

Acute Kidney Injury Payment System (AKI PS) Claims-Based Monitoring Program

Overview of 2017 – 2023 Claims-Based Monitoring Program

Acute Kidney Injury (AKI) is a syndrome characterized a sudden decrease in kidney function and encompasses both structural damage to the kidneys and loss of kidney function. It is a discrete clinical entity from chronic kidney disease, but rarely has a single etiology. It often occurs in hospitalized patients in the presence of one or more physiologic complications, including sepsis, ischemia, and nephrotoxicity, however it also occurs among patients without critical illness.

To promote the recovery of kidney function and prevent the transition to End-Stage Renal Disease (ESRD) for patients with AKI, beginning January 1, 2017, kidney dialysis facilities were authorized to furnish dialysis services to AKI patients with Medicare coverage. Under this provision, Medicare established the AKI Payment System (AKI PS), which pays ESRD facilities for outpatient dialysis treatment for AKI patients (AKI-D) using the ESRD Prospective Payment System (PPS) base rate adjusted by the wage index.

This document, paired with the accompanying workbook, describes the utilization of items and services covered by the AKI PS, as well as selected health outcomes for the AKI-D population. Measures include mortality, AKI-specific health outcomes (e.g., developing ESRD and recovery of kidney function), major health events (e.g., stroke, acute myocardial infarction [AMI], and heart failure), and healthcare utilization (e.g., hospitalization, utilization of dialysis-related drug treatments).

To describe key trends in these measures as they were observed in the AKI-D population over time, patients starting AKI-D within the same month are grouped into a single cohort. For each measure, results are displayed at the monthly cohort level from January 2017 through December 2023. To identify health disparities, measures reported are also stratified by selected patient characteristics, including Medicare & Medicaid dual eligibility status, race/ethnicity, and the age when starting the outpatient dialysis treatments for AKI.

Introduction

Data Sources and Study Overview

Data Types: Medicare Part A and Part B Claims (CWF); Medicare Part D Claims (PDT); Medicare Enrollment Data (EDB); Common Medicare Environment (CME)

CWF Data Processed Through: 6/28/2024

PDT Data Processed Through: 7/26/2024

Beneficiary Enrollment Through: 6/30/2024

Results Presented Period: AKI-D starting between 1/1/2017 to 12/31/2023

Purpose: To summarize health outcomes and healthcare utilization among the Medicare FFS AKI-D population from January 2017 to December 2023.

Organization of Results

Results included in the study are organized into the following topic areas:

- AKI-D Episode Characteristics
- Mortality, AKI-Specific Health Outcomes, and Healthcare Utilization
- Anemias, Vascular Access Complications, and Cardiovascular Events
- Bone & Mineral Management Related Events, and Gastrointestinal (GI) Events
- Fluid Management Related Events
- Calcimimetics Utilization

All measures are stratified by dual eligibility status, race/ethnicity, and age group.

Specifications

Unit of Observation – AKI-D Episodes

- Episodes, rather than individual beneficiaries, are used as the unit of observation for the purposes of this report.
- AKI-D episodes are constructed based on the gap in time between two consecutive AKI dialysis sessions for an individual beneficiary as recorded on outpatient 72x claims. Specifically, an AKI-D episode starts on the date of a beneficiary's first ever AKI-D 72x claim (72x claim with Condition Code = 84) or any AKI-D 72x claim that has no AKI-D within 30 days prior. The episode continues as long as the gap between two consecutive AKI-D 72x dialysis sessions is no more than 30 days. Finally, the episode ends after the last AKI-D 72x dialysis session that is followed by a gap of greater than 30 days without AKI-D 72x dialysis.
- To ensure the data quality, results are only presented for beneficiaries who are continuously enrolled in Medicare FFS Parts A and B for three months after the start of an episode.¹ Additionally, episodes with ESRD 72x dialysis in the six months before the start of the episode or any prior kidney transplant are excluded.
- It is possible for an individual beneficiary to have more than one episode of AKI-D, although this happens rarely.

¹ If a beneficiary dies within three months after the start of the episode, the episode is still included in the analysis as death is an outcome of interest.

