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Medical Policy

Subject:	**Cell-free DNA Testing to Aid in the Monitoring of Kidney Transplants for Rejection**		
Document#:	**LAB.00038**	**Publish Date:**	**04/07/2021**
Status:	**New**	**Last Review Date:**	**02/11/2021**

Description/Scope

This document addresses the use of cell-free DNA (cfDNA) as a method of detecting kidney transplant recipients at risk for transplant rejection. cfDNA-based tests for detection of kidney transplant rejection may use blood or urine samples and include, but may not be limited to, QiSant™ (NephroSant, Inc., Brisbane, CA), AlloSure® (CareDX, Inc., San Francisco, CA), Transplant Rejection Allograft Check (TRAC®) (Viracor, Lee's Summit, MO) and Propsera™ Organ Transplant Rejection Assessment Test (Natera, Inc., San Carlos, CA). This document does not address the use of organ biopsy or serum creatinine monitoring to detect kidney transplant rejection.

Note: Please see the following related document for additional information:

- **CG-TRANS-02 Kidney Transplantation**

Position Statement

Investigational and Not Medically Necessary:

Cell-free DNA testing is considered investigational and not medically necessary as a non-invasive method of determining the risk of rejection in kidney transplant recipients.

Rationale

Following a renal transplant, monitoring the health of the allograft is crucial for detecting evidence of rejection as early as possible. Early detection of rejection enables individualized adjustments to immunosuppressive therapy whereby decreasing the likelihood of transplant failure. The most widely accepted method for surveillance of renal allograft rejection is achieved by monitoring serum creatinine levels. Confirmatory diagnosis is made by histologic analysis of the allograft via needle biopsy, the current

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gold standard for diagnosis. While serum creatinine allows estimation of the glomerular filtration rate (GFR) in routine monitoring, it is not specific or sensitive for transplant rejection. Use of a biopsy for more frequent, routine monitoring is not ideal due to the invasiveness of the procedure. Measurement of donor-derived cell-free DNA (dd-cfDNA) in the blood and urine has been proposed as a noninvasive testing method that may be more specific than serum creatinine monitoring while enabling more frequent monitoring of allograft injury than biopsy permits.

Propsera

In 2018, Sigdel and colleagues published results of a single center, retrospective study in which the Propsera cfDNA test kit was used to analyze 300 plasma samples from 193 unique renal transplant recipients (217 of which were biopsy-matched [38 with active rejection, 72 borderline rejection, 82 stable allografts, and 25 with other graft injuries]). The median dd-cfDNA levels were significantly higher in samples with biopsy-proven active rejection (2.3%) relative to borderline rejection (0.6%), other injuries (0.7%), and stable allografts (0.4%) (p<0.0001; all comparisons). The Prospera assay discriminated active from non-rejection status with a sensitivity of 88.7% (95% confidence interval [CI], 77.7 to 99.8%) and specificity of 72.6% (95% CI, 65.4 to 79.8%). At 6 months post transplantation, of the13 recipients with biopsy-confirmed rejection, 12 (92%) were dually identified by cfDNA testing. Study authors conclude that use of Propsera in the clinical setting is feasible. Further investigation is warranted in the setting of a prospective, randomized clinical trial. Currently, the manufacturer is conducting two prospective multi-center clinical trials with estimated study completion dates in 2027 (NCT04091984; estimated enrollment of 3000) and 2028 (NCT03984747; estimated enrollment of 500).

AlloSure

Based on earlier data published by Grskovic (2016), Bloom and colleagues (2017) prospectively collected 107 blood specimens from 102 kidney transplant recipients at regular intervals (months 1, 2, 3, 4, 6, 9, and 12) and at the time of clinically indicated biopsies (based on creatinine levels). Donor-derived plasma cfDNA levels were measured using the AlloSure assay and then correlated with biopsy-confirmed allograft rejection status. Using a diagnostic cutoff of 1.0% dd-cfDNA (< 1% reflects the absence of active rejection), the positive and negative predictive values for active rejection were 61% and 84%, respectively. The AlloSure successfully discriminated between biopsy specimens confirming any type of rejection (T cell-mediated rejection or antibody-mediated rejection) and controls, p<0.001 (area under the curve [AUC], 0.74; 95% CI, 0.61 to 0.86). The AUC for specifically discriminating antibody-mediated rejection from allografts without

