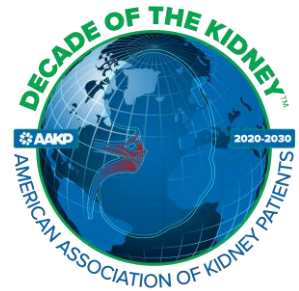




American Association of Kidney Patients
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AAKP CLOSER LOOK

MOLECULAR BLOOD TESTING & KIDNEY TRANSPLANT SURVEILLANCE:

UNEQUAL KIDNEY TRANSPLANT RECIPIENT ACCESS:
CMS MEDICAL ADMINISTRATIVE CONTRACTOR
PALMETTO GBA AND BLUECROSS BLUESHIELD OF SOUTH
CAROLINA

How a New Double Standard for Medicare Transplant Patients, Created Under the Auspices of HHS, CMS & a CMS Federal Contractor, Contradicts and Undermines the Biden Administration's Stated Commitments to Greater Transparency, Removal of Barriers and Improved Outcomes in Organ Transplantation

ISSUE OVERVIEW:

In March of 2023, Palmetto GBA, a Center for Medicare and Medicaid Services (CMS) Medical Administrative Contractor, which is paid with U.S. taxpayer funds, imposed significant **new restrictions** on Medicare coverage for critical molecular diagnostic blood testing for kidney transplant recipients.

These restrictions **changed** longstanding CMS/Medicare coverage policy (tests had been covered by Medicare for surveillance use for transplant recipients since 2017) and created **a new double standard and disparity** between Medicare kidney transplant recipients covered under new policies developed by Palmetto GBA for CMS and kidney transplant recipients commercially insured through Palmetto GBA's parent company, BlueCross BlueShield of South Carolina.

Molecular diagnostic bloods tests are highly valued by kidney transplant patients, and the doctors they choose to care for them, since these tests help detect organ rejection earlier, allowing transplant professionals greater time to respond while also avoiding the serious risks associated with invasive biopsies including infection, excessive bleeding, organ damage, or death. **Kidney transplant recipients welcomed non-invasive blood tests as an innovation and as a critical tool transplant professionals utilize to maintain their kidney transplants and avoid organ loss, which has devastating consequences such as a return to dialysis, the organ waiting list, or premature death.**

KEY FACTS:

- Palmetto GBA is the Medicare Administrative Contractor responsible for the “MolDX” program, which develops coverage policies for molecular diagnostic testing for Medicare beneficiaries, including kidney transplant recipients.
- BlueCross BlueShield of South Carolina owns Palmetto GBA, as part of a group of subsidiaries called the “Celerian Group” of companies.
- Palmetto’s nine-member Board is dominated by BCBS South Carolina business executives including Mr. Mike Mizeur, CEO of BCBS South Carolina, Mr. David Pankau, Chair of BCBS Board and former CEO of BCBS South Carolina, and Ms. Lori Hair, EVP, CFO, and Treasurer of BCBS South Carolina.
- Despite the common ownership and board personnel, BCBS South Carolina and the Palmetto MolDX program **have diverged** both in their coverage of critical diagnostic testing and their consideration of kidney transplant recipients.
- In March 2023, Palmetto and its MolDX program **imposed new coverage restrictions** reducing access to this testing for **Medicare patients**. This decision departed dramatically from **historic Medicare coverage and from BCBS South Carolina’s own policy for their commercially insured patients. This created a double standard and disparity among kidney transplant recipients.**

- In March of 2023, the MolDX program issued a “Billing Article” that **imposed substantial new coverage restrictions** on non-invasive donor derived cell-free DNA testing to detect organ rejection, which included **limiting coverage of routine, surveillance testing for Medicare kidney transplant recipients to otherwise receive an invasive biopsy.** MolDX issued a new proposed formal coverage policy in August 2023 nearly identical to the “Billing Article.”
- The Billing Article and proposed coverage policy **impose significant restrictions in coverage for Medicare kidney transplant recipients.** Routine surveillance with cell-free DNA testing can help detect the early stages of rejection before clinical signs or symptoms are evident. Many clinicians do not utilize biopsies on a routine, surveillance basis because of their invasive nature and other limitations.
- Yet, in contrast, on November 6, 2023, BCBS South Carolina published a medical policy update that **reaffirmed** coverage of donor-derived cell-free DNA **as medically necessary testing monthly** during the first four months of the kidney transplant and four times per year thereafter - **with none of the restrictions tying coverage to whether a biopsy would be performed.**

