ESRD Prospective Payment System (ESRD PPS)

Overview of 2011 - 2018 Claims-Based Monitoring Program

Since the implementation of the End-Stage Renal Disease Prospective Payment System (ESRD PPS) in January 2011, CMS has monitored outcomes for Medicare beneficiaries receiving outpatient maintenance dialysis. This document describes several key trends from 2011 through 2018.

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

Outcomes were also stratified by provider's ESRD Seamless Care Organization (ESCO) status, with the three groups being whether the provider joined the Comprehensive ESRD Care (CEC) model in Phase 1, joined in Phase 2, or 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 care for ESRD beneficiaries. In the CEC model, dialysis facilities, nephrologists, and other providers join together to coordinate care for ESRD patients, forming an ESCO.

While the ESRD PPS impacted utilization of certain ESRD-related services and procedures, CMS monitoring revealed no sustained negative changes in beneficiary health status from 2011 to 2018. Specific key findings from this monitoring are summarized throughout the document, organized by topic.

For each outcome, monthly data is presented for the year prior to the implementation of the ESRD PPS and for each month from January 2011 to December 2018 (with the exception of TDAPA drug utilization, which started in 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, which ranged from July 1, 2011, to June 30, 2013, with the exclusion of January 1, 2010, to June 30, 2011, as a transition period. [1]

This 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' claims-based monitoring program.

Introduction

Folder Name: ESRD_PPS_Public_Release_File_2018_Q4_ESCO
Upload Date: September 20, 2019
Observation Period: 1/1/2010 to 12/31/2018
Claims Processed Through: 06/29/2019
Beneficiary Enrollment Through: 5/31/2019
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 2011 to 2018.

The key findings are organized by the following topic areas: General Mortality & Morbidity; Home Dialysis, Training, & Onset; Anemia & Vascular Management; Bone & Mineral Management; Fluid Management; and TDAPA Drug Utilization.

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).

[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.

Splitting 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 (i.e. Phase 2 of CEC Model)
- Non-ESCO Facility: dialysis facilities that never joined an ESCO in Phases 1 or 2
- Beneficiaries are split based on the dialysis facility on their 72x claims in that month.

Outcome Definitions

General Mortality & Morbidity

- Death: As observed in the Medicare Enrollment Database.
- Hospitalization: As indicated by the service date of Inpatient (IP) claim.
- ED: As indicated by the service date of Outpatient (OP) claim with emergency department flag, or the service date of Inpatient (IP) claim with emergency department flag.[2]
- Skilled Nursing Facility (SNF): As indicated by the service date of Skilled Nursing (SN) claim.

Home Dialysis, Training, & Onset

- 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.

Anemia & Vascular Access Management

- 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 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.

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[2] Previous iterations of the PUF only looked at OP claims.

[3] Previous iterations of the PUF presented cumulative incident rates by yearly cohort for stroke, heart failure, and AMI. This iteration presents monthly rates.

Bone & Mineral Management

- Fracture and Kidney Stones: As indicated by the relevant procedure code or ICD-9 or ICD-10 diagnosis code. For the list of codes used to define each outcome, please refer to Codes_Bone_Mineral_Mgmt_Fracture.csv and Codes_Bone_Mineral_Mgmt_Kidney_Stones.csv.
- Peptic 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

- Congestive Heart Failure (CHF), Fluid Overload, and Dehydration: 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 Utilization

- Sensipar: As indicated by HCPCS code J0604.
- Parsabiv: 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 manual review. While some outcome rates experience changes 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 Mortality & Morbidity

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

The monitoring program observes seasonal trends in overall monthly mortality (i.e., higher mortality during winter months) but a generally flat rate across years during the study period. Beneficiaries who visited dialysis facilities not participating in an ESCO had consistently higher rates of mortality (1.7%) compared to beneficiaries who visited facilities participating in Phase 1 and Phase 2 ESCOs in the CEC Model, whose rates both 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 since then, with this trend being consistent across beneficiaries who visited dialysis facilities both participating and not participating in ESCOs in the CEC Model. Like mortality, overall monthly skilled nursing facility (SNF) rates fluctuate seasonally but remained mostly constant at just above 5% from 2010 through 2017; rates start to slowly decline in 2018, with about a 4.6% rate by the end of the year. Monthly SNF rates for beneficiaries who visited dialysis facilities not participating in ESCOs remained slightly above rates for beneficiaries who visited dialysis facilities participating in ESCOs (both Phase 1 and 2) in the CEC Model. Monthly emergency department rates, on the other hand, have risen slightly from 19.1% in 2010 to

19.7% in 2018. Across the various ESCO categorizations, there was high overlap in emergency department rates.

Home Dialysis, Training, & the Onset of Dialysis

This section presents data on the utilization of home dialysis. It also investigates rates 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 steadily increased from 8.3% in 2010 to 10.7% in 2014, when it plateaued until early 2017. Since then, rates have gradually increased (average monthly rate of 11.4% in 2018). This trend does not appear to have been affected by the implementation of the ESRD PPS. The same general trend was seen regardless of whether the beneficiary visited a dialysis facility participating in an ESCO or a facility not participating in an ESCO, in that rates increased from 2010-2014, plateaued until early 2017, and have gradually risen since. Rates for beneficiaries who visited dialysis facilities participating in Phase 1 ESCOs were similar to rates for beneficiaries who visited dialysis facilities participating in Phase 2 ESCOs in the CEC Model, starting at just over 6% in 2010 and increasing to about 9.2% by end of 2018. Rates for beneficiaries who visited facilities that did not participate in ESCOs in the CEC Model were consistently 2.5-3% higher than rates for beneficiaries who visited facilities that participated in ESCOs, starting at 8.5% at the beginning of 2010 and ending up at just over 12% at the end of 2018.

