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Kidney Patients Target Medicare Transplant Double Standard

***Biden Administration Commitment to Improve Organ Transplantation
Contradicted and Undermined by Medicare Contractor and
Leadership Failures at CMS and HHS***

Medicare Kidney Transplant Recipients Endure Unequal Treatment

Washington, D.C.: Today, the American Association of Kidney Patients (AAKP), the largest and oldest kidney patient organization in the nation, issued an **Official Statement** (appears below) and an [AAKP Closer Look](#) report highlighting **a new, double standard and unequal access** for Medicare kidney transplant recipients who rely upon molecular blood tests for organ health surveillance and the identification of early organ rejection. Kidney disease and kidney failure disproportionately impact minority Americans. Federal data consistently demonstrates that, among historically disadvantaged communities, there are tremendous barriers and lack of opportunity to receive a kidney transplant and furthermore, re-transplantation when a donor organ fails.

AAKP has a 50-year history of fighting for greater patient care choice, full access to care innovations, and disability rights. Since 2018, AAKP has conducted the largest national voter registration and mobilization initiative in the kidney space, titled [KidneyVoters™](#). The effort engages patients, organ transplant recipients, families and loved ones, allied medical professionals, researchers, and medical industry employees on critical issues impacting the kidney health and patient outcomes and mobilizes them to raise their voices to policymakers and hold elected leaders accountable.

The AAKP Official Statement and Closer Look report focus on new policy changes and major access restrictions imposed on Medicare transplant recipients in March 2023 by Palmetto GBA, a Medicare Administrative Contractor headquartered in South Carolina; the Centers for Medicare and Medicaid Services (CMS); and the U.S.

Department of Health and Human Services (HHS). The new restrictions severely limit Medicare patients and transplant professionals from accessing molecular blood tests, covered by Medicare and utilized since 2017. The tests detect early organ rejection, allow greater time for intervention, and help patients avoid risky, invasive tissue biopsies. AAKP and transplant experts have alerted Congress and the media that more than 28,000 fewer surveillance tests for Medicare kidney transplant recipients were obtained in the nine months following the new restrictions in coverage than in the nine months preceding the coverage restrictions.

As Palmetto GBA, CMS, and HHS imposed new restrictions on Medicare kidney transplant recipients, BlueCross BlueShield of South Carolina, the company that owns Palmetto GBA, continued full coverage for the same molecular blood surveillance tests for their paying beneficiaries with kidney transplants. AAKP believes this new double standard contradicts and undermines the stated commitments of President Biden and the Biden Administration to improve transparency, remove barriers, and improve health outcomes in organ transplantation, especially for people of color and historically underserved communities.

AAKP believes all organ transplants should be highly valued and equally protected and that all transplant recipients, including those on Medicare, should have equal access to surveillance blood testing and timely interventions to save their donor organ when medically necessary. AAKP has called upon HHS and CMS leaders to immediately rescind the March 2023 policy changes made by Palmetto GBA and to restore prior coverage for molecular blood tests for Medicare kidney transplant recipients. Further, AAKP has also called for a halt to any ongoing efforts by Palmetto GBA and CMS to ratify the unnecessary and fact-free March 2023 decision into any new policy or Local Coverage Determination (LCD) that would continue to disrupt care access and coverage for Medicare transplant recipients and the transplant professionals who are committed to their long-term transplant outcomes.

Palmetto GBA and top appointed leaders at CMS and HHS have drawn fierce backlash from kidney patients, transplant recipients, organ donors and donor families, transplant professional organizations, including the American Society of Transplant Surgeons (ASTS [October letter](#) and [March letter](#)) and the American Society of Transplantation (AST [April letter](#)), religious leaders, multiple broad-based community coalitions including the Health Equity in Transplantation Coalition ([HEITC](#)), led by transplant recipient and recording artist Al B. Sure!, and national policy experts including [former U.S. House Speaker Newt Gingrich](#), whose family has been impacted by organ failure and transplantation.