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antibody-mediated rejection was slightly higher at 0.87 (95% CI, 0.75 to 0.97); positive and negative predictive values were 44% and 96%, respectively. In this relatively small prospective cohort, AllSure's performance as a non-invasive test for detection of allograft injury is promising. Further investigation in the setting of a large, randomized trial is warranted to establish ~~clinical utility and a net health benefit from implementation of~~whether use of AlloSure ~~relative to the current standard of~~ materially improves net health outcomes compared to established alternatives,~~care~~ such as monitoring serum creatinine levels.

CareDx, the manufacture of AlloSure, is currently conducting three prospective clinical trials with estimated completion in 2020 (NCT04566055; actual enrollment of 1000), 2025 (NCT03326076; estimated target enrollment of 5000) and 2026 (NCT04601155; estimated target enrollment of 3500.

NephroSant

Based on the foundational work by Watson (2019) and Yang (2020), Nolan and colleagues (2020) published validation study results of a urine-based cfDNA test known as the NephroSant QiSant Assay, comprised of six urinary DNA, protein, and metabolic biomarkers known as the Q-score. The study involved 223 kidney transplant recipient urine samples collected from 215 pediatric and adult recipients with kidney biopsy matched samples. Out of the 223 samples, acute rejection was detected in 71 samples, while 152 remained stable allografts. Additional urine samples were collected for up to 4 years post-transplant. The NephroSant Assay was able to detect acute rejection in pediatric transplant recipients with an Area Under the Curve of 100% (95% CI, 1.00 to 1.00; p<0.0001) and 99.8% in adult transplant recipients (95% CI, 0.995 to 1.00; p<0.0001). Study limitations include the cross-sectional, single-arm study design. Although initial study of NephroSant's performance in detecting allograft rejection is promising, it has not been proven to materially improve the net health outcome or be as beneficial as established alternatives (e.g., monitoring serum creatinine levels)~~its utility beyond the standard of care in the clinical setting remains to be determined~~. Additional study in the setting of a randomized controlled trial is warranted to establish improvement in net health outcomes.

Other cfDNA Assays

Gielis and colleagues (2020) published a non-manufacturer sponsored study of 107 kidney transplant recipients. Plasma samples were collected prospectively up to 3 months post-transplantation. Increases of the dd-cfDNA% above a threshold value of 0.88% were significantly associated with the occurrence of episodes of acute rejection (p=0.017), acute tubular necrosis (p=0.011) and acute pyelonephritis (p=0.032). Although

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increases in cfDNA were associated with graft injury, authors conclude that the testing method was not specific to rejection and failed to outperform the diagnostic capacity of serum creatinine levels in the detection of acute rejection.

Summary

Two systematic reviews have investigated the use of cfDNA in monitoring allograft health after kidney transplantation (Knight, 2019; Wijtvliet, 2020). While both conclude that cfDNA is a promising biomarker, "future studies will need to define how it can be used in routine clinical practice and determine clinical benefit with routine prospective monitoring" (Knight, 2019).

Currently, there is no guidance from specialty medical societies addressing the clinical utility of cfDNA in monitoring kidney allografts for rejection.

The published peer-reviewed medical literature has not established cfDNA testing for detection of kidney allograft rejection as a proven method that materially improves net health outcomes nor has any benefit been established beyond currently available alternatives (e.g. serum creatinine testing).

Background/Overview

In 2019, approximately 37 million Americans reportedly had chronic kidney disease (CKD), with nearly 118,000 requiring initiation of treatment for kidney failure, also known as end stage renal disease (ESRD) (CDC, 2019). There was a steady rise in the rate of ESRD from 1980 to 2011, since then, the incident rate of ESRD has started to decline. As of December 2019, the Organ Procurement and Transplantation Network (OPTN) reported that there were about 95,000 Americans on the wait-list for kidney transplantation with approximately 21,000 kidney transplants performed in 2019 (OPTN, 2019). The total number of living kidney transplant recipients with a functioning graft is projected to surpass 250,000 in the next few years. The 1-, 3-, and 5-year survival rates for individuals receiving primary kidney transplants between 2008 and 2015 were 97.1%, 92.9% and 86.3%, respectively.

