# Concert Genetic Testing: ~~Kidney Disorders~~Nephrology

Reference Number: LA.CP.CG.11
Date of Last Revision ~~01/25~~03/26
Revision Log

Coding implications

**See** Important Reminder **at the end of this policy for important regulatory and legal information.**

# OVERVIEW

~~Inherited kidney disorders and inherited disorders that indirectly affect the kidneys can be common, such as autosomal dominant polycystic kidney disease, or rare, such as Lowe syndrome and Fabry disease. Identifying the genetic cause of an inherited kidney disorder can help direct treatment, inform family members, and contribute to the overall understanding of the genetic etiology of chronic kidney disease. More advanced next-generation sequencing, such as exome sequencing and comprehensive genetic testing panels, are emerging as a first-line diagnostic method for patients with chronic kidney disease.~~

~~With the use of donor-derived cell-free DNA (ddcfDNA), biomarker tests have been developed as an alternative to more invasive procedures for post-renal transplant care to optimize graft longevity while avoiding side effects and toxicity of immunosuppressive therapies.~~

This policy addresses the use of tests for known or suspected kidney disorders, including testing of asymptomatic potential living donors.

For additional information see the Rationale section.

# POLICY REFERENCE TABLE

**Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted ~~2023~~2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

The tests, ~~associated laboratories,~~ CPT codes, and ~~CPT~~ICD codes ~~contained within~~referenced in this ~~document serve only as examples to help users navigate claims and corresponding criteria; as such, they~~policy are not comprehensive, and ~~are~~their inclusion does not represent a guarantee of coverage or non-coverage. Please see the ~~Concert Platform~~Concert Platform for ~~a comprehensive list of~~additional registered tests.

**NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis. The non-covered codes will only be denoted in the table below and not throughout the policy. Please only reference the policy reference table for covered and non-covered codes.**

| ~~Criteria Sections~~ CRITERIA SECTIONS | ~~Example Tests (Labs)~~EXAMPLE TESTS (LABS) | ~~Common CPT Codes~~COMMON BILLING CODES | ~~Common ICD Codes~~REF | ~~Ref~~ |
|---|---|---|---|---|
| ~~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~~ | ~~1,~~ |
| | ~~Polycystic Kidney Disease Panel (GeneDx)~~ | | | |
| ~~Comprehensive Kidney Disease Panels~~ | | | | |

| | | | | |
|---|---|---|---|---|
| ~~Comprehensive Kidney Disease Panels~~ | ~~RenaSight (Natera)~~ | ~~81401*, 81402*, 81403*, 81404*, 81405*, 81406*, 81407*, 81408*, 81479~~ | ~~N00-N08, N10-N19, Q61, R31~~ | ~~3,~~ |
| | ~~KidneySeq Version 5 Comprehensive Testing (Iowa Institute of Human Genetics)~~ | | | |
| | ~~RenalZoom (DNA Diagnostic Laboratory - Johns Hopkins Hospital)~~ | | | |
| ~~***APOL1* Mediated Kidney Disease~~ | | | | |
| ~~*APOL1* Targeted Variant Analysis~~ | ~~Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping (Quest Diagnostics)~~ | ~~0355U*~~ | ~~N00-N08, N10-N19~~ | ~~7~~ |
| | ~~APOL1 Genotype, Varies (Mayo Clinic Laboratories)~~ | ~~81479~~ | | |
| ~~**Donor-Derived Cell-free DNA for Kidney Transplant Rejection**~~ | | | | |
| ~~Donor-Derived Cell-free DNA for Kidney Transplant Rejection~~ | ~~Allosure Kidney (CareDx, Inc.)~~ | ~~81479~~ | ~~T86.11, T86.12, Z94.0~~ | ~~9,~~ |
| | ~~Prospera (Natera)~~ | ~~0493U*~~ | | |
| | ~~Viracor TRAC Kidney dd-cfDNA (Viracor Eurofins)~~ | ~~0118U*~~ | | |
| | ~~VitaGraft Kidney Baseline + 1st Plasma Test (Oncocyte Corporation)~~ | ~~0508U*~~ | | |
| | ~~VitaGraft Kidney Subsequent (Oncocyte Corporation)~~ | ~~0509U*~~ | | |
| ~~**Other Covered Kidney Disorders**~~ | | | | |
| ~~Other Covered Kidney Disorders~~ | ~~See list below~~ | ~~81400*, 81401*, 81402*, 81403*, 81404*, 81405*, 81406*, 81407*, 81408*~~ | | ~~4,~~ |

