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KidneyIntelX and KidneyIntelX.dkd Testing

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

KidneyIntelX or KidneyIntelX.dkd testing **may be considered medically necessary** when **ALL** the following criteria are met:

- Performed once per lifetime; AND
- Results are used to facilitate therapeutic prognostic decision-making in the medical management of a selected patient population; AND
- Results are used to assess the risk of progressive decline (See Policy Guidelines) in kidney function in patients >21 years of age with:
  - Type 2 diabetes (T2D) and existing early-stage chronic kidney disease (CKD) (stages 1-3b); and
  - Test is ordered by the treating physician or qualified non-physician practitioner; and
  - Test is performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory qualified to perform high complexity testing; and
  - Specific reason for test must be documented by the treating practitioner in the medical documentation and demonstrate that the test is medically reasonable and necessary.

KidneyIntelX or KidneyIntelX.dkd testing **is considered not medically necessary** for:

- Patients with estimated glomerular filtration rate (eGFR) <30;
- Patients with eGFR ≥60 ml/min/1.73 m^2 without albuminuria;
- Patients with end-stage renal disease (ESRD) or on renal recovery treatments;
- Patients who are pregnant;
- Patients who are currently hospitalized;
- Patients taking etanercept;
- When performed as a screening or standalone diagnostic.

Policy Guidelines

Kidney function decline is defined as:

- A decline in estimated glomerular filtration rate (eGFR) slope of ≥ 5 ml/min/1.73 m^2/year; or
- A sustained decrease in eGFR ≥40% confirmed at least 3 months apart; or
- Kidney failure, defined by sustained eGFR <15.

Description

Kidney disease affects over 850 million people globally. In the United States (U.S.) alone, over 40 million people are identified as having chronic kidney disease (CKD). Approximately 50 percent of individuals with advanced (Stage IV) kidney disease are unaware of the severity of their reduced kidney function. Therefore, many individuals progress to kidney failure in an unplanned manner requiring dialysis without previously seeing a nephrologist. (2) The most common causes of CKD in adults are diabetes and high blood pressure. Other risk factors include heart disease, obesity, a family history of CKD, inherited kidney disorders, past damage to the kidneys, and older age. (3)

CKD is defined by the Kidney Disease Improving Global Outcomes (KDIGO) organization as abnormalities of kidney structure or function, present for > 3 months. (4) In the KDIGO Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease, factors associated with CKD progression to inform prognosis include the etiology of CKD (e.g., diabetes, hypertension, etc.), level of glomerular filtration rate (GFR), level of albuminuria, age, sex, race/ethnicity, elevated blood pressure, hyperglycemia, dyslipidemia, smoking, obesity, history of cardiovascular disease and ongoing exposure to nephrotoxic agents (ungraded recommendation). A standardized system for integrating sociodemographic risk factors with clinically relevant biomarkers to accurately identify those most at risk for progression is not yet available in most practice settings, potentially hampering clinicians' timely intervention in CKD management. Recently, the use of machine learning approaches that can combine biomarkers and electronic health record data to produce prognostic risk scores have been explored. One such approach is the KidneyIntelX proprietary artificial intelligence-enabled algorithm which combines blood-based biomarkers, genetics and personalized data from electronic health records to generate a unique risk score which is then used to develop a prediction of progressive kidney function decline in diabetes-related CKD.

Health disparities in patients with CKD and diabetes are significant and multifaceted. Studies consistently reveal disproportionate prevalence among minority populations, emphasizing the intersectionality of factors like race, socioeconomic status, and access to healthcare. (5) These disparities manifest in higher rates of CKD and diabetes, delayed diagnosis, and increased complications. Studies have found that kidney disease disproportionately affects communities of color. Black or African Americans are almost four times more likely, and Hispanics or Latinos are 1.3 times more likely to have kidney failure compared to White Americans. Although they make up only 13.5% of the population, Black or African Americans make up more than 35% of dialysis patients.

