

ESRD Prospective Payment System (ESRD PPS) Claims-Based Monitoring Program

Overview of 2010 - 2021 Claims-Based Monitoring Program

Since the implementation of the End-Stage Renal Disease Prospective Payment System (ESRD PPS) in January 2011, CMS has monitored utilization of services and health outcomes for Medicare beneficiaries receiving outpatient maintenance dialysis. This document, paired with the accompanying workbook, describes several key trends from January 2010 through December 2021.

Since 2010, CMS has observed utilization for ESRD-related drugs, biologicals, and dialysis related procedures. CMS has also tracked general health outcomes including not only mortality and morbidity, but also several ESRD-specific health outcomes including cardiovascular morbidity, vascular access complications, bone and mineral metabolism indicators, and fluid management indicators, as well as treatment and drug utilization, including home dialysis, erythropoietin-stimulating agents, and calcimimetics.

Outcomes are also stratified by ESRD beneficiaries' patient-level characteristics, including monthly Medicare & Medicaid eligibility status, race/ethnicity, and the age group that a beneficiary falls in at the beginning of a month. Patient characteristics are monitored in an effort to identify health disparities among ESRD beneficiaries, as health equity takes an increasingly pivotal role in the healthcare policy-making at the federal level.

While initial implementation of the ESRD PPS in 2011 resulted in changes in the utilization of certain ESRD-related items and services, ongoing monitoring has revealed no sustained negative impacts in beneficiary health status from January 2010 through December 2021. Key findings from this monitoring effort are summarized throughout the document, organized by topic.

For each outcome, monthly data are presented for the year prior to the implementation of the ESRD PPS and for each month from January 2010 to December 2021 (with the exception of calcimimetics data, as coverage of calcimimetic utilization began with the implementation of the Transitional Drug Add-on Payment Adjustment [TDAPA] under the ESRD PPS in January 2018). Inclusion of baseline year data allows for the separation of historical trends from changes that could be related to the new payment system.

Impact of COVID-19

In early 2020, the SARS CoV-2 (COVID-19) pandemic spread to the United States, leading to the declaration of a National Emergency by the White House on March 13, 2020.¹ The impact of the COVID-19 National Emergency on ESRD-related resource utilization and health outcomes can be observed in

¹ <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

the months following this declaration. In particular, mortality among ESRD beneficiaries increased in April 2020, while it decreased in April of other years. Additionally, utilization of services and outcomes typically measured for this report were observed to have markedly changed, beginning in March and April of 2020.² These outcomes include hospitalization, emergency department visit, Skilled Nursing Facility (SNF) stay, transfusion, stroke related hospitalization, heart failure related hospitalization, acute myocardial infarction (AMI) related hospitalization, vascular access complications, fracture, upper GI bleeding, ulcer, congestive heart failure, fluid overload, and body fluid depletion. With the exception of SNF stays, utilization of these services and occurrence of these outcomes increased in the following months, but have not thus far returned pre-pandemic levels. The impact of COVID-19 persisted through the end of 2021. The decrease in overall hospitalizations during 2020 relative to previous years has been documented in other research, including that of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which identified a similar trend among dialysis patients, and the Kaiser Family Foundation (KFF), which noted similar trends for the general population. Decreases in hospitalizations could result in decreases in the incidence of selected health outcomes and the use of selected procedures that are generated from diagnosis and procedure codes on hospital claims.^{3,4}

Overview of the CMS-FDA Collaborative Assessment

Along with the implementation of the ESRD PPS in 2011, the FDA also updated labeling for erythropoiesis-stimulating agents (ESAs) in 2011. This led to a collaboration between CMS and FDA to evaluate the impact of the changes. The study compared outcomes for patients in a pre-policy implementation cohort, including ESRD patients enrolled in Medicare from January 1, 2008 to December 31, 2009, to those for patients in a post-policy cohort that was followed from July 1, 2011, to June 30, 2013, with the exclusion of January 1, 2010, to June 30, 2011, as a transition period.⁵

The resultant published study showed that there was a significant decrease in ESA use, a modest increase in blood transfusions, a significant (>20%) reduction in stroke, and an insignificant reduction in acute myocardial infarction among patients who initiated dialysis after the policy and labeling changes. Overall, there were no changes in other clinical outcomes, including a composite measure of major adverse cardiovascular events (acute myocardial infarction, stroke, and death), death, congestive heart failure, or venous thromboembolic events. Moreover, black patients had substantial reductions in the risks of major adverse cardiovascular events and death after implementation of the new payment policy.