Outcome Stratifications

Stratifying Beneficiaries Based on Medicare & Medicaid Dual Eligibility Status

- Dual Eligible: Beneficiaries that are dually eligible for Medicare and Medicaid in the month when episode starts
- Non-Dual Eligible: Beneficiaries that are not dually eligible for Medicare and Medicaid in the month when episode starts

Stratifying Beneficiaries Based on Race/Ethnicity

- White: Beneficiaries with Research Triangle Institute (RTI) race code² "1" (Non-Hispanic White)
- Black: Beneficiaries with RTI race code "2" (Black or African-American)
- Asian/Pacific Islander: Beneficiaries with RTI race code "4" (Asian/Pacific Islander)
- Hispanic: Beneficiaries with RTI race code "5" (Hispanic)
- American Indian/Alaska Native: Beneficiaries with RTI race code "6" (American Indian/Alaska Native)
- Other/Unknown: Beneficiaries with RTI race code "3" (Other), or "0" (Unknown), or missing RTI race code

Stratifying Beneficiaries by Age Group

- Age <=59 years: Beneficiaries aged 59 years and below at the start of the episode
- Age 60-69 years: Beneficiaries aged between 60 and 69 years at the start of the episode
- Age 70-79 years: Beneficiaries aged between 70 and 79 years at the start of the episode
- Age >=80 years: Beneficiaries aged 80 years and above at the start of the episode

Measure Specifications

- Metrics:
 - Percentage of AKI-D episodes that meet the definition of a measure within a window of observation
 - Windows of observation are 30, 60, and 90 days following the AKI-D episode start date.
- Measure Summary Level
 - For overall trends: AKI-D episodes starting in the same month are in the same cohort. Measures are summarized at the cohort level.
 - For stratified measures: Measures are summarized at the population level.

² The Research Triangle Institute (RTI) race code is the beneficiary race modified using RTI algorithm, an enhanced race/ethnicity designation based on first and last name. The algorithm takes the beneficiary race code that has historically been used by the Social Security Administration (and is in turn used in CMS's enrollment database), and classifies beneficiaries as Hispanic or Asian if their SSA race code equals 4 (Asian) or 5 (Hispanic), or if they have a first or last name that was likely Hispanic or Asian in origin. This algorithm was developed by RTI, and is thus often referred to as the "RTI race code".

Measure Definitions

Episode Characteristics

- Number of AKI-D Episodes: Measured by the number of all AKI-D episodes.
- Number of AKI-D Beneficiaries: Measured by the number of first-time AKI-D beneficiaries and the number of beneficiaries who had AKI-D before.
- Length of AKI-D Episodes: Measured by the average days of episodes and median days of episodes.
- Dialysis Sessions in AKI-D Episodes: Measured by the average number of hemodialysis-equivalent dialysis sessions per episode and per week.

Mortality, AKI-Specific Health Outcomes,³ and Healthcare Utilization

- Death: As observed in the Medicare Enrollment Database.
- ESRD Development: As indicated by an ESRD PPS claim (72x type) filed during the window of observation.
- Recovery (Proxy): Defined as a beneficiary's continuous enrollment in Medicare Parts A and B, but no death, hospice, ESRD development, or transplant event for at least 30 outpatient days (i.e., a total of 30 days, gaps allowed, without an inpatient claim) following the last AKI-D 72x dialysis session.
- Hospitalization: As indicated by the service date of inpatient claim during the window of observation.
- Emergency Department (ED) visit: As indicated by the service date of outpatient claim with ED flag or the service date of inpatient claim with ED flag during the window of observation.
- Skilled Nursing Facility (SNF): As indicated by the service date of skilled nursing facility claim during the window of observation.

Anemias, Vascular Access Complications, and Cardiovascular Events

- Erythropoiesis-Stimulating Agents (ESAs) and Transfusions: As indicated by the relevant procedure code or revenue center code recorded during the window of observation. For the list of codes used to define each measure, please refer to *Codes-Anemia-Mgmt-ESA.xlsx* and *Codes-Anemia-Mgmt-Transfusion.xlsx*.
- Hemoglobin Levels: As indicated using Value Code 48 on 72x claims for ESA-treated beneficiaries during the window of observation. In cases where hematocrit was reported instead of hemoglobin, the value was converted by dividing hematocrit (Value Code 49) by 3.