| | | | |
|---|---|---|---|
| ~~OTHER~~ **Polycystic Kidney Disease** | | | |
| Polycystic Kidney Disease Panels | Hereditary Cystic Kidney Diseases Panel (PreventionGenetics, part of Exact Sciences) | 81404*, 81405*, 81406*, 81407*, 81408*, 81479, N18, Q61 | 1, 9 |
| | Polycystic Kidney Disease Panel (GeneDx) | | |
| **Comprehensive Kidney Disease Panels** | | | |
| Comprehensive Kidney Disease Panels | KidneySeq Version 5 Comprehensive Testing (Iowa Institute of Human Genetics) | 81401*, 81402*, 81403*, 81404*, 81405*, 81406*, 81407*, 81408*, 81479, N00-N08, N10-N19, Q61, R31 | 2, 7, 8 |
| | RenaSight (Natera) | | |
| | RenalZoom (DNA Diagnostic Laboratory - Johns Hopkins Hospital) | | |
| ***APOL1*-Mediated Kidney Disease** | | | |
| *APOL1*-Targeted Variant Analysis | Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping - 0355U (Quest Diagnostics) | 0355U*, 81479, N00-N08, N10-N19 | 6 |
| | APOL1 Genotype, Varies (Mayo Clinic Laboratories) | | |
| **Other Covered Kidney Disorders** | | | |

| | | | |
|---|---|---|---|
| Other Covered Kidney Disorders | See list below | 81400*, 81401*, 81402*, 81403*, 81404*, 81405*, 81406*, 81407*, 81408* | 3, 4, 5 |

# RELATED POLICIES

This policy document provides criteria for ~~hereditary~~ testing related to kidney disorders. Please refer to:

- ***~~Genetic~~Specialty* Testing: Multisystem *~~Inherited Disorders, Intellectual Disability, and Developmental Delay~~Genetic Conditions*** for criteria related to diagnostic tests for genetic disorders that affect multiple organ systems (e.g. whole exome and genome sequencing, chromosomal microarray, and multigene panels for broad phenotypes).
- ***~~Genetic~~Oncology* Testing: Hereditary Cancer Susceptibility** for criteria related to von Hippel Lindau (VHL) syndrome and other hereditary cancer syndromes.
- ***~~Genetic~~Specialty* Testing: *Hematology*** for criteria related to diagnostic tests for benign (non-cancerous) hematologic conditions including sickle cell disease, inherited anemias, and hemophilias.
- ***General Approach to ~~Genetic and Molecular~~Laboratory* Testing** for criteria related to ~~genetic~~nephrology, including known familial variant testing ~~for kidney disease~~, that is not specifically discussed in this or another non-general policy~~, including known familial variant testing~~.
- ~~***Genetic Testing Hematologic Conditions Non-Cancerous*** for criteria related to hematologic disorders that affect the kidneys.~~

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# CRITERIA

It is the policy of Louisiana Healthcare Connections that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

# POLYCYSTIC KIDNEY DISEASE ~~PANELS~~

## Polycystic Kidney Disease Panels

I. Genetic testing using a polycystic kidney disease panel ~~(81404, 81405, 81406, 81407, 81408, 81479)~~ to confirm or establish a diagnosis of polycystic kidney disease (PKD) is considered **medically necessary** when:

A. The member/enrollee has any of the following clinical features of ~~polycystic kidney disease~~PKD:

1. ~~Multiple bilateral renal~~Kidney cysts, **OR**

2. Cysts in organs other than the kidneys (especially the liver, seminal vesicles, pancreas, and arachnoid membrane), **OR**

~~1. Hypertension in an individual younger than age 35, **OR**~~

3. Bilaterally enlarged and diffusely echogenic kidneys~~.~~.

II. ~~Genetic~~Current evidence does not support genetic testing using polycystic kidney disease panels ~~(81404, 81405, 81406, 81407, 81408, 81479)~~ to confirm or establish a diagnosis of polycystic kidney disease ~~is considered **investigational**~~(PKD) for all other indications.