The remaining sections of this document refer only to CMS' claims-based monitoring program.

² The monitoring program displays national rates, and therefore does not capture localized surges in outcomes.

³ United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. Chapter 13: COVID-19 Supplement. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

⁴ Trends in Overall and Non-COVID-19 Hospital Admissions. Kaiser Family Foundation. February 18, 2021.

⁵ Wang, Cunlin et al. "Association between changes in CMS reimbursement policy and drug labels for erythrocyte-stimulating agents with outcomes for older patients undergoing hemodialysis covered by fee-for-service Medicare." *JAMA Internal Medicine*. Published online October 24, 2016. doi:10.1001/jamainternmed.2016.6520.

Introduction

Observation Period: 1/1/2010 to 12/31/2021

Claims Processed Through: 7/1/2022

Beneficiary Enrollment Through: 6/30/2022

Data Types: Original Medicare (Part A and Part B) Claims; Medicare Enrollment Data; Common Medicare Environment (CME)

Purpose: To summarize beneficiary health outcomes and utilization among the Medicare ESRD population (aged 18 years and older) from January 2010 to December 2021.

The key findings are organized into the following topics: General Morbidity & Mortality; Home Dialysis, Training, and Home Dialysis Utilization After Training by Onset and Non-Onset Beneficiaries; Anemias, Vascular Access Complications, and Cardiovascular Events; Bone & Mineral Management Related Events, and Gastrointestinal (GI) Events; Fluid Management Related Events; and Calcimimetics Utilization. Service utilization and health outcome data are stratified by dual eligibility status, race/ethnicity group, and age group.

Specifications

Study Population

- Monthly ESRD Population: All persons who were enrolled in Medicare A/B FFS during the month of observation AND had ≥ 1 ESRD claim (type of bill = 072x without Condition Code 84) in the month. If a beneficiary died in a given month and had no 72x claim, the beneficiary was in the population if he or she had a 72x claim in the prior month of observation. This workbook presents results for the adult ESRD population (beneficiaries 18 years and older).

Stratifying Beneficiaries Based on Medicare & Medicaid Dual Eligibility Status

- Dual Eligible: beneficiaries that are dually eligible for Medicare and Medicaid in a given month
- Non-Dual Eligible: beneficiaries that are not dually eligible for Medicare and Medicaid in a given month

Stratifying Beneficiaries Based on Race/Ethnicity

- White: beneficiaries with Research Triangle Institute (RTI) race code⁶ “1” (Non-Hispanic White)
- Black: beneficiaries with RTI race code “2” (Black or African-American)

⁶ 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”.

- Asian/Pacific Islander: beneficiaries with RTI race code “4” (Asian/Pacific Islander)
- Hispanic: beneficiaries with RTI race code “5” (Hispanic)
- AI/AN: 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 and below at the beginning of a given month
- Age 60-69 years: beneficiaries aged between 60 and 69 at the beginning of a given month
- Age 70-79 years: beneficiaries aged between 70 and 79 at the beginning of a given month
- Age >=80 years: beneficiaries aged 80 and above at the beginning of a given month

Outcome Definitions

General Morbidity & Mortality

- Death: As observed in the Medicare Enrollment Database.
- Hospitalization: As indicated by the service date of Inpatient (IP) claim.
- Emergency Department (ED) visit: As indicated by the service date of Outpatient (OP) claim with ED flag, or the service date of Inpatient (IP) claim with ED flag.⁷
- Skilled Nursing Facility (SNF): As indicated by the service date of Skilled Nursing (SN) claim.

