

Genetic testing: kidney disorders

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for the following services:

- Polycystic Kidney Disease Panels
- Comprehensive Kidney Disease Panels
- Targeted Variant Analysis for APOL1-Mediated Kidney Disease
- Donor-Derived Cell-free DNA for Kidney Transplant Rejection
- Covered Kidney Disorders
- Testing that is associated with a procedure code listed in "Box A", below.

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

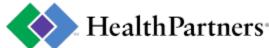
Box A: Genetic testing procedure codes that require prior authorization	
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)	
Unlisted multianalyte assays (CPT 81599)	
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test.	

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Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes
Polycystic Kidney Disease		•	•
Polycystic Kidney Disease Panels	Hereditary Cystic Kidney Diseases Panel (PreventionGenetics, part of Exact Sciences)	81404, 81405, 81406, 81407, 81408, 81479	Q61, N18
	Polycystic Kidney Disease Panel (GeneDx)		
Comprehensive Kidney Dise	ase Panels		
Comprehensive Kidney Disease Panels	RenaSight (Natera)	81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81479	N00-N08, N10-N19, Q61, R31
	KidneySeq Version 5 Comprehensive Testing (Iowa Institute of Human Genetics)		
	RenalZoom (DNA Diagnostic Laboratory - Johns Hopkins Hospital)		
APOL1-Mediated Kidney Dis	ease		
APOL1-Targeted Variant Analysis	Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping (Quest Diagnostics)	0355U	N00-N08, N10-N19
	APOL1 Genotype, Varies (Mayo Clinic Laboratories)	81479	
Donor-Derived Cell- free DN	A for Kidney Transplant Rejection		
	Allosure Kidney (CareDx, Inc.)	81479	T86.11, T86.12, Z94.0
	Prospera Kidney (Natera)	0493U	



Donor-Derived Cell-free DNA for Kidney Transplant Rejection	Viracor TRAC dd-cfDNA (Viracor Eurofins)	0118U			
	VitaGraft Kidney Baseline + 1st Plasma Test (Oncocyte Corporation)	0508U			
Other Covered Kidney Disorders					
Other Covered Kidney Disorders	See list below	81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 0268U			

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Coverage

Polycystic Kidney Disease

Polycystic Kidney Disease Panels

- 1. Genetic testing using a polycystic kidney disease panel to confirm or establish a diagnosis of polycystic kidney disease is considered **medically necessary** when:
 - A. The member has any of the following clinical features of polycystic kidney disease:
 - i. Multiple bilateral renal cysts
 - ii. Cysts in organs other than the kidneys (especially the liver, seminal vesicles, pancreas, and arachnoid membrane)
 - iii. Hypertension in an individual younger than age 35
 - iv. Bilaterally enlarged and diffusely echogenic kidneys
- 2. Genetic testing using polycystic kidney disease panels to confirm or establish a diagnosis of polycystic kidney disease is considered **investigational** for all other indications.

Back to top

Comprehensive Kidney Disease Panels

- 1. Genetic testing for kidney disease via a comprehensive kidney disease panel is considered **medically necessary** when:
 - A. The member has chronic kidney disease with an undetermined cause after undergoing standard-of-care workup studies (e.g., history and physical examination, biochemical testing, renal imaging, or renal biopsy), **and**
 - B. The member meets at least one of the following:
 - Onset of chronic kidney disease under 40 years of age, or
 - ii. One or more first or second-degree relatives with chronic kidney disease, or
 - iii. Consanguineous family history, or
 - iv. Cystic renal disease or
 - v. Congenital nephropathy, or
 - vi. Syndromic/multisystem features, or
 - vii. There is a possibility of identifying a condition amenable to targeted treatment
- 2. Genetic testing for kidney disease via a comprehensive kidney disease panel is considered **investigational** for all other indications.

Back to top

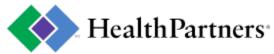
APOL1-Mediated Kidney Disease APOL-1 Targeted Variant Analysis

- 1. Targeted variant analysis for the APOL1 high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2) is considered medically necessary when:
 - A. The member has kidney disease, and
 - B. The member meets at least one of the following:
 - i. The member is of African ancestry, **or**
 - ii. The member has a family member with a confirmed APOL1 high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2)
- 2. Targeted variant analysis for the APOL1 high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2) is considered **investigational** for all other indications.

Back to top

Donor-Derived Cell-Free DNA for Kidney Transplant Rejection

- 1. The use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after renal transplantation is considered **medically necessary** when:
 - A. The member has undergone kidney transplantation, and



- B. The test has not been performed in the previous 12 months, and
- C. The member meets at least one of the following:
 - i. The member has clinical signs of acute rejection, or
 - ii. A biopsy was done to check for signs of acute rejection and is inconclusive, or
 - iii. The member is being monitored for adequate immunosuppression
- 2. The use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after renal transplantation is considered **investigational** for all other indications.

Back to top

Covered Kidney Disorders

- 1. Genetic testing to establish or confirm one of the following genetic kidney disorders to guide management is considered **medically necessary** when the member demonstrates clinical features* consistent with the disorder:
 - A. Alport Syndrome
 - B. C3 Glomerulopathy
 - C. Congenital nephrotic syndrome
 - D. Cystinosis
 - E. Cystinuria
 - F. Fabry Disease
 - G. Genetic (familial) atypical hemolytic-uremic syndrome (aHUS)
 - H. Primary Hyperoxaluria
- 2. Genetic testing to establish or confirm the diagnosis of all other kidney disorders not specifically discussed within this or another medical policy will be evaluated by the criteria outlined in **General Approach to Genetic Testing** (see policy for coverage criteria).

*Clinical features for a specific disorder may be outlined in resources such as GeneReviews, OMIM, National Library of Medicine, MedlinePlus, or other scholarly source.

Definitions

- 1. Close relatives include first, second, and third degree **blood** relatives on the same side of the family:
 - A. **First-degree relatives** are parents, siblings, and children
 - B. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings
 - C. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins

Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee 6/15/2021, 12/20/21, 3/6/23, 9/12/23, 9/10/24 Annual Review 7/2022, 1/2023, 7/2023, 1/2024, 7/2024, 1/2025

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