³ AKI-specific health outcomes include development of ESRD and recovery of kidney function. As there is no standardized, clinical guidance on when to classify a patient with AKI as having gone into kidney failure and become ESRD, we have relied on dialysis sessions recorded on ESRD PPS 72x claims to make that determination. With regard to recovery of kidney function, this outcome was defined by a process of elimination of other possible outcomes, such as death, hospice, transition to ESRD, etc. The methodology for identifying these outcomes from claims was developed in consultation with clinical nephrologists. In the clinical setting, these outcomes would be determined by the physician on a case-by-case basis and recorded in the patient's medical record.

- Stroke, Heart Failure, and AMI: As indicated by the relevant ICD-10 diagnosis code during the window of observation, limited to the first diagnosis positions on the inpatient claim. For the list of codes used to define each measure, please refer to *Codes-Anemia-Mgmt-Stroke.xlsx*, *Codes_Anemia-Mgmt-Heart-Failure.xlsx*, and *Codes-Anemia-Mgmt-AMI.xlsx*.
- Vascular Access Complications: As indicated by the ICD-10 diagnosis code during the window of observation. For the list of codes, please refer to *Codes-Vascular-Access.xlsx*.

Bone & Mineral Management Related Events, and GI Events

- Fracture: As indicated by the relevant procedure code or ICD-10 diagnosis code during the window of observation. For the list of codes used to define the measure, please refer to *Codes-Bone-Mineral-Mgmt-Fracture.xlsx*.
- Ulcer: As indicated by the relevant ICD-10 diagnosis code on non-72x claims only during the window of observation. For the list of codes, please refer to *Codes-Bone-Mineral-Mgmt-Ulcer.xlsx*.
- Upper Gastrointestinal (GI) Bleeding: As indicated by the relevant ICD-10 diagnosis code on non-72x claims only during the window of observation. For the list of codes, please refer to *Codes-Bone-Mineral-Mgmt-Upper-GI-Bleed.xlsx*.

Fluid Management Related Events

- Congestive Heart Failure (CHF), Fluid Overload, and Body Fluid Depletion: As indicated by relevant ICD-10 diagnosis code recorded during the window of observation, limited to the first nine diagnosis positions on the claims form. For the list of codes, please refer to *Codes-Fluid-Mgmt.xlsx*.

Calcimimetics Utilization

- Cinacalcet: As indicated by cinacalcet national drug code and procedure code (HCPCS code J0604 and J0606) recorded during the window of observation. For the list of codes, please refer to *Codes-Cinacalcet.xlsx*.

Episode Characteristics

This section summarizes AKI-D episode characteristics, including the numbers, durations, and dialysis sessions by monthly cohort and beneficiary characteristics, for AKI-D episodes from January 2017 through December 2023.

The number of monthly AKI-D episodes increased over time, from approximately 800 episodes per month in early 2017 to greater than 1200 episodes in early 2021. However, from mid-2021 through 2023, the number dropped to less than 1,000 for most months. The data indicate that most episodes reflect first-time diagnosis of AKI-D. There were relatively few beneficiaries, fewer than 50 each month, experiencing multiple episodes of AKI-D during the study period. AKI-D episodes are generally longer after mid-2018 than before. In recent years, the average length of AKI-D episodes is between 50 and 60 days, while the median length is between 40 and 50 days. The number of hemodialysis-equivalent

dialysis sessions stabilized at about 22-23 per episode, averaging slightly more than three sessions per week.

When describing episode duration by patient characteristics, dual beneficiaries had longer episodes of AKI-D compared to non-dual beneficiaries. The average length of AKI-D episodes for dual beneficiaries was 57 days, which was two days longer than the average length of AKI-D episodes for non-dual beneficiaries. Asian/Pacific Islanders and Hispanic beneficiaries had longer episode durations than other race/ethnic groups. The average lengths of episodes for Asian/Pacific Islanders and Hispanic beneficiaries were 61 and 62 days, respectively, while average episode length was less than 60 days for other races/ethnicities. Older beneficiaries were found to have slightly longer episodes than younger AKI-D patients. Beneficiaries younger than 60 years had an average episode length of 53 days, while average episode length for older beneficiary groups was greater than 55 days.