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# COMPREHENSIVE KIDNEY DISEASE PANELS

## Comprehensive Kidney Disease Panels

I. Genetic testing for kidney disease via a comprehensive kidney disease panel ~~(81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81479)~~ is considered **medically necessary** when:

A. The member/enrollee has chronic kidney disease with an undetermined cause after undergoing standard-of-care workup studies (~~examples:~~e.g., history and physical examination, biochemical testing, renal imaging, or renal biopsy), **AND**

1. The member/enrollee meets at least one of the following:

a) Onset of chronic kidney disease under ~~40~~50 years of age, **OR**

b) ~~One or more first- or second-degree relatives~~One or more first-degree relatives with chronic kidney disease, **OR**

c) Consanguineous family history, **OR**

d) Cystic renal disease, **OR**

e) Congenital nephropathy, **OR**

f) Syndromic/multisystem features, **OR**

g) There is a possibility of identifying a condition amenable to targeted treatment~~.~~, **OR**

h) ~~Genetic~~The member/enrollee is being wait-listed for kidney transplant, **AND**

(1) A close relative is considering kidney donation to the member/enrollee, **OR**

B. The member/enrollee is asymptomatic, **AND**

1. The member/enrollee is being considered as a kidney donor, **AND**

2. The member/enrollee has at least one first-degree relative with kidney disease suggestive of autosomal dominant or X-linked inheritance, **AND**

3. No causative mutation has been established yet for the kidney disease seen in the family.

II. Current evidence does not support genetic testing for kidney disease via a comprehensive kidney disease panel ~~(81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81479) is considered **investigational** for~~ for all other indications.

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# APOL1-MEDIATED KIDNEY DISEASE

## *APOL1* ~~-~~-Targeted Variant Analysis

I. Targeted variant analysis for the *APOL1* high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2) ~~(0355U, 81479)~~ is considered **medically necessary** when:

A. The member/enrollee has kidney disease, **AND**

B. The member/enrollee meets at least one of the following:

1. The member/enrollee is of African ancestry, **OR**

2. The member/enrollee has a ~~family member~~close relative with a confirmed *APOL1* high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2).

II. ~~Targeted~~Current evidence does not support targeted variant analysis for the *APOL1* high-risk genotype (i.e., G1/G1, G1/G2, or G2/G2) ~~(0355U, 81479) is considered **investigational** for all other indications.~~

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## ~~DONOR-DERIVED CELL-FREE DNA FOR KIDNEY TRANSPLANT REJECTION~~

### ~~Donor-Derived Cell-free DNA for Kidney Transplant Rejection~~

~~I. The use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after renal transplantation (81479, 0493U, 0118U, 0508U, 0509U) is considered **medically necessary** when:~~

~~A. The member/enrollee 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:~~

~~1. The member has clinical signs of acute rejection, **OR**~~

~~2. A biopsy was done to check for signs of acute rejection and is inconclusive, **OR**~~

~~3. The member is being monitored for adequate immunosuppression.~~

~~II. The use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after renal transplantation (81479, 0493U, 0118U, 0508U, 0509U) is considered **investigational** for all other indications.~~

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# OTHER COVERED KIDNEY DISORDERS

## Other Covered Kidney Disorders

The following is a list of conditions that have a known genetic association. Due to their relative rareness, it may be appropriate to cover these genetic tests to establish or confirm a diagnosis.

I. Genetic testing to establish or confirm one of the following genetic kidney disorders to guide management is considered **medically necessary** when the member/enrollee demonstrates clinical features~~*~~ consistent with the disorder (the list is not meant to be comprehensive, see II below):

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.

II. 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 and Molecular~~Laboratory Testing* (see policy for criteria).

~~*~~**NOTE:** Clinical features for a specific disorder may be outlined in resources such as GeneReviews, OMIM, ~~National Library of Medicine, Genetics Home Reference~~National Library of Medicine, Genetics Home Reference, or other scholarly source.