COVERED DONOR-DERIVED CELL-FREE DNA TESTS FOR ORGAN TRANSPLANT REJECTION FOR ROUTINE, SURVEILLANCE TESTING		
	Months 1-4 Post Transplant	Greater than 6 Months Post Transplant
U.S. Medicare Beneficiaries - prior to March 2023	Covered	Covered
U.S. Medicare Beneficiaries - after March 2023 (where not tied to biopsy use)	Not covered	Not covered
BCBS South Carolina Medical Policy - updated coverage, published November 2023	Covered - 4 Tests During Period <u>No Requirement for Biopsy</u>	Covered - 4 Tests Annually <u>No Requirement for Biopsy</u>

QUESTIONS YET TO BE ANSWERED BY HHS & CMS:

1.) How does the March 2023 change in Medicare coverage policy for molecular blood testing for kidney transplant surveillance and the new double standard for Medicare patients, initiated by Palmetto, GBA, honor the stated commitments to kidney patients and organ donors made by the President Joe Biden, HHS Secretary Xavier Becerra, and a bipartisan majority of the U.S. Congress to improve the U.S. transplant system and transplant outcomes?

2.) How is the March 2023 policy change in Medicare coverage policy for molecular blood testing for kidney transplant surveillance and the new double standard for Medicare patients consistent with key bipartisan achievements in kidney care/transplant policy made over the past decade under Presidents Obama, Trump, and Biden as well as multiple Congresses?

3.) When will HHS and CMS act on the serious concerns already raised by impacted stakeholders - including kidney transplant recipients, patients on the waiting list, organ donors, transplant professional, the Congressional Kidney Caucus, and the Congressional Black Caucus - and move rescind the March 2023 policy change promulgated by Palmetto, GBA and restore molecular blood test access exactly to CMS's 2021 policy, thereby eliminating the new double standard for Medicare transplant recipients?

BIDEN ADMINISTRATION ON THE RECORD: COMMITMENTS IMPACTING KIDNEY TRANSPLANT RECIPIENTS, OFFICIAL STATEMENTS, & SOURCES: 2021 - 2023

Commitment – President Biden Executive Order 13985, January 20, 2021: *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*

“Our country faces converging economic, health, and climate crises that have exposed and exacerbated inequities, while a historic movement for justice has highlighted the unbearable human costs of systemic racism. Our Nation deserves an ambitious whole-of-government equity agenda that matches the scale of the opportunities and challenges that we face.”

“Consistent with these aims, each agency must assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.”

Commitment – President Biden, Executive Order 14091, February 16, 2023: *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*

This order builds upon my previous equity-related Executive Orders by extending and strengthening equity-advancing requirements for agencies, and it positions agencies to deliver better outcomes for the American people. In doing so, the Federal Government shall continue to pursue ambitious goals to build a strong, fair, and inclusive workforce and economy; invest in communities where Federal policies have historically impeded equal opportunity—both rural and urban—in ways that advance equity in health, including mental and behavioral health and well-being;

Commitment – President Biden, Proclamation on Donate Life Month, March 31, 2021

“Current statistics show that Americans belonging to minority groups make up nearly 60 percent of those waiting for an organ transplant. Although a transplant can be successful regardless of the race or ethnicity of the donor and recipient, there is a greater chance of longer-term survival for the recipient if the genetic background of the donor and recipient are closely matched. Americans from every community are needed to help make a life-saving difference.”

Commitment – President Biden, Proclamation on Donate Life Month, March 31, 2022:

“Waitlist data shows that people of color make up nearly 60 percent of individuals awaiting an organ transplant. To increase access to transplantation for everyone, we recommit to promoting greater diversity in organ donation, as we continue to advance health equity for all communities, including those that have gone underserved, across our Nation.”

“While transplantation continues to increase substantially and meet the needs of many people with organ failure, we must continue our efforts to shorten the waiting list and encourage organ donation.”

Commitment – President Biden Proclamation on Donate Life Month, March 31, 2023:

“My Administration is working across the board to support organ donation and to make sure living donors and recipients have the affordable health care and prescription drug coverage they need before and after a transplant and throughout their lives.”

“We are committed to a modernized OPTN that is transparent, accountable, and equitable.”