A growing bipartisan coalition of U.S. Congressional leaders has called on HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure to explain the actions of Palmetto GBA and defend their own inaction in addressing the negative repercussions among impacted kidney transplant patients and transplant professionals. Leaders including Representative Steven Horsford, Chair of the Congressional Black

Caucus ([Congressional Black Caucus](#)), Representative Michael Burgess, and Representative Anna Eshoo ([Burgess-Eschoo letter](#)), as well as Representative Larry Bucshon, Co-Chair of the Congressional Kidney Caucus and over a dozen other [Congressional leaders](#) have pushed HHS and CMS officials for transparency and any data that supported the March 2023 Palmetto GBA action.

National media, including [USA TODAY](#), [Real Clear Politics](#), and the Wall Street Journal have paid close attention to the controversy and the voices of negatively impacted Medicare transplant recipients. The Wall Street Journal has published three editorials (read the [September 10 editorial](#), [September 22 editorial](#), and [September 26 editorial](#)) on the issue.

OFFICIAL AAKP STATEMENT

"In March 2023, during the nation's annual National Kidney Month, kidney transplant recipients on Medicare were subjected to major new restrictions in their access to the critical molecular blood tests they have depended on since 2017 for organ health and surveillance for possible early rejection indicators. These tests are highly regarded by transplant recipients and the transplant professionals caring for them. They constitute a critical innovation able to detect early and often asymptomatic organ rejection before any previously available tests, thus providing an earlier diagnosis of organ injury and critical lead time for intervention. A normal test result is also important for patients because that can allow avoidance of unnecessary, invasive tissue biopsies and the attendant risks associated with these biopsies, including infection, excessive bleeding, organ damage, or even death.

The new restrictions were initiated by Palmetto GBA, a federal Medicare Administrative Contractor paid with U.S. taxpayer funds and working under the auspices of the Center for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services (HHS). The restrictions were announced on March 2, 2023, in a published notice called a "Coverage Article," without prior public notice and without precedent because it directly contradicted existing CMS coverage policy by ***suddenly tying*** surveillance blood test access to invasive, risky, and expensive surgical biopsies. The ***tie*** to biopsies directly contradicted language in the 2021 Medicare announced policy, which specifically said Medicare coverage of surveillance blood tests ***was not tied*** to biopsies.

Because of the new coverage restrictions, more than 28,000 fewer surveillance tests for Medicare kidney transplant recipients were obtained in the nine months following the coverage change in March 2023 than in the nine months preceding the coverage restriction by Palmetto GBA. These negative consequences were effectuated by a private company contractor without legal authority to do so and the failure of CMS and HHS officials to protect the long-term interests of Medicare patients. This negative Government Determinant of Health (GoDH) action has significantly and adversely impacted transplant patients, caused great anxiety and

concern among innocent kidney patients and their families, and is contrary to the best interests of American taxpayers.

Yet, for unclear reasons, in September 2023, CMS not only publicly defended Palmetto GBA in a press statement, but it also parroted the contractor's erroneous claims that there were "no changes" in Medicare policy or patient access to the tests. The claims of "no changes" in the CMS press statement were directly contradicted by existing Medicare coverage for the blood testing, as stated in the 2021 official CMS coverage policy, which indicated no link to a biopsy was necessary to receive Medicare coverage of these molecular blood tests. CMS repeated similar inaccurate claims to a bipartisan coalition of concerned Congressional leaders who were demanding clear answers on behalf of impacted Medicare kidney transplant constituents. Once again, CMS never referred to the existing 2021 CMS policy that specifically stated there were no ties to biopsies needed in order to obtain Medicare coverage for these vital, non-invasive blood tests. CMS and Palmetto GBA have yet to provide any data to Congress or the public to adequately justify the original basis of their decision. HHS, CMS, and Palmetto GBA continue to ignore the basic principles of public transparency and accountability.

