

ESRD Prospective Payment System (ESRD PPS)

Overview of 2011 - 2020 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 2020.

Since 2010, CMS has observed utilization for ESRD-related drugs, biologicals, and dialysis related procedures. CMS has also tracked general health outcomes including mortality, hospitalizations, and emergency department visits, as well as several ESRD-specific health outcomes including cardiovascular morbidity, vascular access complications, bone and mineral metabolism indicators, and fluid management indicators. Additionally, beginning in 2018, CMS has been monitoring utilization of drugs that are eligible for a Transitional Drug Add-on Payment Adjustment (TDAPA).

Outcomes described above were stratified into three groups by provider's ESRD Seamless Care Organization (ESCO) status, including: (1) providers who joined the Comprehensive ESRD Care (CEC) model during Phase 1, (2) providers who joined during Phase 2, and (3) providers who never joined. Phase 1 commenced in October 2015, while Phase 2 started in January 2017. The CEC model is an effort by CMS's Center for Medicare & Medicaid Innovation (CMMI) to test and evaluate new ways to improve and streamline care for ESRD beneficiaries. In the CEC model, dialysis facilities, nephrologists, and other providers can form an ESCO to formally coordinate care for ESRD patients.

While implementation of the ESRD PPS resulted in changes in the utilization of certain ESRD-related services and procedures, ongoing monitoring has overall revealed no sustained negative impacts in beneficiary health status from January 2011 to December 2020. Specific 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 2011 to December 2020 (with the exception of TDAPA drug utilization data, as that program started in January 2018). The baseline year 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 the months following this declaration. In particular, mortality among ESRD beneficiaries increased in

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

April 2020, while it decreased in April of other years. Additionally, the percentage of ESRD beneficiaries experiencing other outcomes markedly decreased in March and April of 2020.² These outcomes include Hospitalization, Emergency Department Visit, Skilled Nursing Facility (SNF), 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 use, the incidence of each of these outcomes then increases in the immediate following months. The decrease in overall hospitalizations during this period relative to previous years has been documented in other research, including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) identifying this trend among dialysis patients and Kaiser Family Foundation (KFF) identifying this trend for the overall population.^{3, 4} A decrease in hospitalizations could lead to a decrease in the incidence of outcomes that are generated from diagnosis and procedure codes on these claims.

Overview of the CMS-FDA Collaborative Assessment

In addition to implementation of the PPS, 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 cohort, which was January 1, 2008 to December 31, 2009, to outcomes 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 for patients who initiated dialysis after the policy and labeling changes. Overall, there was no change in other clinical outcomes including a composite 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.

The remaining sections of this document refer only to CMS's 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 Heist, T., [Schwartz](#), K., Butler, S. *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 12/31/2020

Claims Processed Through: 6/25/2021

Beneficiary Enrollment Through: 5/31/2021

Data Types: Original Medicare (Part A and Part B) Claims; Medicare Enrollment Data; CM/CMMI Central Repository of Alignment Files

Purpose: To summarize beneficiary health outcomes and utilization among the Medicare ESRD population (aged 18 years and older) from January 2011 to December 2020.

The key findings are organized by the following topic areas: General Morbidity & Mortality; Home Dialysis, Training, & Utilization of Home Dialysis 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 Transitional Drug Add-on Payment Adjustment (TDAPA) Drug Utilization. Service utilization and outcome data are stratified by ESCO participation status.

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 Facility ESCO Status

- ESCO Phase 1 Facility: dialysis facilities that joined an ESCO in 2015 or 2016 (i.e. Phase 1 of CEC Model)
- ESCO Phase 2 Facility: dialysis facilities that joined an ESCO in 2017 or later (i.e. Phase 2 of CEC Model)
- Non-ESCO Facility: dialysis facilities that never joined an ESCO in Phases 1 or 2

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.⁶
- Skilled Nursing Facility (SNF): As indicated by the service date of Skilled Nursing (SN) claim.

Home Dialysis, Training, & 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, national drug code, or ICD-9 or ICD-10 diagnosis 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.
- 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.⁷ 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.

