

Anemia Prevalence and Treatment Patterns in Non-Dialysis-Dependent Chronic Kidney Disease Patients Before and After Revised FDA Label and Anemia Guidelines for Erythropoiesis-Stimulating Agents

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Introduction

- Anemia is common among patients with chronic kidney disease (CKD); treatment usually consists of an erythropoiesis-stimulating agent (ESA), iron, and/or red blood cell (RBC) transfusion.
- Three events in 2009-2011 potentially shaped the landscape of anemia treatment in stage 3-5 non-dialysis-dependent (NDD)-CKD patients: the Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT), the Food and Drug Administration (FDA) revised label for ESAs, and release of new Kidney Disease: Improving Global Outcomes (KDIGO) anemia treatment guidelines.
- Few data examine the effect of these events on anemia treatment patterns in NDD-CKD patients.

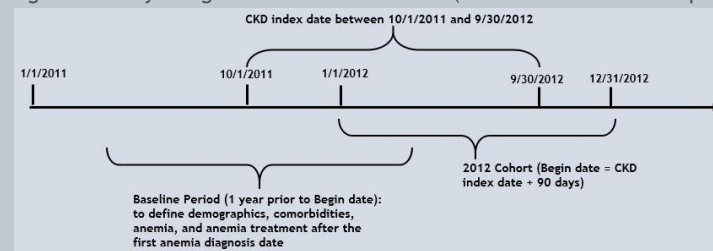
Objective

- To examine anemia prevalence and treatment patterns before and after the TREAT study, the FDA revised label for ESAs, and release of new KDIGO anemia treatment guidelines for stage 3-5 NDD-CKD patients.

Methods

- The MarketScan database, containing inpatient and outpatient health care claims and medications, was used to identify stage 3-5 NDD-CKD patients aged 18-63 years.
- Two study cohorts were created: 2008 and 2012, consisting of patients identified from 2007-2008 and 2011-2012 claims, respectively.
- CKD stage, anemia, and comorbid conditions were defined from ICD-9-CM diagnosis codes on one or more inpatient claims or two or more outpatient claims on different dates within 365 days (Figure 1).
 - Anemia was defined by diagnosis codes due to lack of hemoglobin values in the database.
- Anemia prevalence and treatment patterns in each cohort were characterized.
- ESA, intravenous (IV) iron, and RBC transfusion (at least one transfusion) use and time to use were evaluated from the date of anemia diagnosis during the baseline year in each cohort.
- Consistent ESA treatment was defined as ≥ 1 monthly administration of ESA in $\geq 80\%$ of 12 follow-up months; inconsistent treatment was defined as ESA use in $>0\%$ and $<80\%$ of follow-up months.

Figure 1: Study Design for Each Cohort Period (2012 Cohort as an Example)



Results

- The 2008 and 2012 cohorts included 6,425 and 15,716 stage 3-5 NDD-CKD patients with anemia, respectively (Table 1).
- Anemia prevalence was 29% in the 2008 cohort and 28% in the 2012 cohort.
- Comparing 2012 with 2008, we observed the following regarding anemia treatment rates (Figure 2 and Table 2):
 - ESA treatment declined by 62% (28.4% to 10.8%).
 - IV iron use increased by 24% (7.6% to 9.4%).
 - RBC transfusion use increased by 16% (10.1% to 11.7%).
- The greatest decline in ESA use and the greatest increase in IV iron use in 2012 vs. 2008 were among stage 4-5 NDD-CKD patients (Table 2).
- The largest increase in RBC transfusion use in 2012 compared with 2008 was among stage 4-5 CKD patients (Table 2).
- In 2008, 7.7% of stage 3-5 NDD-CKD patients received consistent ESA treatment, declining to 2.6% in 2012 (Figure 3).
- Median time to treatment initiation from anemia diagnosis nearly tripled for ESAs (8 to 21 days), increased by 10 days for IV iron (34 to 44 days), and decreased by 4 days for RBC transfusions (37 to 33 days).

Conclusions

- This is the first study to report on the effect of the TREAT study and FDA and KDIGO actions on anemia treatment patterns in commercially insured stage 3-5 NDD-CKD patients.
- Anemia prevalence remained stable in the 2008 and 2012 cohorts.
- ESA use decreased by 62% from 2008 to 2012; use of IV iron and RBC transfusions increased by 24% and 16%, respectively.

Table 1: Patient Characteristics and Comorbid Conditions in Stage 3-5 NDD-CKD Patient with Anemia (2008 and 2012 Cohorts)

	2008 Cohort	2012 Cohort
N of Patients	6,425	15,716
Age, %		
18-44 yrs.	10.6	11.0
45-54 yrs.	24.4	23.9
55-59 yrs.	29.1	28.3
60-63 yrs.	35.9	36.8
Gender, % Female	54.6	52.1
Comorbidity, %		
Atherosclerotic heart disease	23.2	23.6
Congestive heart failure	20.7	21.4
CVA/TIA	9.3	10.0
Peripheral vascular disease	15.7	19.1
Cardiac (other)	21.0	23.5
COPD	12.3	15.7
Gastrointestinal bleeding	8.3	8.9
Liver disease	5.1	7.1
Dysrhythmia	14.9	19.5
Cancer	12.9	14.2
Diabetes	54.8	52.5
Hypertension	76.1	85.4

CVA/TIA: cerebrovascular disease/transient ischemic attack
COPD: chronic obstructive pulmonary disease

Table 2: Anemia Treatment by Stage in Baseline Year of 2008 and 2012 Cohorts of Stage 3-5 NDD-CKD Patients with Anemia

	2008 Cohort CKD Stage				2012 Cohort CKD Stage			
	3-5	3	4	5	3-5	3	4	5
Total N	6,425	3,409	1,811	1,205	15,716	9,519	3,713	2,484
Patients with the following treatment, %								
ESA	28.4	21.7	34.4	38.3	10.8	6.5	15.7	19.9
IV iron	7.6	6.7	8.4	9.1	9.4	7.8	11.3	12.9
RBC	10.1	9.4	9.6	12.7	11.7	10.9	11.7	15.0
Any	37.7	31.0	43.2	48.4	26.2	21.3	31.1	37.4

RBC: red blood cell transfusion

Figure 2: Anemia Treatment in Baseline Year of 2008 and 2012 Cohorts of Stage 3-5 NDD-CKD Patients with Anemia

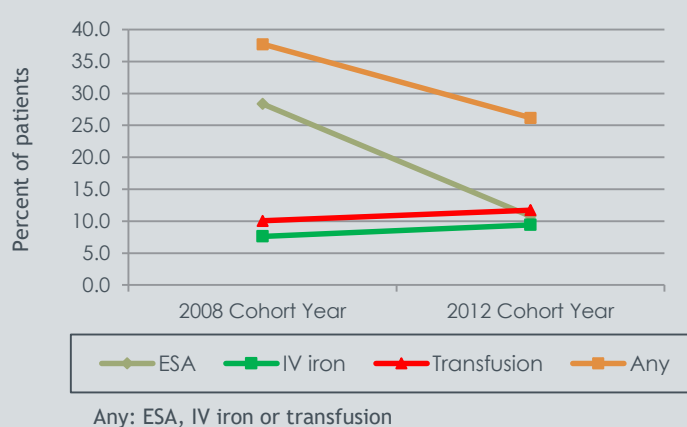


Figure 3: ESA Treatment Patterns in Stage 3-5 NDD-CKD Patients with Anemia in 2008 and 2012 Cohorts

