

Clinical Policy Title:	inavolisib
Policy Number:	RxA.890
Drug(s) Applied:	Itovebi
Original Policy Date:	6/19/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of advanced or metastatic breast cancer with PIK3CA mutation;
2. Disease is HR-positive and HER2-negative;
3. Prescribed in combination with Ibrance (palbociclib) and fulvestrant;
4. Member must not have experienced disease progression on or following other PI3K inhibitors or CD4K/6 inhibitors;
5. If the member has received adjuvant therapy (e.g. chemotherapy), recurrence within 12 months of completing adjuvant therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Breast Cancer (must meet all):

1. Auto-approval based on lookback functionality within 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>
2. U.S. Food and Drug Administration. FDA approves inavolisib with palbociclib and fulvestrant for endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, advanced breast cancer. October 10, 2024. Accessed May 8, 2025. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-inavolisib-palbociclib-and-fulvestrant-endocrine-resistant-pik3ca-mutated-hr-positive>
3. Hanan EJ, et al. Discovery of GDC-0077 (inavolisib), a highly selective inhibitor and degrader of mutant PI3K α . J Med Chem. 2022;65(24):16589–16621. doi:10.1021/acs.jmedchem.2c01422
4. Highlights of prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219249s001lbl.pdf

Review/Revision History

Review/Revised Date

P&T Approval Date

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy established.	6/19/2025	6/19/2025
Policy reviewed	12/11/2025	12/11/2025