The American Association of Kidney Patients (AAKP), the largest kidney patient organization in the nation, believes statements made by CMS and Palmetto GBA have been repeatedly disingenuous, intentionally misleading, and shockingly callous toward kidney transplant recipients on Medicare, their families, and the courageous organ donors providing the gift of life.

Meanwhile, the company that owns Palmetto GBA—BlueCross BlueShield of South Carolina—continued to provide its own kidney transplant beneficiaries within South Carolina full access to these same molecular blood tests without ties to a biopsy. The onerous restrictions Palmetto GBA, CMS, and HHS imposed on Medicare kidney transplant recipients were not applied to private BlueCross BlueShield beneficiaries. It is absolutely clear this is a new double standard for Medicare transplant recipients. If you are a BlueCross BlueShield beneficiary, your insurance covers non-invasive blood tests to detect early organ transplant rejection. But if you are a Medicare transplant recipient, you must first demonstrate the need for an invasive and risky biopsy before potentially gaining access to the tests, defeating the purpose of surveillance testing and the benefits of early rejection detection and timely intervention. Today, Medicare patients with a kidney transplant in South Carolina and across the nation face the new reality of unequal treatment to protect their precious gifts of life. This is in addition to barriers that already exist, well known to CMS and HHS leaders, among historically disadvantaged communities in need of greater access to kidney transplantation and re-transplantation when transplanted organs fail.

AAKP believes the March 2023 action of Palmetto GBA must be immediately rescinded and prior coverage for molecular blood tests for kidney transplant patients must be fully restored. Further, the ongoing effort by Palmetto GBA to ratify its unnecessary and fact-free March 2023 actions in new policy or a Local Coverage Determination (LCD) must be halted.

The failure of HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure to listen to impacted transplant patients, show empathy and respect for their legitimate concerns, and respond to the oversight demands of Congress is inexplicable and unacceptable. They have ignored the distress and angst patients have communicated in multiple public meetings and before Congress and they have diminished the significance of bipartisan inquiries from leaders of both the Congressional Black Caucus and the Congressional Kidney Caucus. Their failed leadership has empowered unelected, unaccountable, and faceless for-profit contractors to make life and death decisions that negatively impact kidney transplant patients on Medicare.

Worse, their unresponsiveness as the new double standard in kidney transplant health was developed on their watch has undermined the clearly stated and repeated commitments of President Biden to better serve all people suffering from kidney failure and in need of a life-saving transplant, including people of color and underserved communities. President Biden, like his predecessors, has been clear to the kidney community in his commitments to improve kidney health, remove barriers to transplantation, and improve transplant outcomes. The time is now for his team of HHS political appointees to follow his direction and execute his policy directives, lest they ring hollow.

Until that occurs, AAKP will view forthcoming Biden Administration announcements on kidney health and kidney transplantation with serious reservations. Reducing the kidney transplant waiting list is a shared national goal, and a key part of that effort is to make certain all current kidney transplant recipients have an equal opportunity to maintain their transplanted organs, which requires fair and equal access to surveillance blood testing. Efforts to encourage greater kidney transplantation that fall short of the moral imperative and established standard of helping patients protect transplanted organs is a step backward for American health policy. **AAKP will continue to educate all Medicare patients at the community, state, and national level on this issue, encourage them to register to vote, and to hold their elected leaders fully accountable.**”

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Since 1969, The American Association of Kidney Patients has been a patient-led organization driving policy discussions on kidney patient care choice and medical innovation. Over the past decade, AAKP patient advocates have helped advance lifetime transplant drug coverage for kidney transplant recipients (2020); the presidential Executive Order on Advancing American Kidney Health (2019); new job protections for living organ donors under the Family Medical Leave Act (FMLA) via the U.S. Department of Labor (2018); and Congressional legislation allowing HIV-positive organ transplants for HIV-positive patients (2013). Follow AAKP on social media at [@kidneypatient](#) on Facebook, [@kidneypatients](#) on X, and [@kidneypatients](#) on Instagram, and visit www.aakp.org for more information.