Mortality, AKI-Specific Health Outcomes, and Healthcare Utilization

Mortality, AKI-specific health outcomes, and healthcare utilization are presented in this section as overarching measures of AKI-D beneficiary health status and proxy indicators for the cost of care. Mortality is ascribed to the death date information recorded on a beneficiary's enrollment file. As AKI-D may also resolve by recovery of kidney function or progression to ESRD, these events are described as AKI-specific outcomes. Healthcare utilization is assessed by monitoring beneficiary hospitalizations, ED visits, and SNF use.

Overall, AKI-D patients had a high, but overall stable mortality rate. The percentage of AKI-D beneficiaries dying within 30, 60, and 90 days following the start of an episode remained stable at 8%, 14%, and 19%, respectively, throughout the study period.

Percentages of episodes (patients) whose claims changed from AKI PS to ESRD PPS claims at the end of an episode remained relatively stable, although they decreased slightly in 2019 through 2023, compared to previous years. The 90-day percentages of episodes transitioning from AKI to ESRD, for example, decreased from nearly 40% in early 2019 to 30% at the end of 2023. Regarding the recovery of kidney function, the percentages generally decreased from 2017 to mid-2022. In May 2022, approximately 10% and 19% of AKI-D patients were estimated to recover kidney function (using the proxy measure described above) within 60 and 90 days of episode start, respectively. Starting from mid-2022, the percentages began to increase. In December 2023, the 60-day and 90-day recovery percentages increased to around 12% and 25%, respectively.⁴

Utilization of healthcare facilities was markedly affected by the onset of the COVID-19 pandemic. Percentages of episodes which included a hospitalization within 30, 60, and 90 days following the date of AKI-D episode start averaged 30%, 42%, and 49%, respectively, between 2017 and early 2020.

⁴ The 30-day recovery percentages are not reported because an AKI-D beneficiary cannot recover in 30 days based on the definition of recovery in this analysis.

Hospitalizations decreased noticeably in March and April 2020 to approximately 25%, 36%, and 42%, before increasing afterwards, stabilizing at lower percentages compared to years prior to 2020.

Percentages of episodes that included an ED visit within 30, 60, and 90 days following the start of an episode remained around 41%, 55%, and 62% from 2017 to early 2020, then decreased markedly beginning March 2020. These percentages increased afterwards, then stabilized at lower percentages compared to years prior to 2020. At the end of 2023, the 30, 60, and 90-day ED visit percentages centered around 42%, 54%, and 61%, respectively.

Percentages of AKI-D episodes with a SNF stay within 30, 60, and 90 days following the start of an episode averaged between 30% and 40% through early 2020. These percentages then decreased from March 2020 to January 2021 to as low as 22%, before increasing to around 30%.

When stratified by patient characteristics, because of their longer episode durations, dual-eligible AKI-D beneficiaries had lower mortality rates and lower recovery (proxy) percentages than non-dual beneficiaries in fixed windows of observation. At the same time, dual beneficiaries were more likely to transition to ESRD than non-dual beneficiaries. Within 90 days following the start of an AKI-D episode, the ESRD development percentage was nearly 39% for dual beneficiaries and less than 33% for non-dual beneficiaries. White beneficiaries had higher mortality rates and recovery (proxy) percentages as compared to other races/ethnicities. They also developed ESRD at lower percentages than non-White beneficiaries. In terms of healthcare facility utilization, Black and White beneficiaries generally had higher utilization percentages compared to other races/ethnicities. Beneficiaries aged 80 and above had the highest mortality and lowest recovery (proxy) percentages. Beneficiaries aged below 60 years were more likely to develop ESRD than older beneficiaries. Older age was correlated with increased SNF utilization.

Anemia, Vascular Access Complications, and Cardiovascular Events

The measures summarized in this section pertain to ESAs, blood transfusions, hemoglobin levels, vascular access complications, and cardiovascular events, including stroke, heart failure, and acute myocardial infarction (AMI).

Anemia related measures remained stable throughout the study period. The data show that 30, 60, and 90-day the blood transfusion percentages hovered around 8% to 20%. The ESA utilization percentages throughout the study period ranged from approximately 67% to 85%, although a small decrease is observed in 2023. Median hemoglobin levels also remained stable at approximately 9 gm/dL, with the 90-day levels slightly higher than the 30-day and 60-day levels.