A kidney transplant involves the surgical removal of a diseased kidney and replacement with a healthy kidney from a deceased or living donor. Monitoring the health of the transplant is vital to the survival of both the transplant and the transplant recipient. The most widely accepted method for the surveillance of an

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allograft for rejection is monitoring of serum creatinine with confirmatory diagnosis achieved by histologic analysis of the allograft via needle biopsy, the current gold standard. Immunosuppressive drug therapy is adjusted according to transplant monitoring with the end-goal of preserving the allograft's function, hence delaying or preventing graft rejection (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2018).

Definitions

Allograft: The transplant of an organ or tissue from one individual to another of the same species with a different genotype; for example, a transplant from one person to another, but not an identical twin.

Chronic renal disease: The permanent loss of kidney function.

End stage renal disease: Persistent decline in renal function as documented by falling creatinine clearance in an individual diagnosed with a renal disease whose natural history is progression to renal impairment requiring renal replacement (dialysis or transplant).

Glomerular filtration rate (GFR): A test used to check how well the kidneys are functioning by estimating how much blood passes through the glomeruli each minute.

Glomeruli: A cluster of nerve endings, spores, or small blood vessels, in particular a cluster of capillaries around the end of a kidney tubule, where waste products are filtered from the blood.

Nephropathy: Refers to damage or disease of the kidney.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

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For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA Viracor TRAC™ dd-cfDNA, Viracor Eurofins, Viracor Eurofins
81479	Unlisted molecular pathology procedure [when specified as a dd-cfDNA test for kidney transplant rejection risk]
81599	Unlisted multianalyte assay with algorithmic analysis [when specified as a dd-cfDNA test for kidney transplant rejection risk]

ICD-10 Diagnosis	
T86.10-T86.19	Complications of kidney transplant
Z48.22	Encounter for aftercare following kidney transplant
Z94.0	Kidney transplant status

References

Peer Reviewed Publications:

1. Bloom RD, Bromberg JS, Poggio ED, et al. Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Active Rejection in Kidney Transplant Recipients (DART) Study Investigators. Cell-Free DNA and Active Rejection in Kidney Allografts. J Am Soc Nephrol. 2017; 28(7):2221-2232.
2. Garg N, Hidalgo LG, Aziz F, et al. Use of donor-derived cell-free DNA for assessment of allograft injury in kidney transplant recipients during the time of the coronavirus disease 2019 pandemic. Transplant Proc. 2020; 52(9):2592- 2595.
3. Gielis EM, Ledeganck KJ, Dendooven A, et al. The use of plasma donor-derived, cell-free DNA to monitor acute rejection after kidney transplantation. Nephrol Dial Transplant. 2020; 35(4):714-721.
4. Grskovic M, Hiller DJ, Eubank LA, et al. Validation of a clinical-grade assay to measure donor-derived cell-free DNA in solid organ transplant Recipients. J Mol Diagn. 2016; 18(6):890-902.
5. Jordan SC, Bunnapradist S, Bromberg JS, et al. Donor-derived cell-free DNA identifies antibody-mediated rejection in donor specific antibody positive kidney transplant recipients. Transplant Direct.

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2018. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6133406/. Accessed on November 29, 2020.