Home Dialysis, Training, and Utilization of Home Dialysis After Training by Onset and Non-Onset Beneficiaries

- Home Dialysis: As indicated by the related condition code 74 on 72x claims.
- Training: As indicated by related condition code 73 or 87, or HCPCS code 90989 or 90993 on 72x claims.
- Onset Period: The beneficiary’s first four months of maintenance dialysis.
- Home Dialysis After Training: As indicated by a home dialysis claim in at least one of the three months following the start of training.

Anemias, Vascular Access Complications, and Cardiovascular Events

- ESAs and Transfusions: As indicated by the relevant procedure code or revenue center code. For the list of codes used to define each outcome, 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. In cases where hematocrit was reported instead of hemoglobin, the value was converted by dividing hematocrit (Value Code 49) by 3.

⁷ Iterations of the PUF prior to the 2018 Q4 only looked at OP claims.

- Stroke, Heart Failure, and AMI: As indicated by the relevant ICD-9 or ICD-10 diagnosis code, limited to the first diagnosis positions on the inpatient (IP) claim.⁸ For the list of codes used to define each outcome, 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-9 or ICD-10 diagnosis code. 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-9 or ICD-10 diagnosis code. For the list of codes used to define the outcome, please refer to Codes_Bone_Mineral_Mgmt_Fracture.xlsx.
- Ulcer: As indicated by the relevant ICD-9 or ICD-10 diagnosis code on non-72x claims only. For the list of codes, please refer to Codes_Bone_Mineral_Mgmt_Ulcer.xlsx.
- Upper Gastrointestinal (GI) Bleeding: As indicated by the relevant ICD-9 or ICD-10 diagnosis code on non-72x claims only. 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 the relevant ICD-9 or ICD-10 diagnosis code. For the list of codes, please refer to Codes_Fluid_Mgmt.xlsx.

Calcimimetics Utilization

- Cinacalcet: As indicated by HCPCS code J0604 (from 2018 onward) and national drug code (from 2021 onward). For the list of codes, please refer to Codes_Cinacalcet.xlsx.
- Etelcalcetide: As indicated by HCPCS code J0606.

Limitations

- For all outcomes defined by ICD diagnosis or procedure codes, outcome percentages may be affected by the transition from ICD-9 to ICD-10 in October 2015. Mappings were generated using CMS general equivalence mappings (GEMs) and clinical review. While some outcome percentages changed at the transition point, overall trends appear undisturbed. For more information, see the CMS website: <https://www.cms.gov/Medicare/Coding/ICD10/index.html>

General Morbidity & Mortality

Morbidity and mortality data for the ESRD PPS population are presented in this section as overarching measures of ESRD beneficiary health status. Beneficiary morbidity, taken here to mean the general health status of the beneficiary, was assessed by monitoring beneficiary hospitalizations, emergency department visits, and skilled nursing facility use.

⁸ Iterations of the PUF prior to 2018 Q4 presented cumulative incident rates by yearly cohort for stroke, heart failure, and AMI. Starting with the 2018 Q4 iteration, the PUF presents monthly percentages.

Seasonal trends in overall monthly mortality (i.e., higher mortality during winter months) are observed, however the mortality rate was flat overall from 2010 to early 2020. The percentage of ESRD beneficiaries dying increased markedly in April 2020, with another noticeable increase at the end of 2020. These peaks correspond in time to the initial surge in cases of COVID-19 in the U.S. and to its continued spread during the winter months of 2020, before vaccinations became available. In late 2021, mortality incidence climbed again to reach a peak similar to that of April 2020. This peak corresponds in time to the appearance of the delta variant in the U.S. Beneficiaries who did not have dual coverage had consistently higher mortality from 2010 to early 2020, though dual eligible beneficiaries had rising mortality beginning in 2017. In April 2020, mortality for dual eligible beneficiaries surpassed that of non-dual eligible beneficiaries. This trend was transitory, however, and non-dual eligible beneficiaries continued to have higher mortality through the end of 2021. Mortality rates were higher among White beneficiaries from 2010 through 2021, with the exception of December 2020 when mortality rates for AI/AN beneficiaries surpassed that for whites. There is no significant difference in the percentages of mortality among Black, Asian, Hispanic, and AI/AN beneficiaries during the study period. To be expected, older beneficiaries experienced noticeably higher percentages of mortality across the study period.

