ESRD Prospective Payment System (ESRD PPS)

Overview of 2011 - 2019 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 describes several key trends from January 2010 through December 2019.

Since 2010, CMS has observed utilization rates for ESRD-related drugs, biologicals, and dialysis related procedures. CMS has also tracked general health outcomes including mortality rates, 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 revealed no sustained negative impacts in beneficiary health status from January 2011 to December 2019. 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 2019 (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.

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. [1]

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.

Introduction

Observation Period: 1/1/2010 to 12/31/2019
Claims Processed Through: 1/8/2021
Beneficiary Enrollment Through: 12/31/2020
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 rates among the Medicare ESRD population (aged 18 years and older) from January 2011 to December 2019.

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

[1] 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.

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

- 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.[2]
- Skilled Nursing Facility (SNF): As indicated by the service date of Skilled Nursing (SN) claim.
- Death: As observed in the Medicare Enrollment Database.

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.csv and Codes_Anemia_Mgmt_Transfusion.csv.
- 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 position on the inpatient (IP) claim.[3] For the list of codes used to

[2] Iterations of the PUF prior to the 2018 Q4 only looked at OP claims.
[3] 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 rates.

define each outcome, please refer to Codes_Anemia_Mgmt_Stroke.csv, Codes_Anemia_Mgmt_Heart_Failure.csv, and Codes_Anemia_Mgmt_AMI.csv.
- 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.csv.

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.csv.
- Upper Gastrointestinal (GI) Bleeding/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.csv

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.csv.

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 rates 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 rates 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 rates are flat overall across the years included in the study period. Beneficiaries who visited non-ESCO facilities had consistently higher rates of mortality (1.7%) compared to beneficiaries who visited facilities participating in Phase 1 or Phase 2 ESCOs. Mortality rates at these facilities hovered around 1% over the course of the study period.

Overall monthly hospitalization rates declined from 2010 (14.3%) to 2015 (12.5%) and have remained stable ever since, with this trend being consistent amongst beneficiaries at ESCO and non-ESCO facilities

alike. Similar to mortality, overall monthly skilled nursing facility (SNF) rates fluctuate seasonally but remained mostly constant at just above 5% from 2010 through 2017; rates began a slow decline in 2018, with a rate of 4.5% observed in December 2019. Monthly SNF rates for beneficiaries who visited non-ESCO facilities remained slightly above rates for beneficiaries who visited ESCO facilities (both Phase 1 and 2 ESCOs) in the CEC Model. Monthly emergency department rates, on the other hand, have risen slightly from 19.1% in 2010 to just under 20% in 2019. Across the various ESCO categorizations, there was high overlap in emergency department rates.

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.[4] 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, rates have gradually increased (with an average monthly home dialysis rate of 12.1% in 2019). 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 slightly over 10% in December 2019. Home dialysis utilization rates among beneficiaries who visited non-ESCO facilities were consistently 2-3% higher than rates for those who visited ESCO facilities, starting at 8.6% at the beginning of 2010 and rising to 13% in December 2019.

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 rates 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 rates of vascular access complications.

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 rate continued to decline to 74.9% by 2017, and has remained at this level through December 2019. ESA utilization rates were 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

[4] This includes both home hemodialysis (HD) and home peritoneal dialysis (PD).

and non-ESCO 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 rate of 2.7%) and peaked in January 2013 at 3.76%. Since then, overall transfusion rates declined to 2.2% by December 2019. Transfusion rates 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 rates decreased slightly from 0.22% in 2010 to approximately 0.15% in 2019. Stroke-related hospitalization rates were similar across both ESCO categories and non-ESCO facilities. Overall rates of acute myocardial infarction (AMI) related hospitalizations have remained steady at 0.36% throughout the monitoring period. As with stroke-related hospitalization rates, AMI-related hospitalization rates were essentially the same across both ESCO categories and among non-ESCO beneficiaries.

Overall monthly rates of heart failure-related hospitalizations declined through late 2015, then increased through late 2016 to rates 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.

As for vascular access related events, the overall percentage of ESRD beneficiaries experiencing complications gradually decreased until late 2015, after which it remained relatively flat. The small (2%) decrease in rates in late 2015 corresponds with the transition from ICD-9 to ICD-10. Rates among beneficiaries who visited non-ESCO facilities were slightly lower (1-2%) than those for beneficiaries who visited ESCO facilities (both Phase 1 and Phase 2) from 2010 to December 2019.

Bone & Mineral Management Related Events, and Gastrointestinal Events

Presented in this section are beneficiary outcomes related to bone and mineral metabolism, primarily fractures and upper gastrointestinal (GI) bleeding/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.

Average monthly fracture rates for ESRD beneficiaries were around 2.5% from 2010 to October 2015, when rates dropped to approximately 1.8%, and remained at that level through 2018. In 2019, fracture rates rose slightly to about 2.0%. The drop in rates in late 2015 corresponds with the transition from ICD-9 to ICD-10 codes. Rates for beneficiaries at both ESCO and non-ESCO facilities followed this same general pattern. Overall monthly rates of upper GI bleeding/ulcers remained at 0.42% from 2010 to October 2015, after which rates rose to 0.50% for the rest of the study period. This trend is generally consistent across beneficiaries who visited ESCO and non-ESCO participating facilities. As with fracture rates, the change in upper GI bleeding/ulcer rates at October 2015 corresponds with the ICD-9 to ICD-10 transition.

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 has decreased only slightly from 1.2% at the time of PPS implementation to 0.9% during 2019. Body fluid depletion rates 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.[5]

Overall fluid overload rates remained around 5% to 6% from 2010 to late 2015, when rates increased to about 8%, corresponding with the ICD-9 to ICD-10 transition. Fluid overload rates have also increased since late 2016, as have congestive heart failure rates. 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 rates in 2016 through the end of the study period, December 2019. This increase from late 2016 is seen for all beneficiaries, regardless of whether or not their facility participated in an ESCO. For both congestive heart failure and fluid overload, rates for beneficiaries who visited non-ESCO facilities were slightly higher than rates for beneficiaries who visited ESCO facilities (both Phase 1 and Phase 2). Fluid overload rates for beneficiaries who visited Phase 1 and Phase 2 ESCOs were similar from 2010 to December 2019, while rates for beneficiaries who

[5] 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 rates can easily be influenced by the behavior of an individual facility or small group of facilities.

visited Phase 1 ESCOs were slightly lower than rates for beneficiaries who visited Phase 2 ESCOs for congestive heart failure from 2013 to late 2018. In late 2018 and 2019, congestive heart failure rates for beneficiaries who visited Phase 1 and Phase 2 ESCOs were similar.

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. During the study period, only Cinacalcet (oral) and Etelcalcetide (IV) were eligible for a TDAPA.[6]

From January 2018 to February 2018, the percentage of ESRD beneficiaries who used Cinacalcet increased by 4.5 percentage points (17.8% to 22.3%). Rates remained stable until July 2018, when the percentage of ESRD beneficiaries using Cinacalcet began to slightly decrease until it was about 20% in February 2019. Cinacalcet rates remained at 20% through December 2019. The percentage of ESRD beneficiaries who use Etelcalcetide gradually increased from 1% in January 2018 to over 8% in December 2019. 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.

[6] With the 2019 Q4 update, the names of these outcomes were changed from Sensipar and Parsabiv to Cinacalcet and Etelcalcetide, respectively. Cinacalcet includes utilization of the generic form of the drug.

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 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 rates 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.