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# ~~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.~~a. ~~**Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings~~

~~c.~~a. ~~**Third-degree relatives** are great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins~~

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# RATIONALE

## Polycystic Kidney Disease Panels

~~*GeneReviews: Polycystic Kidney Disease, Autosomal Dominant and*~~*Kidney Disease: Improving Global Outcomes (2025)*

KDIGO developed a Clinical Practice Guideline for the Evaluation, Management, and Treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD) with collaborators and representatives from multiple US-based institutions. Figure 2, Chapter 1 (p. 4) supports genetic testing for ADPKD in individuals with a positive family history of the condition for the following scenarios:

1. Equivocal or atypical features on ultrasound
2. Atypical extra-renal features
3. When prognostic information is requested following an ultrasound diagnostic for ADPKD
4. When the patient's presentation is very different from the familial phenotype

Figure 3, Chapter 1 (p. 5) addresses genetic testing for ADPKD in individuals without a family history of the condition (ie, incidentally detected kidney or liver cysts on ultrasound, MRI, or CT). The guideline includes genetic testing as part of the diagnostic algorithm in the following scenarios:

1. An atypical or mild presentation leading to an uncertain ADPKD diagnosis
2. A presentation consistent with a clinical ADPKD diagnosis

*GeneReviews:* *Autosomal Recessive Polycystic Kidney Disease - PKHD1*

*GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.*

The recommended polycystic kidney disease testing for ~~autosomal dominant polycystic kidney disease (ADPKD) and~~ autosomal recessive polycystic kidney disease (ARPKD) is as follows:

~~"ADPKD should be suspected in individuals with the following:~~

- ~~Multiple bilateral renal cysts and the absence of manifestations suggestive of a different renal cystic disease~~
- ~~Cysts in other organs, especially the liver, but also seminal vesicles, pancreas, and arachnoid membrane…~~
- ~~Hypertension in an individual younger than age 35 years~~

"Autosomal recessive polycystic kidney disease – PKHD1 (ARPKD-PKHD1) should be suspected in probands with the following age-related clinical and ultrasonographic findings at presentation…:

Infantile presentation (age 4 weeks to 1 year)

- Bilaterally enlarged kidneys (in relation to age-, height-, or weight-based normal range) that usually retain their typical shape
  Note: (1) Bilaterally enlarged kidneys can be interspersed with macrocysts. (2) During later disease stages relative kidney length may decrease again.
- Increased echogenicity…
- High-resolution ultrasonography may demonstrate innumerable very small cysts (rarely exceeding 1-2 mm) in the cortex and medulla.

Childhood/Young Adulthood Presentation (age >1 year)

- Imaging findings typically are the following:

Enlarged kidneys with multiple macrocysts, increased echogenicity, and reduced or absent corticomedullary differentiation…"

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## Comprehensive Kidney Disease Panels

*Hays et al (2020)*

"We propose the following approach, based on a review of current literature and our practical experience. This approach assumes individuals have already undergone an initial nephrologic workup, including biochemical and serologic testing, imaging of the kidneys, and renal biopsy if indicated.

…[A]fter a negative or inconclusive initial workup, a patient is considered to have KDUE [kidney disease of unknown etiology] and may then be stratified according to the probability of a genetic disease. We consider higher probability patients as those with the following risk factors: early-onset disease (age <40 years), a positive family history of CKD [chronic kidney disease], consanguinity, extrarenal anomalies, cystic renal disease, or congenital nephropathy~~". "~~ (p. 594~~))~~.

*Kidney Disease: Improving Global Outcomes (KDIGO) (2024)*

KDIGO developed a Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease in 2024. ~~The guideline states the following:~~Section 1.1.4 discusses evaluating the cause of chronic kidney disease (CKD) and recommends genetic testing as an important component of this evaluation. Per this guideline, testing has identified pathogenic or likely pathogenic variants in more than 10% of individuals, and results may impact medical management (p. S173).

