# TSAT and Serum Ferritin Increases Associated with Ferric Citrate Use May Lead to Dialysis Cost Savings

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## Introduction

- Ferric citrate, an investigational phosphate binder (PB) for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) has been shown in clinical trials to increase serum ferritin (SF) and saturated transferrin (TSAT), reducing erythropoiesis-stimulating agent (ESA) and intravenous iron (IV Fe) use in patients receiving ferric citrate.[1]
- ***We conducted a retrospective analysis of changes in ESA and IV Fe doses made by physicians in response to non-treatment-related increases in patients' SF and TSAT, and used the data to calculate the potential cost savings associated with ferric citrate use compared to alternative PBs.***

## Methods

- We retrospectively analyzed electronic medical records of ESRD patients (6/1/2008-5/31/2010) experiencing non-treatment-related concurrent rises in SF and TSAT [ TSAT (> 10%) and SF (15% to 25%)]. The magnitude of these rises have been associated with the use of ferric citrate in clinical trials.[2]
- Eligible patients were 18 years old; prescribed a PB; on dialysis > 120 days; without significant change in IV Fe or ESA dose (-30% to 10%) from the prior month; and without change in PB type.
- Per session ESA and IV Fe use was compared for 60 days before and after the index date.
- We constructed a cost-offset model for ferric citrate use in moderate and high ESA users considering PB, ESA, and IV Fe costs.
- The model assumed equivalency in price and efficacy between ferric citrate and comparator PBs to manage bone and mineral disease.
- Per patient monthly costs were calculated for ferric citrate and the comparator PBs.
- Costs for PBs, ESAs, and IV iron were derived from 2011 published sources.[3,4]
- Results are reported for the overall study population, and according to baseline resource use groups:
  - ESA dose per session: lowest (1 to < 2000 units), low (2000 to < 4500 units), moderate (4500 to < 9000 units), and high (≥ 9000 units)
  - IV Fe dose: 0 to < 16 mg, 16 to < 32 mg, and ≥ 32 mg

## Results

### *Table 1. Patient Demographics*

| General | N | Mean (SD) |
|---|---|---|
| Age in years | 1,983 | 63.2 (14.5) |
| Vintage in years | 1,940 | 5.32 (3.5) |
| Race | n | % |
| White | 819 | 41.3 |
| Black | 755 | 38.1 |
| Hispanic | 237 | 12.0 |
| Asian | 70 | 3.5 |
| Primary cause ESRD | n | % |
| Diabetic kidney disease | 906 | 45.7 |
| Hypertensive | 564 | 28.4 |

### *Table 2: Patient Proportions for ESA and IV Fe Dosing at Baseline**

| Baseline iron dose group (mg) | Baseline ESA Dose Group (Units) Lowest 1-< 2000 | Low 2000-< 4500 | Moderate 4500-< 9000 | High ≥ 9000 | All |
|---|---|---|---|---|---|
| 0 to < 16 | 221 (10.84) | 235 (11.53) | 150 (7.36) | 92 (4.51) | 698 (34.26) |
| 16 to < 32 | 197 (9.67) | 243 (11.92) | 196 (9.62) | 137 (6.72) | 773 (37.94) |
| ≥ 32 | 51 (2.50) | 123 (6.03) | 148 (7.26) | 244 (11.98) | 566 (27.78) |
| All | 469 (23.02) | 601 (29.50) | 494 (24.25) | 473 (23.22) | 2037 (100) |

**Numerals in parentheses indicate the percentage of patients in each baseline dose group*

### *Table 3: Absolute Changes in ESA and IV Fe Dosing by Baseline Groups**

| Baseline IV Fe dose group (mg) | | Baseline ESA Dose Group (Units) Lowest 1-< 2000 | Low 2000-< 4500 | Moderate 4500-< 9000 | High ≥ 9000 | All |
|---|---|---|---|---|---|---|
| 0 to < 16 | ESA | +772.1 (1,484.0) | +660.5 (2,456.6) | +51.8 (2,662.9) | -888.2 (4,811.6) | +360.9 (2,751.4) |
| | Fe | -0.92 (5.75) | -0.98 (4.66) | -0.07 (6.68) | -0.23 (8.81) | -0.67 (6.13) |
| 16 to < 32 | ESA | +542.0 (1,485.4) | -51.0 (1,884.7) | -1,081.8 (2,675.0) | -1,328.6 (4,079.2) | -387.7 (2,635.9) |
| | Fe | -4.23 (8.53) | -3.76 (9.50) | -3.38 (8.78) | -4.54 (11.01) | -3.92 (9.37) |
| ≥ 32 | ESA | +226.7 (1,197.6) | -274.0 (1,659.6) | -1,332.8 (3,174.6) | -3,080.7 (5,583.8) | -1,715.7 (4,288.3) |
| | Fe | -15.19 (16.05) | -13.16 (17.93) | -11.32 (17.36) | -17.33 (22.05) | -14.66 (19.65) |
| All | ESA | +616.1 (1,463.9) | +181.6 (2,121.5) | -812.8 (2,883.7) | -2,146.7 (5,124.8) | -500.2 (3,316.5) |
| | Fe | -3.87 (9.57) | -4.60 (11.43) | -4.75 (12.42) | -10.30 (18.85) | -5.79 (13.62) |

**Values shown are mean ± (SD)*

## Conclusions

- Physicians responded to non-treatment related rises in SF and TSAT by reducing ESA and IV Fe doses
  - Mean reductions in ESA (500 U) and Fe (5.79 mg) dose per dialysis session were observed for the overall study population.
    - ESA reductions were greater for patients with the highest mean baseline ESA doses.
- For moderate and high ESA users, the estimated monthly cost savings due to reductions in ESA and IV Fe were $123 and $315, respectively.
- For a dialysis clinic with 96 patients, assuming 70% of patients are prescribed PBs, the monthly savings would be $6,071 with ferric citrate use compared to alternative PBs.

## References

1. Sika M et al. *J Am Soc Nephrol.* 2010;21,783A.
2. Niecestro R et al. *J Am Soc Nephrol.* 2006;17:76A/
3. Red Book Thompson Reuters. http://www.redbook.com/redbook/index.html Accessed May 24, 2011.
4. Center for Medicare and Medicaid Services. July 2011 ASP Pricing file. https://www.cms.gov/McrPartBDrugAvgSalesPrice/01a18_2011ASPFiles.asp Accessed July 2011.

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