⁶ Iterations of the PUF prior to the 2018 Q4 only looked at OP claims.

⁷ 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.

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.

TDAPA Drug Utilization

- Cinacalcet: As indicated by HCPCS code J0604.
- 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

Overall morbidity and mortality 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.

Seasonal trends in overall monthly mortality (i.e., higher mortality during winter months) are observed, however mortality incidence is flat overall from 2010 to early 2020. The percentage of ESRD beneficiaries dying then peaks in April 2020, with another noticeable increase at the end of the year. Beneficiaries who visited non-ESCO facilities had consistently higher percentages of mortality (1.7%) compared to beneficiaries who visited facilities participating in Phase 1 or Phase 2 ESCOs. Mortality percentages at these facilities hovered around 1% over the course of 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 before increasing in subsequent months. Percentages remained below 12% for the rest of the year until December, when approximately 12.4% of beneficiaries were hospitalized. This trend is generally consistent amongst beneficiaries at ESCO and non-ESCO facilities alike. 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; utilization began a slow decline in 2018, with approximately 4.2% of beneficiaries admitted to SNFs in December 2020. Monthly SNF utilization for beneficiaries who visited non-ESCO facilities remained slightly above that of beneficiaries who visited ESCO facilities (both Phase 1 and 2 ESCOs) in the CEC Model. Monthly emergency department visits, on the other hand, rose 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, before increasing again in the following months. Approximately

18.7% of beneficiaries were admitted to the emergency department in December 2020, which is lower than percentages observed prior to early 2020. Across the various ESCO categorizations, there was high overlap in emergency department trends.

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.⁸ 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 until early 2017. Since then, home dialysis utilization has gradually increased (with approximately 13.5% of beneficiaries using home dialysis at the end of 2020). This trend does not appear to have been affected by the implementation of the ESRD PPS. The same general trend was observed among beneficiaries at both ESCO and non-ESCO facilities. Home dialysis utilization among both beneficiaries who visited Phase 1 and Phase 2 ESCO facilities were approximately 6% in 2010 and increased to 10.7% for beneficiaries at Phase 1 ESCOs and 11.9% for beneficiaries at Phase 2 ESCOs in December 2020. Home dialysis utilization among beneficiaries who visited non-ESCO facilities was consistently 2-3% higher than utilization for those who visited ESCO facilities, starting at 8.6% of beneficiaries at the beginning of 2010 and rising to 13.9% in December 2020.

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. Home dialysis training and initiation percentages were similar between patients who received treatment at ESCO and non-ESCO facilities.

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 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 in the beneficiary population declined from 91.0% in 2010 to 83.1% in 2012. This percentage continued to decline to 74.9% by 2017 and generally remained at this level through 2019. ESA utilization was slightly lower in 2020, with about 72.7% of beneficiaries using ESAs on average. ESA utilization was similar among beneficiaries who visited ESCO facilities and non-ESCO facilities until early 2015, when utilization among beneficiaries who visited Phase 2 ESCOs declined more steeply relative to beneficiaries who visited Phase 1 ESCOs and non-ESCO

⁸ This includes both home hemodialysis (HD) and home peritoneal dialysis (PD).

participating facilities. 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 providers' ESCO participation status.

The overall monthly percentage of ESRD beneficiaries who receive blood transfusions has fluctuated since 2010 (average monthly percentage of 2.7%) and peaked in January 2013 at 3.76%. Since then, overall transfusion declined to 2.4% by December 2020. Transfusion percentages for beneficiaries who visited non-ESCO facilities were slightly higher than those for beneficiaries who visited ESCO facilities throughout the course of the study period.

As for cardiovascular outcomes, overall monthly stroke-related hospitalization incidence gradually decreased from 0.22% in 2010 to approximately 0.17% in October 2015. Incidence of stroke-related hospitalizations generally remain at this level through the end of 2020, with the exception of a brief dip to 0.15% in April 2020. The trends for stroke-related hospitalizations were similar across both ESCO categories and non-ESCO facilities. 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 is slightly lower in 2020, driven by a brief dip in April 2020. As with stroke-related hospitalization incidence, AMI-related hospitalization incidence was essentially the same across both ESCO categories and among non-ESCO beneficiaries.

