ESRD Prospective Payment System (ESRD PPS)

# Overview of 2011 - 2016 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 January 2011 through June 2016.

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 January 2011 to June 2016. 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 June 2016. 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]](#footnote-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\_2016\_Q2

Upload Date: November 21, 2016

Observation Period: 1/1/2010 to 6/30/2016

Claims Processed Through: 11/4/2016

Beneficiary Enrollment Through: 10/31/2016

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 2016 Q2.

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

* ESRD Population: All persons who were enrolled in Medicare A/B FFS during the month of observation AND had 1 or more ‘type 72x’ claims 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 on Medicare A/B FFS claims, including ‘type 72x’ claims, for ESA-treated beneficiaries in the ESRD population. In cases where hematocrit was reported instead of hemoglobin, the value was converted by dividing the hematocrit 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 procedure code or related condition code. For the list of codes, please refer to Codes\_Home\_Dialysis.csv.
* Training: As indicated by the related condition code “73”.
* 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, which requires separate outcome definitions that may not be perfectly clinically compatible. 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 found a slight declining trend in monthly mortality rates from 1.7% in 2010 to 1.6% through the second quarter of 2016. Hospitalization rates also declined from 2010 to 2016, from 14.3% to 12.6%. Skilled nursing facility utilization has remained mostly constant, just above 5%. Emergency department rates, on the other hand, have risen slightly from 10.7% in 2010 to 11.8% in mid-2016.

It is important to note that mortality and morbidity rates generally display seasonal trends; the first quarter of each year typically has elevated rates.

# 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 in 2013 (80.9%), and has since slowed. By 2016, the percentage of ESRD patients receiving ESAs has dipped below 80%. 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 below 3% in 2016.

Finally, though anemia treatment patterns changed throughout the monitoring period, the cumulative percentage of beneficiaries experiencing stroke and heart failure declined each year from 2007 through 2015. These declines were gradual and did not correspond with the implementation of the ESRD PPS. In contrast, cumulative rates of acute myocardial infarctions (AMI) are consistent between pre-PPS and post-PPS ESRD cohorts.

Note: In this section, heart failure is defined using diagnoses in the first diagnosis position on the claim form, while congestive heart failure in the Fluid Management section is defined using diagnoses in the first nine positions. Additionally, the two outcomes do not have exact diagnosis code definitions, so rates will differ.

Note: Unlike the other outcomes presented, the Stroke, Heart Disease, and AMI data are cumulative. Each CSV file follows nine cohorts comprised of beneficiaries undergoing outpatient maintenance dialysis in each January from 2007 through 2016. Downward trends are indicated if the rates for a particular cohort are lower than the cohorts from past Januarys. Similarly, upward trends are indicated if the rates for a particular cohort are higher than cohorts from past Januarys. 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 averaged 15.4% in 2010 and has declined slightly in the following years. Average monthly rates sit at 13.1% in 2016.

# 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 10.8% in 2016. This trend does not appear to have been affected by the implementation of the ESRD PPS.

Data also revealed 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.

Note: Since the Training and Home Dialysis analyses looks three months into the future, data is provided through March 2016 rather than June 2016. ESRD beneficiaries in this analysis are enrolled in the current month as well as the subsequent three months.

# 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. The rates of these outcomes have maintained similar to their 2010 levels through the second quarter of 2016.

# 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 congestive heart failure or dehydration diagnoses have remained stable since implementation of the PPS. Fluid overload, however, has increased slightly since 2010. In the year prior to PPS implementation, the occurrence rate was 5.5%; the average rate in 2016 is 6.2%.

Note: In this section, congestive heart failure is defined using diagnoses in the first nine diagnosis positions on the claim form, while heart failure in the Anemia & Vascular Management section is defined using diagnoses in the first position only. Additionally, the two outcomes do not have exact diagnosis code definitions, so rates will differ.

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. [↑](#footnote-ref-1)