Overall monthly hospitalization incidence declined from 14.3% of ESRD beneficiaries in 2010 to 12.5% in 2015, where it remained through early 2020. The percentage of beneficiaries hospitalized fell below 10% in April 2020, in conjunction with the initial lockdowns that occurred at the beginning of the pandemic; hospitalizations subsequently increased, following the increase in COVID-19 cases. Percentages remained below 12% for the rest of the year until December 2020, when approximately 12.4% of beneficiaries were hospitalized. In 2021, percentages hovered around 12% and did not return to pre-pandemic levels. Monthly hospitalization percentages were higher for dual beneficiaries compared to non-dual beneficiaries throughout the study period. Percentages are generally highest for White beneficiaries, and are lowest for beneficiaries that are Asian/Pacific Islanders compared with other race/ethnicity groups. Additionally, hospitalization percentages are generally higher among older beneficiaries, although the differences became smaller in 2020 and 2021.

Similar to mortality, overall monthly skilled nursing facility (SNF) utilization fluctuates seasonally but remained mostly constant at just above 5% of beneficiaries from 2010 through 2017. A slow decline of utilization started in 2018, followed by a more noticeable drop in mid-2020. In December 2021, approximately 4.5% of beneficiaries were admitted to SNFs. Dual beneficiaries have higher utilization percentages than their non-dual counterparts across the study period. In March 2020, monthly SNF percentages for non-dual beneficiaries dropped noticeably, while percentages for dual beneficiaries increased. Across races/ethnicities, SNF utilization percentages are the highest and second highest for White beneficiaries and Black beneficiaries, respectively, with percentages being lower and relatively similar for other races/ethnicities. Across age groups, there is a noticeable trend that SNF utilization increases with age. In 2020, the first year of the pandemic, utilization decreased across age groups with the exception of beneficiaries below 60, which remained constant.

Monthly emergency department visits rose only slightly from 19.1% in 2010 to just under 20% in 2019. After a seasonal peak in January 2020, the percentage of beneficiaries going to the emergency

department decreased to a low of 14.5% in April 2020, before increasing again in the following months. Throughout the year 2021, emergency department visits remained lower than pre-pandemic levels, with 18.7% of beneficiaries admitted to the emergency department in December 2021. Emergency department visit percentages for dual beneficiaries are consistently higher than for non-dual beneficiaries. In general, White and Black beneficiaries have higher percentages of emergency department visits than other races/ethnicities, with Asian/Pacific Islanders having the lowest percentages. There is no significant difference in emergency department visits among age groups.

Home Dialysis, Training, & Utilization of Home Dialysis After Training by Onset and Non-Onset Beneficiaries

This section presents data on the utilization of home dialysis.⁹ It also reports on the utilization of dialysis training and the subsequent utilization of home dialysis among onset and non-onset beneficiaries. Onset is defined as the beneficiary's first four months of maintenance dialysis.

The average monthly percentage of ESRD beneficiaries utilizing home dialysis increased slowly from 8.3% in 2010 to 10.7% in 2014, when it plateaued through early 2017. Subsequently, home dialysis utilization has gradually increased with over 14% of beneficiaries using home dialysis in January 2021. Utilization continued to increase for the remainder of 2021. Non-dual beneficiaries had consistently higher usage of home dialysis than dual beneficiaries throughout the study period. Across races/ethnicities, White and Asian/Pacific Islander beneficiaries had higher percentages of home dialysis use compared to that of other races/ethnicities. Across age groups, home dialysis percentages decrease as beneficiary age increases.

Data also reveal that beneficiaries are more likely to receive home dialysis training and then continue with home dialysis during their dialysis onset period as compared to maintenance dialysis patients. In both the onset and maintenance populations, the home dialysis training percentages are higher for non-dual beneficiaries than dual beneficiaries, though the difference is more pronounced for the onset population. There is no significant difference between dual and non-dual beneficiaries for home dialysis percentages in the three months after the start of training. Across age groups, home dialysis training percentages decrease with the increase of beneficiaries' age. However, different age groups have similar percentages for home dialysis utilization in the three months after the start of training. There is no significant difference across races/ethnicities in home dialysis training or utilization in the three months after the start of training.