Incidence of stroke-related hospitalizations generally remained below 2% in 30, 60, and 90 days following the start of the episode. The heart failure-related hospitalization percentages in 30 days following the start of an episode remained stable at 4% throughout the study period, while the 60-day and 90-day heart failure-related hospitalization percentages decreased after the start of the pandemic in March 2020. Similarly, the incidences of AMI-related hospitalizations decreased from early 2020 through the end of 2022, but started to increase in 2023. The 90-day AMI-related hospitalization

percentages, in particular, decreased from greater than 2% in late 2017 to less than 1% in late 2022, and increased to 1.7% in late 2023. Finally, vascular access complications exhibited a decrease in frequency throughout the study period. The 30, 60, and 90-day vascular access complication percentages decreased from 14%, 22%, and 27% in early 2017 to 9%, 14%, and 18% in late 2023, respectively.

Stratifying anemia, vascular access complications, and cardiovascular events by patient characteristics yielded varied results. Dual beneficiaries had overall higher percentages of these complications than non-dual AKI-D beneficiaries. For example, the 90-day vascular access complication percentage for dual beneficiaries was over 25%, while it was less than 22% for non-dual beneficiaries. Stratifying measures by race/ethnicity, Asian/Pacific Islanders had higher ESA utilization percentages than other races/ethnicities. Black beneficiaries had the highest vascular access complications percentages. Regarding cardiovascular events, White beneficiaries had the highest percentages of heart failure-related hospitalizations, followed by Black beneficiaries. The 90-day heart failure-related hospitalization percentage was 7.7% for White beneficiaries and 6.7% for Black beneficiaries, while the percentage for other known races/ethnicities was 6.8%. When stratified by age, the data demonstrated that incidences of blood transfusion were highest among beneficiaries aged 60-69 years. The data further showed that people under 60 years had lower percentages of cardiovascular events than other subgroups, while their vascular access complication percentages were highest among all age groups. Approximately 28% of AKI-D episodes with beneficiaries under 60 years had a diagnosis of vascular access complications within 90 days following episode start date, while this percentage was less than 23% for other age groups.

Bone & Mineral Management Related Events, and Gastrointestinal Events

This section presents data on health outcomes related to bone and mineral metabolism, including fractures, ulcers, and upper GI bleeding.

Overall, during the study period, measures pertaining to bone and mineral metabolism remained relatively stable. Fracture percentages 30, 60, and 90 days following the start of an episode remained at approximately 3%, 5%, and 6%, respectively, throughout the study period. The percentage of beneficiaries diagnosed with ulcers increased slightly. The 30-day ulcer percentages increased from approximately 2.5% in 2017 to approximately 2.9% in late 2023. Upper GI bleeding percentages also saw slight increases throughout the study period. The 90-day percentages for upper GI bleeding, for example, increased from approximately 2% in 2017 to 2.8% towards the end of 2023.

Stratifying fractures, ulcers, and upper GI bleeding by patient characteristics revealed higher incidences for non-dual, White, Asian/Pacific Islanders, and older beneficiaries. When examining dual eligibility status, non-dual AKI-D beneficiaries were more likely to be diagnosed with fractures, ulcers, and upper GI bleeding than dual eligible beneficiaries, although the differences between the two groups were generally small, ranging from 0.3 to 0.5 percentage points. Among different races/ethnicities, the percentages of episodes with fractures were highest for White and American Indian/Alaska Native beneficiaries, while the percentages of episodes with ulcers and upper GI bleeding were highest amongst Asian/Pacific Islander beneficiaries compared to other known races/ethnicities. The 90-day

fracture percentage for American Indian/Alaska Native beneficiaries was 7.0%, while the percentage for Black beneficiaries was 3.8%, as a comparison. Asian/Pacific Islanders had a 90-day ulcer percentage of 6.3%, while the percentage for other races was 5.1% or lower. Additionally, beneficiaries of Other/Unknown races also had high incidences of fractures, ulcers, and upper GI bleeding. When stratifying by beneficiary age groups, data showed that increases in age are correlated with an increase in having an episode with fractures, ulcers, and upper GI bleeding. For beneficiaries aged 80 years and above, the 30, 60, and 90-day upper GI bleeding percentages were 2%, 2.6%, and 3%, respectively, as compared to 1.1%, 1.6%, and 2% for beneficiaries aged below 60 years.

