

Genetic Analysis of PIK3CA Status in Tumor Cells

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Definitions

Mutations to the Phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha (PIK3CA) gene are suggested to be linked to the development of several cancers including breast cancer, colorectal cancer, endometrial cancer, gastric cancer and lung cancer.

Related Medical Guidelines

[Gene Expression Profiling](#)

[Genetic Counseling and Testing](#)

Guideline

Analysis of PIK3CA status in tumor cells is considered investigational and not medically necessary for all indications. *

* Note: Pharmacogenetic testing (using an FDA approved companion diagnostic test) may be considered medically necessary for members with PIK3CA-mutated, advanced or metastatic breast cancer, who are under consideration for treatment with Piqray® (apfelsib), as determined through the Pharmacy preauthorization process.

Applicable Procedure Codes

81404	Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)
81479	Unlisted molecular pathology procedure

Revision History

Feb. 14, 2020 — added PIK3CA pharmacogenetic testing for Piqray consideration as a covered exception.

References

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3. Fiala O, Pesek M, Finek J, et al. Gene mutations in squamous cell NSCLC: insignificance of EGFR, KRAS and PIK3CA mutations in prediction of EGFR-TKI treatment efficacy. *Anticancer Res.* 2013; 33(4):1705-1711.
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5. National Center for Biotechnology Information (NCBI). GTR: Genetic Testing Registry. PIK3CA Mutation by Sequencing. Last updated June 17, 2014. Available at: <http://www.ncbi.nlm.nih.gov/gtr/tests/514565/performance-characteristics/>.
6. Ogino S, Liao X, Imamura Y, et al. Predictive and prognostic analysis of PIK3CA mutation in stage III colon cancer intergroup trial. *J Natl Cancer Inst.* 2013; 105(23):1789-1798.
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