6. **Knight SR, Thorne A, Lo Faro ML. Donor-specific cell-free DNA as a biomarker in solid organ transplantation. A systematic review. Transplantation. 2019; 103(2):273-283.**
7. **Nolan N, Valdivieso K, Mani R, et al. Clinical and analytical validation of a novel urine-based test for the detection of allograft rejection in renal tansplant patients. J Clin Med. 2020. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7465561/. Accessed on November 29, 2020.**
8. **Oellerich M, Shipkova M, Asendorf T, et al. Absolute quantification of donor-derived cell-free DNA as a marker of rejection and graft injury in kidney transplantation: Results from a prospective observational study. Am J Transplant. 2019; 19(11):3087-3099.**
9. **Sigdel TK, Archila FA, Constantin T, et al. Optimizing detection of kidney transplant injury by assessment of donor-derived cell-free DNA via massively multiplex PCR. J Clin Med. 2018. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6352163/. Accessed on November 29, 2020.**
10. **Stites E, Kumar D, Olaitan O, at al. High levels of dd-cfDNA identify patients with TCMR 1A and borderline allograft rejection at elevated risk of graft injury. Am J Transplant. 2020; 20(9):2491-2498.**
11. **Watson D, Yang JYC, Sarwal RD, et al. A novel multi-biomarker assay for non-invasive quantitative monitoring of kidney injury. J Clin Med. 2019. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6517941/. Accessed in November 29, 2020.**
12. **Wijtvliet VPWM, Plaeke P, Abrams S, et al. Donor-derived cell-free dna as a biomarker for rejection after kidney transplantation: A systematic review and meta-analysis. Transpl Int. 2020 Sep 27. [Epub ahead of print].**
13. **Yang JYC, Sarwal RD, Sigdel TK, et al. A urine score for noninvasive accurate diagnosis and prediction of kidney transplant rejection. Sci Transl Med. 2020; 12(535):eaba2501.**

Government Agency, Medical Society, and Other Authoritative Publications:

1. **CareDx. Assessing AlloSure Dd-cfDNA Monitoring Insights of Renal Allografts With Longitudinal Surveillance (ADMIRAL). NLM Identifier: NCT04566055. Updated October 5, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04566055?term=cfdna&cond=Kidney+Transplant+Rejection&draw=2&rank=1. Accessed on November 29, 2020.**
2. **CareDx. Transition of Renal Patients Using AlloSure Into Community Kidney Care (TRACK). NLM Identifier: NCT04601155. Updated October 26, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04601155?term=cfdna&cond=Kidney+Transplant+Rejection&draw=2&rank=5. Accessed on November 29, 2020.**

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3. **CareDx. Evaluation of Patient Outcomes From the Kidney Allograft Outcomes AlloSure Registry (KOAR). NLM Identifier: NCT03326076. Updated October 23, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03326076?term=cfdna&cond=Kidney+Transplant+Rejection&draw=2&rank=7. Accessed on November 29, 2020.**
4. **Centers for Disease Control and Prevention. National chronic kidney disease fact sheet. Available at: https://www.cdc.gov/kidneydisease/pdf/2019_National-Chronic-Kidney-Disease-Fact-Sheet.pdf. Accessed on November 17, 2020.**
5. **Natera, Inc. Study for the Prediction of Active Rejection in Organs Using Donor-derived Cell-free DNA Detection (SPARO). NLM Identifier: NCT03984747. Last updated June 24, 2019. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03984747?term=cfdna&cond=Kidney+Transplant+Rejection&draw=2&rank=9. Accessed on November 29, 2020.**
6. **Natera, Inc. The PROspera Kidney Transplant ACTIVE Rejection Assessment Registry (ProActive). NLM Identifier: NCT04091984. Last updated September 16, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04091984?term=cfdna&cond=Kidney+Transplant+Rejection&draw=2&rank=6. Accessed on November 29, 2020.**
7. **National Institute of Diabetes and Digestive and Kidney Diseases. Kidney Transplant (NIDDK). Updated January 2018. Available at: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/kidney-transplant. Accessed on November 29, 2020.**
8. **Organ Procurement and Transplantation Network. Available at: http://optn.transplant.hrsa.gov/. Accessed on November 17, 2020.**

Websites for Additional Information

1. **American Society of Nephrology. Available at: https://www.asn-online.org/. Accessed on November 17, 2020.**
2. **United Network for Organ Sharing. Available at: http://www.unos.org/. Accessed on November 17, 2020.**

Index

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AlloSure

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QiSant
Propsera
Viracor TRAC™

Document History

Status	Date	Action
New	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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