Anemias, Vascular Access Complications, and Cardiovascular Events

This section presents findings on ESA and blood transfusion utilization, median hemoglobin levels, the incidence of cardiovascular events (stroke, heart failure, and acute myocardial infarctions), and vascular

⁹ This includes both home hemodialysis (HD) and home peritoneal dialysis (PD).

access complications. Refer to Appendix B for changes made to the codes used for stroke hospitalizations in the 2020 Q4 update of the ESRD Claims-Based Monitoring Program.

Following the implementation of the ESRD PPS, overall ESA usage among ESRD beneficiaries declined from 91.1% in 2010 to 83.2% in 2012. This percentage continued to decline to 75.0% by 2017 and generally remained at this level through 2021, which saw 74.8% of beneficiaries using ESAs on average. Dual beneficiaries have slightly higher monthly ESA utilization percentages than non-dual beneficiaries. Across races/ethnicities, monthly ESA utilization percentages are slightly higher for beneficiaries that are Asian/Pacific Islanders. Across age groups, percentages are higher for older beneficiaries, though they range from 70% to 80% for all age groups starting from 2018.

Average hemoglobin levels for those treated with ESAs declined from 11.4 gm/dL before implementation of the PPS to 10.6 gm/dL by mid-2012 and has remained at that level since. This trend was seen for all beneficiaries, regardless of their age, race/ethnicity, or dual eligibility status.

The overall monthly percentage of ESRD beneficiaries receiving blood transfusions has fluctuated since 2010 (with average monthly percentage that year of 2.7%) and peaked in January 2013 at 3.76%. Since then, overall transfusion declined to 1.9% by April 2020. From mid-2020 to early 2021, transfusion percentages increased and peaked at 2.6% in January 2021. Little difference is seen in receipt of blood transfusions between dual and non-dual beneficiaries. Across races/ethnicities, monthly transfusion percentages are slightly higher for White and Black beneficiaries compared to other races/ethnicities. In general, percentages are higher among older beneficiaries.

As for cardiovascular outcomes, overall monthly stroke-related hospitalization incidence gradually decreased from 0.22% in 2010 to approximately 0.17% in October 2015, where they remained through the end of 2021, with the exception of three brief dips to 0.15% in April 2020, 0.16% in February 2021, and 0.15% in September 2021. This trend is seen across dual eligibility groups and race/ethnicity groups. For beneficiaries below 60 years of age, however, monthly stroke-related hospitalization percentages are noticeably lower when compared to other age groups.

Overall incidence of acute myocardial infarction (AMI) related hospitalizations remained relatively steady at 0.36% of beneficiaries through 2019. The percentage of beneficiaries with AMI-related hospitalizations was slightly lower in 2020, driven by a brief dip in April 2020. After April 2020, AMI-related hospitalizations did not return to previous levels with 0.31% of beneficiaries hospitalized in December 2021. AMI-related hospitalizations are virtually the same across dual eligibility groups and race/ethnicity groups. For beneficiaries below 60 years of age, however, monthly AMI-related hospitalization percentages are noticeably lower when compared to other age groups.

The percentage of ESRD beneficiaries experiencing heart failure-related hospitalizations declined from 1.2% in 2010 to 0.72% in late 2015, then increased through late 2016 to percentages similar to those observed for 2010. From 2016 to early 2020, hospitalizations slowly increased to the peak of 1.5%. Hospitalizations dropped in April 2020, but subsequently continued to increase in 2020 and 2021 to over 1.2%. Similar rates were observed between dual and non-dual beneficiaries from 2010 to 2016.