~~"Genetic testing is emerging as a valuable component for evaluation of cause. In some studies, >10% of people with CKD, regardless of family history, were observed to carry genetic pathogenic and likely pathogenic variant(s) that represent a plausible molecular cause for the development or progression of CKD. In some cases, identification of actionable genes through genetic testing can impact the clinical management of people with CKD. A recent KDIGO Controversies Conference listed the~~The following are recommendations from the guideline for when genetic testing can be particularly informative: ~~(i) high~~

3. High prevalence of monogenic subtypes within the clinical category~~, (ii) early~~
4. Early age of onset of CKD~~, (iii) syndromic~~
5. Syndromic/ multisystem features~~, (iv) consanguinity, (v) possibility~~
6. Consanguinity
7. Possibility of identifying a condition amenable to targeted treatment~~, and (vi)~~
~~1.~~8. CKD/ kidney failure of unknown etiology when kidney biopsy would not be informative due to advanced disease~~."~~" (p. S173~~)~~).

Additionally, the guideline lists the following genes as examples ~~for~~to include in genetic testing evaluation: *APOL1, COL4A3, COL4A4, COL4A5, NPHS1, UMOD, HNF1B, PKD1, PKD2.* ~~It goes on to say this~~The comment in Table 6 of the guidelines says that genetic testing is "evolving as a tool for diagnosis, increased utilization is expected. Recognition that genetic causes are more common and may present without classic family history~~".~~" (p. S150~~)~~).

*National Kidney Foundation (2024)*

The National Kidney Foundation (NKF) developed multiple recommendations for Advancing Genetic Testing in Kidney Disease based on working group consensus. An Algorithm was created (Figure 2, Table 2) for decision-making for genetic testing in symptomatic individuals. The specific recommendations for genetic testing include:

- Family history of CKD (refers to first-degree relatives only, unless there is evidence of autosomal recessive of X-linked inheritance in the family)
- Multi-organ syndrome of unknown etiology
- Atypical clinical disease, to guide therapeutics…
- Kidney biopsy findings suggestive of a genetic cause…
- CKD/ESKD of unknown etiology after a comprehensive clinical evaluation if any of the following are true:

- Age <50
- The patient is being wait listed for kidney transplant and their blood relative is considering kidney donation
- Diagnosis may aid in management of extra-renal manifestation

- Evaluation of patients with atypical cystic kidney or liver disease and no family history

Several recommendations were also made for at-risk relatives, including the following:

- Living donors unrelated to the recipients should undergo genetic testing if they have significant family history (CKD of unknown etiology or early-onset CKD, cystic kidney disease, congenital disease with extrarenal signs, aHUS) (p. 8)

The NKF Algorithm also recommends large multi-disease kidney panel testing (p. 8).

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## *APOL1* -~~-~~Targeted Variant Analysis

*Freedman et al (2021)*

A multidisciplinary group of experts and patient advocates performed a systematic review and created consensus-based guidelines in 2021 to guide health care providers in *APOL1*-associated neuropathy. The guidelines recommend the following:

"...*APOL1* testing should be considered in all patients of African ancestry with kidney disease and in any patient with kidney disease and a family member with a confirmed *APOL1* high-risk genotype~~."~~"" (p. 1768~~)~~).

Regarding the definition of "high-risk phenotype": "Two copies of the *APOL1* variants (G1/G1, G1/G2, G2/G2) are commonly referred to as a 'high-risk' genotype…" (p. 1765~~)~~).

~~**Donor-Derived Cell-Free DNA for Kidney Transplant Rejection**~~

~~*Centers for Medicare and Medicaid Services*~~

~~The CMS local coverage determination (LCD) entitled "MolDX: Molecular Testing for Solid Organ Allograft Rejection" states the following regarding donor-derived cell-free DNA tests in individuals who have had solid organ transplantation:~~

~~"This Medicare contractor will provide limited coverage for molecular diagnostic tests used in the evaluation and management of patients who have undergone solid organ transplantation. These tests can inform decision making along with standard clinical assessments in their evaluation of organ injury for active rejection (AR).~~

~~These tests may be ordered by qualified physicians considering the diagnosis of AR affiliated with a transplant center, helping to rule in or out this condition when assessing the need~~

~~for or results of a diagnostic biopsy. They should be considered along with other clinical evaluations and results and may be particularly useful in patients with significant contraindications to invasive procedures.~~