Fluid Management Related Events

This section presents data on health outcomes related to fluid management, primarily congestive heart failure, fluid overload, and body fluid depletion.

Based on data, the number of AKI-D episodes with health events related to fluid management increased during the first two to three years of the study period, before decreasing or stabilizing through the end of 2023. In fixed windows of observation, the incidence of congestive heart failure increased between 2017 and 2020, then began to decrease in April and May 2020, with the onset of the COVID-19 pandemic, before stabilizing. At the end of 2023, the percentage of episodes for which congestive heart failure was reported within 30, 60, and 90 days following the start of an episode were 45%, 53%, and 57%, respectively. Similarly, the percentage of episodes with fluid overload in fixed observation windows exhibited increases through February 2020 and decreases beginning April 2020. The fluid overload percentage reported within 30-days following the episode start date, for example, increased from approximately 16% in 2017 to nearly 20% in early 2020, then decreased and remained steady through 2023. At the same time, body fluid depletion percentages reported within 30 days following the start of an episode remained stable at around 3%, while the 60-day and 90-day percentages exhibited decreases by the end of 2023 from the early part of 2019, to approximately 4% and 5%, respectively.

Stratifying fluid management related measures by dual eligibility, the percentages of congestive heart failure were found to be slightly higher for dual beneficiaries than for non-dual beneficiaries within 60 and 90 days following the start of an episode. Similarly, fluid overload percentages were higher for dual beneficiaries than they were for non-dual beneficiaries. The 90-day fluid overload percentage for dual beneficiaries was nearly 29.7%, while it was 26.5% for non-dual beneficiaries. Among different races/ethnicities, White and Black beneficiaries had higher percentages of congestive heart failure and body fluid depletion than other races/ethnicities, while percentages of fluid overload were higher for Asian/Pacific Islanders and Hispanic beneficiaries. Additionally, beneficiaries of Other/Unknown races also had higher body fluid depletion percentages relative to the rest of the population. Beneficiaries aged 80 years and older were more likely to experience congestive heart failure following the start of the AKI-D episode than younger beneficiaries. The congestive heart failure percentage within 90 days following the start of an episode was 61.6% for beneficiaries aged 80 years and above, but was less than 45% for the youngest age group. Conversely, the incidences of fluid overload were higher for younger beneficiaries. Beneficiaries aged below 60 years had a 90-day fluid overload percentage of 28.8%. For older age groups, the percentage was 27.7 or lower.

Calcimimetics Utilization

Calcimimetic drugs include both an oral form (cinacalcet) and an intravenous form (etelcalcetide). However, only the oral form is indicated for the treatment of AKI. The utilization of etelcalcetide is allowed after a patient develops ESRD. For AKI-D patients, calcimimetics were only covered by Medicare Part D prior to 2021. Starting in January 2021, these drugs were included in the ESRD PPS bundle and qualified as ESRD outlier-eligible services.

As shown in the workbook, calcimimetics utilization remained steady at a low level among AKI-D beneficiaries from 2017 through 2020. During this period, the percentages of AKI-D episodes utilizing calcimimetics in 30, 60, and 90 days following the start of an episode all averaged below 1%.

Calcimimetic utilization increased noticeably in 2021. By the end of 2023, the percentages of AKI-D episodes utilizing calcimimetics 30, 60, and 90 days following the start of an episode reached 1.5%, 2.0%, and 2.6%, respectively. However, the utilization was still low compared to ESRD beneficiaries.

Stratifying calcimimetics use by patient characteristics, dual-eligible and Black beneficiaries had higher utilization, whereas older beneficiaries had lower utilization. Within the 30, 60, and 90-day windows following the start of an episode, calcimimetics utilization among dual AKI-D beneficiaries was 0.7%, 1.1%, and 1.6%, compared to 0.4%, 0.7%, and 1.0% for non-dual beneficiaries.