

PIK3CA Genetic Testing

Policy Number: PG0507
Last Review: 07/01/2022



IMPORTANT | Paramount medical policies only apply to Paramount Advantage Medicaid claims with dates of service before Feb. 1, 2023. Please contact Anthem, for Medicaid claims with dates of service on or after Feb. 1, 2023.

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

☒ Professional
☐ Facility

DESCRIPTION

Mutations in the PIK3CA gene can lead to the development of a group of rare, non-malignant disorders collectively known as PIK3CA-related overgrowth spectrum (PROS). PROS disorders include fibroadipose hyperplasia, CLOVES syndrome, megalencephaly-capillary malformation (MCAP) syndrome, hemihyperplasia-multiple lipomatosis (HHML) syndrome, hemimegalencephaly and facial infiltrating lipomatosis.

Mutations in the PIK3CA gene can also be found in several types of cancer. Identifying a PIK3CA mutation within a cancer can sometimes allow for the use of targeted therapy for cancer treatment.

POLICY

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid
PIK3CA sequencing analysis requires a prior authorization, CPT codes 81309, 81479.

Paramount Advantage Medicaid
CPT codes 0155U and 0177U are non-covered per the Ohio Department of Medicaid.

Paramount Commercial Insurance Plans, Medicare Advantage Plans
CPT code 0155U requires prior authorization, and CPT code 0177U is non-covered.

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

COVERAGE CRITERIA

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid
PIK3CA Genetic Testing for PIK3CA-Related Overgrowth Spectrum

PIK3CA Sequencing Analysis is considered medical necessary to establish a diagnosis of PIK3CA-Related Segmental Overgrowth when the follow criteria is met:

- The member displays two or more of the following clinical features;
 - Sporadic and mosaic overgrowth in adipose, muscle, nerve, or skeletal tissues
 - Vascular malformations including capillary, venous, arteriovenous malformation, or lymphatic.
 - Epidermal nevus; or
- The member displays one or more of the following clinical features, with a congenital or early childhood onset
 - Large isolated lymphatic malformation
 - Isolated macrodactyly or overgrown splayed feet/ hands, overgrown limbs
 - Truncal adipose overgrowth
 - Hemimegalencephaly (bilateral)/ dysplastic megalencephaly/ focal cortical dysplasia
 - Epidermal nevus
 - Seborrheic keratoses
 - Benign lichenoid keratoses
 - CLOVES syndrome
 - Megalencephaly-capillary malformation syndrome (MCAP syndrome)
 - Fibroadipose hyperplasia
 - Hemimegalencephaly; and
- The results of the genetic test will impact the medical management of the individual (i.e. Vijoice); and
- The specific mutation, or set of mutations, has been established in the scientific literature

PIK3CA deletion/duplication analysis (81479) to establish a diagnosis of PIK3CA-Related Segmental Overgrowth is considered investigational.

Because PIK3CA-Related Segmental Overgrowth syndrome (PROS) is not known to be inherited and most PIK3CA pathogenic variants are mosaic and acquired, more than one tissue type may need to be tested (e.g., blood, skin, saliva).

Other names for PIK3CA include but are not limited to:

- catalytic subunit alpha polypeptide gene
- PI3K
- PI3KCA
- PI3K-alpha
- PI3-kinase p110 subunit alpha

Pre- and post-test genetic counseling is recommended for any individual undergoing genetic testing for any indication.

- Pre-and post-test genetic counseling is considered medically necessary for EITHER of the following:
 - an individual undergoing genetic testing
 - an individual who is a potential candidate for genetic testing
- By ANY of the following:
 - an independent Board-Certified or Board-Eligible Medical Geneticist
 - an American Board of Medical Genetics or American Board of Genetic Counseling-certified Genetic Counselor not employed by a commercial genetic testing laboratory (Genetic counselors are not excluded if they are employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself).
 - a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APNG) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory (Genetic nurses are not excluded if they are employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test)

PIK3CA Genetic Testing for Cancer Treatment

Targeted PIK3CA mutation testing is covered with prior authorization for postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, advanced or

metastatic breast cancer following progression on or after an endocrine-based regimen. Using only a U.S. Food and Drug Administration–approved or –cleared companion test, i.e. theascreen PIK3CA RGQ PCR Kit.

Paramount may consider PIK3CA gene testing to predict treatment response to alpelisib (Piqray) in patients with hormone receptor-positive, HER2 negative advanced or metastatic breast cancer who have progressed on or after an endocrine-based regimen to be eligible for coverage.

CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.

Codes that are covered may have selection criteria that must be met.

Payment for supplies may be included in payment for other services rendered.

CPT CODE	
81309	PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
81479	Unlisted molecular pathology procedure
0155U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3- kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3- kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status
DIAGNOSIS CODE	
C50.011- C50.929 C79.81	Malignant neoplasm of breast
Q87.2	Congenital malformation syndromes predominantly involving limbs
Q87.3	Congenital malformation syndromes involving early overgrowth

REVISION HISTORY EXPLANATION

ORIGINAL EFFECTIVE DATE: 06/01/2022

Date	Explanation & Changes
07/01/2022	<ul style="list-style-type: none">Policy created
03/09/2023	<ul style="list-style-type: none">Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to <https://www.paramounthealthcare.com/services/providers/medical-policies/>.

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

U.S. Preventive Services Task Force, <http://www.uspreventiveservicestaskforce.org/>
Industry Standard Review

Hayes, Inc.

Industry Standard Review

Keppler-Noreuil, et al. Am J Med Genet A. 2015 Feb;167A(2):287-95. doi: 10.1002/ajmg.a.36836. Epub 2014 Dec 31.

National Comprehensive Cancer Network® (NCCN®) Guidelines Version 4.2022, Breast Cancer