Beginning 2017, dual beneficiaries began to have increasingly higher heart failure hospitalization percentages compared to non-dual beneficiaries. Similarly, there is little difference in monthly heart failure hospitalization percentages among race/ethnicities, with White beneficiaries have slightly higher percentages compared to other groups. Across age groups, percentages grow with the increase of beneficiaries' age. The observed increase in October 2016 may be attributable to coding changes contained in the FY 2017 ICD-10 Official Guidelines for Coding and Reporting. Starting in FY 2017, the word "with", in the context of conditions with or without major complications or comorbidities, indicated a causal relationship between different conditions and did not require further documentation from providers explicitly linking the conditions. For example, in the case of heart failure, if a patient had heart failure and hypertension, the two diagnoses are assumed to be associated unless the provider indicated otherwise. This coding change resulted in more cases mapping to DRG 291 (Heart failure & shock with major complications or comorbidities) in October 2016 throughout the overall Medicare population. This increase was reflected in the ESRD population, driven by heart failure IP claims with DGN code I132 (hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease) as the primary diagnosis.

As for vascular access related events, the overall percentage of ESRD beneficiaries experiencing complications each month gradually decreased until late 2015, after which it remained relatively flat around 13.5% through 2021, with the exception of a brief dip in April 2020. The small (2%) decrease in late 2015 corresponds with the transition from ICD-9 to ICD-10. Across most of the study period, dual eligible beneficiaries have slightly higher percentages of vascular access complications compared with non-dual eligible beneficiaries. Percentages are highest for Black beneficiaries and lowest for AI/AN beneficiaries. Vascular access complication percentages are similar for other races/ethnicities. Percentages are nearly indistinguishable for different age groups.

Bone & Mineral Management Related Events, and Gastrointestinal Events

Presented in this section are beneficiary outcomes related to bone and mineral metabolism (primarily fractures), upper gastrointestinal (GI) bleeding, and ulcers. Refer to Appendix A for a summary of changes made to the definition of Bone and Mineral Management outcomes in the 2019 Q4 update of the ESRD Claims-Based Monitoring Program, and Appendix B for changes made to the definition of upper GI bleeding and ulcer outcomes in the 2020 Q4 update.

Average monthly fracture percentages for ESRD beneficiaries hovered around 2.5% from 2010 to October 2015, when percentages dropped to approximately 1.8%, and remained at that level through 2018. The percentage of beneficiaries with fractures in 2019 was approximately 2.0%. Percentages in 2020 briefly dropped to 1.5% in April before rising to 2.1% in 2021. The drop in fracture percentages in late 2015 corresponds with the transition from ICD-9 to ICD-10 codes. Monthly fracture percentages were similar for dual and non-dual beneficiaries, though non-dual beneficiaries started to have higher percentages in 2020. Across races/ethnicities, monthly fracture percentages were highest among White

beneficiaries and lowest among Black beneficiaries. Across age groups, monthly fracture percentages increase with the increase of beneficiaries' age.

The percentage of beneficiaries diagnosed with ulcers increased slightly at the beginning of 2011, after which levels remained relatively flat until October 2015. Ulcer incidence increased slightly after the ICD-9 to ICD-10 transition, and generally remained flat through the end of the study period, apart from a brief dip in Spring 2020. There were no notable differences in the incidence of ulcers between dual and non-dual beneficiaries, particularly after the transition from ICD-9 to ICD-10 in October 2015. There were no significant differences in the occurrence of ulcers among different races/ethnicities. However, across age groups, monthly ulcer percentages were noticeably lower for beneficiaries aged below 60 when compared to all other age groups.

As for incidence of upper GI bleeding, the percentage of beneficiaries affected by this outcome hovered around 0.29% from 2010 to October 2015, after which percentages rose to 0.49% in early 2020. The percentage of beneficiaries with upper GI bleeding briefly drops to 0.36% in April 2020 before increasing in the following months and ending at 0.45% in December 2020. This percentage dropped to 0.42% by December 2021. Percentages of GI bleeding were similar for dual and non-dual beneficiaries throughout the study period. Among different races/ethnicities, there were no significant differences in upper GI bleeding incidence. However, upper GI bleeding percentages were noticeably lower for beneficiaries aged below 60 compared to all other age groups.

Fluid Management Related Events

Presented in this section are beneficiary outcomes associated with fluid management, including body fluid depletion, fluid overload and congestive heart failure. Refer to Appendix A for a summary of changes made to Fluid Management outcomes beginning with the 2019 Q4 update of the ESRD Claims-Based Monitoring Program.

