

ESRD Prospective Payment System (ESRD PPS)

Overview of 2011 - 2017 Claims-Based Monitoring Program

Since the implementation of the 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 2017.

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.

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 2017. 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 2017. 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 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.

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.

Introduction

Folder Name: ESRD_PPS_Public_Release_File_2017_Q4

Upload Date: August 23, 2018

Observation Period: 1/1/2010 to 12/31/2017

Claims Processed Through: 06/29/2018

Beneficiary Enrollment Through: 5/31/2018

Data Types: Original Medicare (Part A and Part B) Claims; Prescription Drug (Part D); Medicare Enrollment Data

Purpose: To summarize beneficiary health outcomes and utilization rates among the Medicare ESRD population (aged 18 years and older) from 2011 to 2017.

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

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 maintenance dialysis 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).

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

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 and second positions on the claim form for AMI, and the first position for stroke and heart failure. 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 Complication: As indicated by the ICD-9 or ICD-10 diagnosis code. For the list of codes, please refer to Codes_Vascular_Access.csv.

Home Dialysis, Training, & Onset

- Home Dialysis: As indicated by the relevant procedure code or related condition code. For the list of codes, please refer to Codes_Home_Dialysis.csv.
- Training: As indicated by Related Condition Code 73 on 72x claims.
- Onset Period: The beneficiary's first 120 days of Medicare-insured maintenance dialysis.

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

- Chronic 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.

Limitation

- For all outcomes defined by ICD diagnosis or procedure codes, outcome rates may be impacted 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

General mortality and morbidity outcomes are presented in this section as overarching measures of ESRD beneficiary health status under the ESRD PPS. 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 monthly mortality (i.e., higher mortality during winter months) but a generally flat rate across years during the study period. Monthly hospitalization rates declined from 2010 (14.3%) to 2015 (12.4%) and have remained stable since then. Like mortality, monthly skilled nursing facility rates fluctuate seasonally but have remained mostly constant year-to-

year at just above 5%. Monthly emergency department rates, on the other hand, have risen slightly from 10.7% in 2010 to 12.1% in 2017.

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, ESA usage declined from 91.0% in 2010 to 83.1% in 2012. This rate continued to decline to 74.9% by 2017. 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.

The monthly percentage of ESRD beneficiaries who receive blood transfusions has fluctuated since 2010 and peaked in 2012. Since then, rates have declined since early 2013 and sit just above 2% by the end of 2017.

Finally, though anemia treatment patterns changed throughout the monitoring period, the cumulative percentage of beneficiaries experiencing stroke has declined each year from 2007 through 2017 while the percentage experiencing acute myocardial infarctions has stayed relatively flat. Cumulative rates of heart failure declined until 2015, but have since risen. However, 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 in order to justify this excess dialysis, the heart failure 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 and 2017.

Unlike the other outcomes presented, the Stroke, Heart Disease, and AMI data are cumulative. Each CSV file follows ten cohorts comprised of beneficiaries undergoing outpatient maintenance dialysis in each January from 2007 through 2017. Downward trends are indicated if the rates for a particular cohort are lower than the cohorts from past Januaries. Similarly, upward trends are indicated if the rates for a particular cohort are higher than cohorts from past Januaries. The beneficiary cohorts were not adjusted for underlying differences in health status or treatment patterns.

As for vascular access management, the 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.

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 first 120 days of Medicare-insured maintenance hemodialysis.

The average monthly percentage of ESRD beneficiaries utilizing home dialysis steadily increased from 8.3% in 2010 to 10.6% in 2014. Since then, growth has slowed and the rate currently sits at 11.0% in 2017. This trend does not appear to have been affected by the implementation of the ESRD PPS.

Data also reveal that beneficiaries in onset undergo home dialysis training and transition to home dialysis at rates that are higher than those in the non-onset population.

Bone & Mineral Management

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

The monitoring program found no change in these adverse health conditions as a result of implementation of the ESRD average monthly PPS; outcome trends have been stable from 2010 through 2017. Once again, small changes in the monthly fracture rate (0.25% decrease) and monthly kidney stone rate (0.1% increase) correspond with the transition from ICD-9 to ICD-10 but do not impact overall trends.

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 remained stable from implementation of the PPS through 2017. As for congestive heart failure and fluid overload, rates have increased in 2016 and 2017, potentially for the same reason as described above in the Anemia and Vascular Management Section. ICD-10 diagnosis codes used to define these conditions are included in the list of codes that can be recorded on the 72x claim to justify additional dialysis.