~~The intended use of the test must be:~~

- ~~To assist in the evaluation of adequacy of immunosuppression, wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy in a patient for whom information from a tissue biopsy would be used to make a management decision regarding immunosuppression, OR~~
- ~~As a rule-out test for AR in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy, OR~~
- ~~For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest, OR~~
- ~~To assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive or limited by insufficient material."~~

~~*European Society of Organ Transplantation*~~

~~The European Society of Organ Transplantation (ESOT, published in 2024) published a Consensus Statement on Testing for Non-Invasive Diagnosis of Kidney Allograft Rejection, which states the following:~~

~~"Recommendation 1.1: We suggest that clinicians consider measuring serial plasma dd-cfDNA in patients with stable graft function to exclude the presence of subclinical antibody mediated rejection. (p. 5)~~

~~Recommendation 2.1: We recommend that clinicians measure plasma dd-cfDNA in patients with acute graft dysfunction to exclude the presence of rejection, particularly antibody mediated rejection." (p. 6)~~

~~*American Society of Transplant Surgeons (ASTS)*~~

~~The ASTS issued a statement on donor derived cell-free DNA (dd-cfDNA) in 2023. At this time, there are no evidence-based screening recommendations for frequency of testing mentioned in this statement.~~

~~*Concert Note*~~

~~For routine monitoring of patients post-transplant, absent clear, specific and evidence-based guideline recommendations for a particular regimen of screening, a default frequency of coverage of once every 12 months will be adopted.~~

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# 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

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| Reviews, Revisions, and Approvals | Revision Date | Approval Date | Effective Date |
|---|---|---|---|
| Converted corporate to local policy. | 09/23 | 11/27/23 | |
| Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced "coverage criteria" with "criteria. For Policy Reference Table; under Single gene of Multigene Panel: added "PreventionGenetics, part of Exact Sciences" throughout; added "APOL1-Mediated Kidney Disease…"; under Other Covered Kidney Disorders: added "81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 0268U". | 12/23 | 2/27/24 | |
| Semi-annual review. Updated title to reflect V2.2024 version. In *APOL-1* Targeted Variant Testing criteria, criteria set name changed (formerly "Targeted Variant Analysis"). Minor rewording for clarity throughout. Coding, reference-table, background and references updated. | 06/24 | 8/19/24 | 9/19/24 |
| Semi-annual review. Updated title to reflect 1.2025 version. Donor-Derived Cell-Free DNA for Kidney Transplant Rejection: Coverage status changed from non-covered to covered based on LCD and society guidelines; Added covered PLA codes to be consistent with LCD; Corrected minor typo in Policy Reference Table; Updated references. Comprehensive Kidney Disease Panels: Added the following criteria based on literature and new guidelines; *Syndromic/multisystem features; * There is a possibility of identifying a condition amenable to target treatment; Added new reference and support in Background and Rationale. Polycystic Kidney Disease - Targeted Variant Analysis: RETIRED; Tests for this condition will now be reviewed using the General policy. Polycystic Kidney Disease Panels: Removed the following criteria; - Intracranial aneurysm- Poor corticomedullary differentiation - Hepatobiliary abnormalities with progressive portal hypertension - Congenital hepatic fibrosis (CHF) with portal hypertension; Former criteria name: "PKD1, PKD2, GAANAB, DNAJB11, PKHD1 Sequencing and/or Deletion/Duplication Analysis or Multigene Panel | 11/25 | 3/31/25 | 5/1/25 |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date | Effective Date |
|---|---|---|---|
| Analysis"; Updated example tests, CPT codes, and common ICD codes in Policy Reference Table;<br>Streamlined portions of Background and Rationale section for brevity; Updated references. Other Covered Kidney Disorders: Updated dates in references. | | | |
| Annual review. Policy name changed from "Concert Genetic Testing: Kidney Disorders" to "Concert Genetic Testing: Nephrology." Polycystic Kidney Disease Panels criteria: The criterion "Hypertension in an individual younger than age 35" was removed; minor update to criterion A.1 based on a recent KDIGO guideline; the phrase "Multiple bilateral renal" was removed and replaced with "Kidney" to capture the variety of imaging findings that could lead to genetic testing. Changed "investigational" policy statements to state "current evidence does not support…" References, rationale, background, and coding updated. | 03/26 | | |

# REFERENCES


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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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