The percentages of ESRD beneficiaries diagnosed with body fluid depletion decreased only slightly from 1.2% at the time of PPS implementation to 0.9% during 2019. Percentages were slightly lower in 2020 and 2021, driven by a dip in April 2020. Dual and non-dual beneficiaries experience similar percentages body fluid depletion. Additionally, there were no notable differences in body fluid depletion across different races/ethnicities, except for slightly higher percentages among White beneficiaries. As beneficiaries increase in age, monthly body fluid depletion percentages increase slightly.

The percentage of beneficiaries experiencing fluid overload remained at 5% to 6% from 2010 to late 2015, when percentages increased to about 8%, corresponding with the ICD-9 to ICD-10 transition. Fluid overload incidence has also increased since late 2016, as has congestive heart failure incidence. This observed increase could be due in part to the policy surrounding the use and reimbursement of "excess" hemodialysis. Local coverage determinations (LCDs) proposed by Noridian and other MACs state that hemodialysis performed or billed more than three times per week is reasonable and medically necessary in the presence of certain conditions, including congestive heart failure and fluid overload. And in order to justify this excess dialysis, the heart failure code or fluid overload code must be recorded on the 72x

claim. The LCD was proposed in 2015 and the claims-based monitoring program observed increased incidence of both conditions beginning in 2016 through the end of the study period, with the exception of a brief marked decrease in Spring 2020. This increase from late 2016 is seen for all beneficiary subgroups. For both congestive heart failure and fluid overload, dual beneficiaries have higher percentages compared to non-dual beneficiaries. The difference between dual and non-dual beneficiary fluid overload percentages has gradually increased since 2016. When stratified by race/ethnicity, White beneficiaries have the highest percentages of congestive heart failure, followed by Black beneficiaries. There are no notable differences in fluid overload percentages among races/ethnicities. Across age groups, congestive heart failure and fluid overload have opposite trends. Monthly congestive heart failure percentages increase with beneficiaries' age, with beneficiaries aged 80 and above having percentages double the value of the percentages for beneficiaries below 60 years of age. In contrast, monthly fluid overload percentages decrease with the increase of beneficiaries' age.

Calcimimetics Utilization

Calcimimetic drugs, cinacalcet and etelcalcetide, were eligible for the TDAPA from 2018 to 2020. Starting in 2021, they were included in the ESRD PPS bundle and qualified as outlier eligible services. Cinacalcet is an oral calcimimetic and etelcalcetide is the injectable form of the same drug. Refer to Appendix C for a summary of changes made to the definitions for calcimimetics utilization in the 2021 Q4 update of the ESRD Claims-Based Monitoring Program.

From January 2018 to February 2018, the percentage of ESRD beneficiaries who used cinacalcet increased by 4.5% (17.8% to 22.3%). Percentages remained relatively stable until July 2018, when the percentage of ESRD beneficiaries using cinacalcet began to slightly decrease until it was approximately 20% in February 2019. Cinacalcet usage percentages remained at 20% through the end of 2020. In the first half of 2021, the percentage increased to over 25%, and remained generally stable since. The percentage of ESRD beneficiaries who use etelcalcetide gradually increased from 1% in January 2018 to about 9% for much of late 2019 and 2020. The percentage of beneficiaries using etelcalcetide remained steady for most of 2020 before decreasing noticeably from January to May 2021, after which the percentage stabilized at around 2.5%. Dual beneficiaries had higher monthly utilization percentages than non-dual beneficiaries for both cinacalcet and etelcalcetide. Across races/ethnicities, Black beneficiaries have the highest utilization percentages for both cinacalcet and etelcalcetide. Cinacalcet and etelcalcetide utilization percentages are both higher for younger beneficiaries compared to older beneficiaries.

Appendix A: Changes Made to 2019 Q4 ESRD Claims-Based Monitoring Program

This appendix summarizes changes made regarding outcomes and utilization monitored, including changes to code lists used to monitor outcomes, effective with the 2019 Q4 update of the ESRD Claims-Based Monitoring Program.

Kidney stones are no longer monitored as of the 2019 Q4 update of the ESRD claims-based monitoring program, as kidney stones were deemed by clinical experts not to be clinically relevant health outcomes for kidney dialysis patients.