Regulatory Status

In June 2023, the United States (U.S.) Food and Drug Administration (FDA) approved KidneyIntelX™ (RenalytixAI) as a class II device under the DeNovo classification for in-vitro diagnostic use. (6) This prognostic test uses an algorithm to combine clinical variables (blood urea nitrogen [BUN], hemoglobin A1c [HbA1c], and urine albumin creatinine ratio [uACR]) and the quantitative measurements of tumor necrosis factor receptor-1 (TNFR-1), tumor necrosis factor receptor-2 (TNFR-2) and kidney injury molecule-1 (KIM-1) in human plasma employing a Meso Sector S 600 electrochemiluminescence immunoassay. It is indicated for use to aid in the assessment of the risk of progressive decline in kidney function (sustained decrease in estimated glomerular filtration rate (eGFR) greater than or equal to 40% lasting more than 3 months) within a period of up to 5 years following KidneyIntelX.dkd level measurement in adult patients with type 2 diabetes and existing CKD (defined for the purposes of this device as patients with an eGFR rate of 30-59 ml/min/1.73m² or eGFR ≥ 60 ml/min/1.73m² with uACR ≥ 30 mg/g). KidneyIntelX.dkd is not intended for screening or as a stand-alone diagnostic test.

Product Code: QWZ

Rationale

This policy is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services specific to KidneyIntelX or KidneyIntelX.dkd testing.

Centers for Medicare and Medicaid Services (CMS)

While Medicare does not currently have a national coverage determination (NCD) on KidneyIntelX or KidneyIntelX.dkd testing, a local coverage determination (LCD) (L39726) was released in 2024. (1) The LCD allows for once in a lifetime KidneyIntelX or KidneyIntelX.dkd testing under the following circumstances:

- "The results are used to facilitate therapeutic prognostic decision-making in the medical management of a selected patient population, and
- The results are used to assess the risk of progressive decline in kidney function in patients over the age of 21 years of age with:
    - Type 2 diabetes (T2D) and existing early-stage chronic kidney disease (CKD) (stages 1-3b), and

- The test is ordered by the treating physician or qualified non-physician practitioner, and
- The test is performed in a CLIA [Clinical Laboratory Improvement Amendments] certified laboratory qualified to perform high complexity testing, and
- The specific reason for the test must be documented by the treating practitioner in the medical documentation and demonstrate that the test is medically reasonable and necessary.

Note: Kidney function decline is defined as:
- a decline in eGFR [estimated glomerular filtration rate] slope of ≥ 5 ml/min/1.73 m^2/year; or
- a sustained decrease in eGFR ≥40% confirmed at least 3 months apart; or
- kidney failure, defined by sustained eGFR <15."

Additionally, the following limitations of coverage were included:
- "KidneyIntelX or KidneyIntelX.dkd test is not medically reasonable and necessary for:
  - Patients with eGFR <30
  - Patients with eGFR ≥60 ml/min/1.73 m^2 without albuminuria
  - Patients with ESRD [end-stage renal disease] or on renal recovery treatments
  - Patients who are pregnant
  - Patients who are currently hospitalized
  - Patients taking Etanercept
- KidneyIntelX or KidneyIntelX.dkd is not covered as a screening or standalone diagnostic."

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0105U, 0407U
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

References

Local Coverage Determination:

1. Centers for Medicare and Medicaid Services. Local Coverage Determination for KidneyIntelX and KidneyIntelX.dkd Testing (L39726) (August 1, 2024). Available at: <https://www.cms.gov> (accessed January 13, 2026).

Other:
2. FDA- FDA grants breakthrough device designation to KidneyIntelX™. May 2, 2019. Available at: <https://prnewswire.com> (accessed January 21, 2026).
3. Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States. 2023. U.S. Department of Health and Human Services. Available at: <https://cdc.gov> (accessed January 21, 2026).
4. Stevens PE, Levin A. KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. Apr 2024. Available at: <https://kdigo.org> (accessed January 13, 2026).
5. National Kidney Foundation Health Disparities. Available at: <https://www.kidney.org> (accessed January 13, 2026).
6. FDA – KidneyIntelX.dkd Summary of Safety and Effectiveness. DEN200052. Food and Drug Administration De Novo Notification Database. Jun 29, 2023. Available at: <https://www.accessdata.fda.gov> (accessed January 13, 2026).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
04/01/2026	Document updated. Coverage unchanged. Removed references 7-15.
10/15/2025	Document updated. Coverage criteria revised to be consistent with coverage guidance from the Centers from Medicare and Medicaid Services. Added references 1, 5, 8, 10-12, and 14-15. Title changed from: “Machine Learning Derived Probability Score for Rapid Kidney Function Decline”.
10/01/2024	New medical document. Use of a machine learning derived probability score (e.g., KidneyIntelX) to predict rapid kidney function decline is considered experimental, investigational and/or unproven for all indications, including but not limited to individuals with chronic kidney disease (CKD).