Data also reveal that beneficiaries in onset undergo home dialysis training and transition to home dialysis in the three months after the start of training at higher rates than those in the non-onset population. Rates between beneficiaries who visited facilities participating in ESCOs and beneficiaries who visited facilities not participating in ESCOs overlapped often over the course of the study period.

Anemia & Vascular Management

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) in the ESRD population, and rates of vascular access complications.

As a result of the PPS, overall ESA usage declined from 91.0% in 2010 to 83.1% in 2012. This rate continued to decline to 74.9% by 2017, and remained at this rate in 2018. Rates between beneficiaries who visited facilities participating in ESCOs and beneficiaries who visited facilities not participating in ESCOs are similar until early 2015, when the rates of beneficiaries who visited Phase 2 ESCOs decreased more compared to beneficiaries who visited Phase 1 ESCOs 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 10.5 in 2014 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 rates have declined and sit just above 2% by the end of 2018. Transfusion rates for beneficiaries who visited non-ESCO facilities were slightly higher than both beneficiaries who visited facilities participating in Phase 1 ESCOs and beneficiaries who visited Phase 2 ESCOs throughout the course of the study period.

As for cardiovascular outcomes, overall monthly stroke hospitalization rates have very slightly decreased from 0.20% in 2010 to about 0.16% in 2018. Regarding ESCO status, there was high overlap in stroke hospitalization rates between beneficiaries who visited dialysis facilities participating in ESCOs in the CEC Model and beneficiaries who visited non-ESCO facilities. Overall rates of acute myocardial infarction (AMI) hospitalization have remained steady at 0.36% throughout the monitoring period. As with stroke hospitalization rates, AMI rates for beneficiaries who visited facilities participating in ESCOs and beneficiaries who visited facilities not participating in ESCOs overlapped often during the study period. Overall monthly rates of heart failure hospitalizations declined until late 2015, and then increased to rates similar to those in 2010, a trend seen for all beneficiaries regardless of their providers' ESCO participation.

As for vascular access management, the overall percentage of ESRD beneficiaries experiencing complications each month has remained flat since 2010, although there is a small (2%) dip in rates that corresponds with the transition from ICD-9 to ICD-10. Rates for beneficiaries who visited non-ESCO participating facilities were slightly lower (1-2%) than rates for beneficiaries who visited ESCO participating facilities (both Phase 1 and Phase 2) from 2010-2018.

Bone & Mineral Management

Presented in this section are beneficiary outcomes related to bone and mineral metabolism, primarily fractures, kidney stones, and peptic ulcers.

Average monthly fracture rates for ESRD beneficiaries have been stable from 2010 through 2018, other than a small decrease (about 0.25%) that corresponds with the transition from ICD-9 to ICD-10. Rates for the various ESCO categorizations followed this same general pattern. Monthly kidney stone rates have risen gradually from 2010 (0.4%) through 2018 (0.7%), including a noticeable increase of about 0.1% at the ICD-9 to ICD-10 transition. Across beneficiaries who visited ESCO and non-ESCO participating facilities, there was high overlap in kidney stone rates throughout the study period. Overall monthly rates of peptic ulcers have remained stable at around 0.02% from 2010 through 2018, generally consistent across beneficiaries who visited ESCO and non-ESCO participating facilities.

Fluid Management

Presented in this section are beneficiary outcomes related to fluid management, primarily congestive heart failure, fluid overload, and dehydration.

The percentages of ESRD beneficiaries diagnosed with dehydration has gradually and slightly decreased from 0.8% at the time of PPS implementation to 0.6% in 2018. Regarding providers' ESCO status, there was high overlap in dehydration rates between beneficiaries who visited ESCO and non-ESCO participating facilities. As for congestive heart failure and fluid overload, rates have increased since late 2016. This observed increase could be due in part to 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 for treating several 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 2018. This increase from late 2016 is seen for all beneficiaries, regardless of whether or not their facility participated in an ESCO in the CEC Model. For both congestive heart failure and fluid overload, rates for beneficiaries who visited facilities not participating in ESCOs were slightly higher than rates for beneficiaries who visited facilities participating in ESCOs (both Phase 1 and Phase 2) in the CEC Model. Fluid overload rates for beneficiaries who visited Phase 1 and Phase 2 ESCOs were similar from 2010 to 2018, while rates for beneficiaries who visited Phase 1 ESCOs were slightly lower than rates for beneficiaries who visited Phase 2 ESCOs for congestive heart failure from 2013 onward.

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 allowing payment for these drugs, while data are being collected to incorporate the new drugs into the ESRD PPS. Currently, only Sensipar (cinacalcet, oral) and Parsabiv (etelcalcetide, IV) are eligible for a TDAPA.

From January 2018 to February 2018, the percentage of ESRD beneficiaries who used Sensipar increased by 4.5% (17.8% to 22.3%). Rates remained stable until July, when the percentage of ESRD beneficiaries using Sensipar began to slightly decrease until it was 20.8% in December 2018. The percentage of ESRD beneficiaries who use Parsabiv gradually increased from 1% in January 2018 to about 6% at the end of 2018. When comparing by providers' ESCO status, beneficiaries at non-ESCO participating facilities used less Sensipar and more Parsabiv in 2018 than beneficiaries who visited dialysis facilities participating in ESCOs (both Phase 1 and Phase 2) in the CEC Model.