The percentage of ESRD beneficiaries experiencing heart failure-related hospitalizations declined through late 2015, then increased through late 2016 to percentages similar to those observed for 2010. This trend was consistent among beneficiaries who visited both ESCO and non-ESCO facilities. 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. In 2020, incidence of heart failure-related hospitalizations was lower, particularly in April 2020.

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 through 2020, 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. The percentage of beneficiaries at non-ESCO facilities was slightly lower (1-2%) than that of beneficiaries who visited ESCO facilities (both Phase 1 and Phase 2) from 2010 to December 2020.

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 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 upper GI bleeding and ulcer outcomes in the 2020 Q4 update.

Average monthly fracture percentages for ESRD beneficiaries were 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%, while percentages in 2020 briefly dropped to 1.5% in April before rising to over 1.9% for much of the latter half of 2020. The drop in fracture percentages in late 2015 corresponds with the transition from ICD-9 to ICD-10 codes. Trends in fractures for beneficiaries at both ESCO and non-ESCO facilities followed this same general pattern.

The percentage of beneficiaries experiencing 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. Trends across beneficiaries at ESCO and non-ESCO facilities exhibit similar patterns. 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. This trend is generally consistent across beneficiaries who visited ESCO and non-ESCO participating facilities.

Fluid Management Related Events

Presented in this section are beneficiary outcomes related to fluid management, primarily congestive heart failure, fluid overload, and body fluid depletion. Refer to Appendix A for a summary of changes made to the Fluid Management outcomes in 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, driven by a dip in April 2020. Body fluid depletion percentages were similar among beneficiaries receiving care at ESCO and non-ESCO facilities during the first part of the study period, but ranged slightly higher among beneficiaries at non-ESCO facilities from early 2016 onward.⁹

⁹ When stratifying by ESCO status, since body fluid depletion is not commonly diagnosed in the ESRD population and there are not many ESCO facilities, changes in percentages can easily be influenced by the behavior of an individual facility or small group of facilities.

The percentage of beneficiaries experiencing fluid overload remained around 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 observes increased incidence 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 groups included, regardless of whether or not their facility participated in an ESCO. For both congestive heart failure and fluid overload, beneficiaries who visited non-ESCO facilities had slightly higher percentages than those observed for beneficiaries who visited ESCO facilities (both Phase 1 and Phase 2). Fluid overload incidence for beneficiaries who visited Phase 1 and Phase 2 ESCOs was similar from 2010 to December 2020, while percentages for beneficiaries who visited Phase 1 ESCOs were slightly lower than percentages for beneficiaries who visited Phase 2 ESCOs for congestive heart failure from 2013 to late 2018. From late 2018 onward, congestive heart failure incidence for beneficiaries who visited Phase 1 and Phase 2 ESCOs was similar. Overall incidence for both fluid overload and congestive heart failure were lower in 2020, driven by sharp decreases in April 2020.

TDAPA Drug Utilization

The Transitional Drug Add-on Payment Adjustment (TDAPA) has been in place since the start of 2018 and is designed to facilitate beneficiary access to certain new injectable, intravenous, or oral products by providing payment for these drugs, while data are being collected to incorporate the new drugs into the ESRD PPS. To this date, only cinacalcet (oral) and etelcalcetide (IV) have been eligible for a TDAPA, with their TDAPA eligibility period spanning 2018-2020.

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 remained at 20% through the end of 2020. 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 decreased slightly at the end of the study period, with approximately 8.3% of beneficiaries using it in December. When comparing use of TDAPA-eligible drugs by providers’ ESCO status, beneficiaries at non-ESCO participating facilities used less cinacalcet and more etelcalcetide throughout the study period compared to beneficiaries at ESCO facilities (both Phase 1 and Phase 2) in the CEC Model.

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.

Kidney stones are no longer monitored starting in the 2019 Q4 update of the ESRD claims-based monitoring program as they were in prior versions, as kidney stones were deemed by clinical experts not to be clinically relevant to patients receiving dialysis.

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 this 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.