



October 7, 2026

Re: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway (CMS-3487-NC), 91 FR 51710

Dear Administrator Oz,

The National Kidney Foundation is pleased to submit comments on the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway. We support CMS's goal of accelerating Medicare beneficiary access to breakthrough medical devices and offer the comments below.

Summary Comments:

- NKF supports the RAPID coverage pathway's goal of aligning Medicare coverage timelines with FDA market authorization for breakthrough devices. We appreciate CMS for specifically recognizing that beneficiaries with end-stage renal disease are among the Medicare subpopulations most likely to be underrepresented in pivotal device trials.
- NKF urges CMS to establish an accelerated pathway for Breakthrough-designated in vitro diagnostics (IVDs) rather than excluding them from RAPID entirely.
- NKF urges CMS to ensure that outcome measures required under RAPID meaningfully capture the experience of medically complex and historically underrepresented Medicare populations.
- NKF urges CMS to ensure that any evidence development requirements imposed under RAPID are not onerous for smaller, earlier-stage manufacturers, consistent with current regulations.

A. The RAPID Coverage Pathway Is a Meaningful Opportunity to Accelerate Patient Access

In the past, delays between FDA market authorization and Medicare coverage have slowed patient access to innovations relevant to kidney disease, including home dialysis technology, vascular access devices, and other emerging renal replacement and monitoring devices. NKF commends CMS for explicitly recognizing that individuals with end-stage renal disease, alongside older beneficiaries and people with disabilities, are among the Medicare subpopulations most likely to be underrepresented in pivotal device trials. We support the pathway's aim of building Medicare-relevant, patient-centered outcome measures into Investigational Device Exemption (IDE) study design from the earliest stages of device development. NKF requests clarification regarding how the requirement that devices be separately payable would apply to kidney technologies furnished under the ESRD Prospective Payment System. CMS should identify opportunities to accelerate beneficiary access to otherwise eligible technologies that may fall outside RAPID because of this requirement.

B. In Vitro Diagnostics Should Have an Accelerated Pathway of Their Own

NKF is concerned that in vitro diagnostics, including Breakthrough-designated diagnostic and biomarker tests, are excluded from RAPID and left to review by Medicare Administrative Contractors (MACs). Much of the innovation in chronic kidney disease is in the diagnostic space, including tools for early detection and risk stratification. These technologies carry the same urgency for Medicare beneficiaries as



therapeutic devices. NKF urges CMS to establish an accelerated pathway for Breakthrough-designated IVDs relevant to chronic disease populations, including kidney disease, rather than routing them exclusively through existing MAC processes.

C. Outcome Measures Should Reflect the Needs of Medically Complex and Underrepresented Populations

NKF supports requiring IDE protocols for devices intended for use in patients with chronic conditions, including kidney disease, evaluate outcomes that are genuinely relevant to that population. They should not rely solely on general Medicare population outcomes that may not capture condition-specific risks and benefits. CMS and FDA should make sure that the outcome measures agreed upon with manufacturers reflect meaningful, patient-centered measures for the populations most affected by the device under review and should consult clinician and patient stakeholder organizations when identifying these measures.

D. Evidence Development Requirements Should Not Be Onerous for Smaller Device Sponsors

Many manufacturers developing devices relevant to chronic kidney disease, including home dialysis and renal replacement technologies, are early-stage companies with more limited resources than sponsors in higher-volume device categories. NKF urges CMS to ensure that any Coverage with Evidence Development requirements imposed under RAPID are not onerous for smaller manufacturers, consistent with current regulations and CMS's stated commitment to minimize burden, so that evidence development does not become a barrier to participation for smaller innovators serving patients with kidney disease and other chronic conditions.

In summary, the National Kidney Foundation (NKF) appreciates CMS's efforts to modernize Medicare's device coverage processes and accelerate beneficiary access to breakthrough technology. We look forward to working with CMS to ensure that beneficiaries with kidney disease and other chronic conditions fully benefit from the RAPID coverage pathway, and we welcome the opportunity to provide additional information or expertise as CMS finalizes this process.

Sincerely,

Dr. Jesse Roach, MD
Senior Vice President, Government Relations
The National Kidney Foundation