Also, to achieve a more comprehensive set of codes, codes were added to a number of existing outcomes, both before and after the ICD-9 to ICD-10 transition. The addition of new codes resulted in slightly different outcome percentages in the 2019 Q4 update compared to prior versions of the ESRD monitoring program for some of the outcomes, namely upper GI bleeding/ulcers (named peptic ulcers prior to 2019 Q4), fluid overload, congestive heart failure, fractures, and body fluid depletion (named dehydration prior to 2019 Q4). However, code changes did not result in different conclusions from previous updates of the ESRD monitoring program.

Prior to the 2019 Q4 update, when monitoring upper GI bleeding/ulcers, the ESRD monitoring program included only peptic ulcers (acute or chronic) with hemorrhage. Starting with the 2019 Q4 update, the ESRD monitoring program now includes peptic, gastric, and duodenal ulcers with or without hemorrhage and/or with perforation. Fractures also include more codes in order to capture a more comprehensive set of codes in the 2019 Q4 update.

In the 2019 Q4 update, codes were also added to each of the fluid management outcomes. When looking at fluid overload, the 2019 Q4 update now includes codes for pulmonary edema. For congestive heart failure, the 2019 Q4 update includes additional codes for systolic and diastolic heart failure. Lastly, codes for hypovolemia and volume depletion are now included when monitoring body fluid depletion.

Appendix B: Changes Made to 2020 Q4 ESRD Claims-Based Monitoring Program

This appendix summarizes changes made regarding the monitoring of ulcers and upper gastrointestinal (GI) bleeding, as well as changes to the code list used to monitor stroke-related hospitalizations.

As of the 2020 Q4 update of the ESRD claims-based monitoring program, ulcers and upper GI bleeding are monitored separately, whereas before they were included as one outcome (upper GI bleeding/ulcers). There is overlap in the diagnosis codes used to identify each outcomes. Upper GI bleeds can increase the complexity of managing patients, especially with respect to costs from differences in ESAs, while ulcers are a reported side effect of calcimimetics. In the 2020 Q4 update, diagnosis codes for gastrojejunal ulcers were also added to the code lists in order to achieve a more comprehensive list of codes.

Additionally, in this update, diagnosis codes I6381 (Other cerebral infarction due to occlusion or stenosis of small artery) and I6389 (Other cerebral infarction) were added to the code list for stroke-related hospitalizations. These codes were created in October 2018, and very slightly increased the percentages (0.02-0.03 percentage points) from October 2018 through 2019 compared results presented in the 2019 Q4 update.

Appendix C: Changes Made to 2021 Q4 ESRD Claims-Based Monitoring Program

This appendix summarizes changes made regarding the monitoring of TDAPA drug utilization (now as calcimimetics utilization), as well as changes to the code list used to monitor ESA utilization and fracture.

In the 2021 Q4 update of the ESRD claims-based monitoring program, the utilization of cinacalcet and etelcalcetide are monitored under a new section “Calcimimetics Utilization”, whereas the section was named as “TDAPA Drug Utilization” before. As both forms of calcimimetics, cinacalcet and etelcalcetide were eligible for TDAPA from 2018 to 2020, indicated by HCPCS code J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) and J0606 (Injection, etelcalcetide, 0.1 mg) respectively on 72x claims. Starting in 2021, the two drugs were no longer eligible for TDAPA. They were included in the ESRD PPS bundle and qualified as outlier eligible services. As the utilization of the two drugs are still of interest, they continue to be monitored in the 2021 Q4 update under the section renamed as “Calcimimetics Utilization”. While etelcalcetide was still indicated by the HCPCS code J0606, the utilization of cinacalcet is now indicated by corresponding NDCs or HCPCS code J0604 recorded on 72x claims.

Additionally, new codes are added to the code lists for ESA utilization and fracture to achieve a more comprehensive set of codes. The addition of new codes resulted in minor differences in the 2021 Q4 update compared to prior versions of the ESRD monitoring program. However, code changes did not result in different conclusions from previous updates of the ESRD monitoring program.