Commitment – HHS Secretary Becerra and CMS Administrator Chiquita Brooks-LaSure: CMS Blog, Organ Transplantation Affinity Group (OTAG): Strengthening Accountability, Equity, and Performance, September 15, 2023:

“Improving the organ transplantation system is a priority for the Biden-Harris Administration. In 2021, the Department of Health and Human Services Secretary Becerra established a coordinated effort to improve organ donation, procurement, and transplantation. Led by the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA), this collaborative seeks to drive improvements in donations, clinical outcomes, system improvement, quality measurement, transparency, and regulatory oversight. The organ transplantation system consists of... Most importantly, people in need of a transplant, their families and caregivers, and living and deceased donors.”

REFERENCES:

1. The MolDX program, administered by Palmetto GBA, develops coverage policy for molecular diagnostic testing, such as blood tests, for Medicare patients (including kidney transplant recipients), is run by Palmetto GBA (“Palmetto”). <https://www.palmettogba.com/molDX>.
2. Palmetto GBA is a subsidiary of BlueCross BlueShield of South Carolina (“BCBS”). It is part of a group of BCBS subsidiaries that BCBS publicly refers to as “The Celerian Group” that specialize in serving federal and state health care programs. <https://www.celeriangroup.com/>.
3. Palmetto GBA Board of Directors: <https://corporate.palmettogba.com/about/board-of-directors/>.
 - a. Board Chair, Mr. Mike Mizeur - President/CEO of BCBS South Carolina
 - b. Other Board Members include:

- i. Mr. David Pankau - Chair of BCBS Board and former CEO of BCBS South Carolina
 - ii. Mr. Bruce Hughes – Described publicly on the Palmetto website as President & COO of The Celerian Group, and listed on LinkedIn as President, Government Programs at BCBS. <https://www.linkedin.com/in/bruce-hughes-937a6b20/>. Another Celerian Group Company, CGS, lists Mr. Hughes as President, Government Services Division of BCBS. <https://www.cgsadmin.com/about/board-of-directors/>.
 - iii. Ms. Lori Hair - EVP, CFO, and Treasurer of BCBS.
4. BlueCross BlueShield of South Carolina’s Medical Policy, Transplant Rejection Testing, CAM 329: Transplant Rejection Testing, November 6, 2023. Relevant excerpts include:

“This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross Blue Shield Association technology assessment program (TEC) and other nonaffiliated technology evaluation centers, reference to federal regulations, other plan medical policies and accredited national guidelines.”

“For single-kidney transplant recipients who are 18 years of age and who are at least 14 days post-transplant, the use of donor-derived cell-free DNA tests (e.g. Allosure) to assess the probability of allograft rejection is considered **MEDICALLY NECESSARY** at the following frequency:

 - a. Once per month for individuals who are 1-4 months post-transplant.
 - b. Every 3 months for individuals who are greater than 6 months post-transplant.”

Source: South Carolina Blues, external policies, transplant rejection testing, 2023

Our Family of Companies

Affiliates licensed with the Blue Cross and Blue Shield Association

[BlueChoice HealthPlan](#)

Our health maintenance organization (HMO), the first in South Carolina. It also offers [Healthy Blue](#)SM, our S.C Healthy Connections (Medicaid) health plan.

[BlueCross BlueShield of South Carolina Foundation](#)

Funds projects that directly benefit South Carolina's most vulnerable populations.

Affiliates Not Licensed with the Blue Cross and Blue Shield Association

[Companion Benefit Alternatives](#)

Behavioral health benefits administrator for employer groups

[Companion Life](#)

Employee benefits specialist, marketing life, disability and dental insurance programs.

[Celerian Group](#)

Specialists in the diverse needs of state and federal government programs. Companies include:

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Administrative services for healthcare programs and stakeholders.

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Secure systems development and managed hosting/outsourcing services; enterprise content and business process management.

[JBS International](#)

Research, evaluation, communications, information and management consulting in the health care, social services and education sectors.

[Karna](#)

Health-related consulting services and support to Federal agencies in the areas of science, research, technology, lab, communications and management consulting.

[Palmetto GBA](#)

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[PGBA, LLC](#)

Fiscal intermediary and management information services for government programs and other large entities.

[Planned Administrators, Inc. \(PAI\)](#)

Third party administrator (TPA) for self-funded plans, limited benefits and other consumer benefits.

[TCC of South Carolina](#)

Full-service third party administrator of fully insured and self-funded group health insurance.

Source: <https://www.southcarolinablues.com/web/public/brands/sc/about-us/family-of-companies/>