at birth) **¥**; **AND**
- Used as subsequent therapy in combination with fulvestrant *(with or without palbociclib)*; **AND**
- Member has locally advanced or metastatic disease without a *PIK3CA* mutation detected❖; **AND**
- Used after disease progression or recurrence after at least one prior line of endocrine therapy in the metastatic setting; **AND**

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- Member does not have untreated or active brain or leptomeningeal metastases

*HER2-negative expression criteria: [1-3]

• Immunohistochemistry (IHC) assay is 0 or 1+***; **OR**
• IHC assay indicating (Group 5) HER2 *(ERBB2)*/CEP17 ratio <2.0 AND average HER2 copy number <4.0 signals/cell; **OR**
• Concurrent dual-probe ISH and IHC assay results indicating one of the following:
  ○ (Group 2) HER2 *(ERBB2)*/CEP17 ratio ≥2.0 AND average HER2 *(ERBB2)* copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; **OR**
  ○ (Group 3) HER2 *(ERBB2)*/CEP17 ratio <2.0 AND average HER2 *(ERBB2)* copy number ≥6.0 signals/cell and concurrent IHC 0-1+; **OR**
  ○ (Group 4) HER2 *(ERBB2)*/CEP17 ratio <2.0 AND average HER2 *(ERBB2)* copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+

****The distinction between HER2 (ERBB2) IHC 0/absent membrane staining, IHC 0+/with membrane staining (faint, partial membrane staining in ≤10%), IHC 1+, or 2+/ISH negative results (on primary or metastatic samples) is currently clinically relevant since members with metastatic disease may be eligible for treatment targeting non-amplified levels of HER2 expression.*

❖*If confirmed using an immunotherapy assay - http://www.fda.gov/companiondiagnostics*

¥ *When an aromatase inhibitor is used in males, suppression of testicular steroidogenesis with a gonadotropin releasing hormone (GnRH) analog is required.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-4]

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe stomatitis, severe rash, severe hyperglycemia, etc.

V. Dosage/Administration [1]

Indication	Dose
Breast Cancer	The recommended dosage is 180 mg as an intravenous infusion over 30 minutes once weekly on Days 1, 8, and 15 of every 28-day cycle, in combination with fulvestrant, with or without palbociclib, until disease progression or unacceptable toxicity.. • *For premenopausal and perimenopausal women, administer a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. For men, consider administering a LHRH agonist according to current clinical practice standards.*

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VI. Billing Code/Availability Information

HCPCS Code(s):

- J9999 –Not Otherwise Classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only)*

NDC(s):

- Revtorpyk 180 mg lyophilized powder for injection in a single-dose vial: 00310-9500-xx

VII. References

1. Revtorpyk [package insert]. Minneapolis, MN; Celcuity, Inc.; July 2026. Accessed July 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) gedatolisib. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2026.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer. Version 5.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2026.
4. Hurvitz SA, Layman RM, Curigliano G, et al; VIKTORIA-1 Study Group. VIKTORIA-1 Trial of Gedatolisib Plus Fulvestrant With or Without Palbociclib in Hormone Receptor-Positive/HER2-/PIK3CA Wild-Type Advanced Breast Cancer. J Clin Oncol. 2026 Apr 20;44(12):1108-1119. doi: 10.1200/JCO-25-02643. Epub 2026 Mar 9.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority

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Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast

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ICD-10	ICD-10 Description
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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