

Calcimimetic Use in United States (US) Hemodialysis Facilities in First Two Years after Launch of Etelcalcetide

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INTRODUCTION

- A common complication of end-stage kidney disease (ESKD) is secondary hyperparathyroidism (SHPT), characterized by elevated parathyroid hormone (PTH) leading to increased risk of fractures and cardiovascular morbidity.
- Calcimimetics, oral cinacalcet and intravenous etelcalcetide, reduce PTH levels.
- This study aimed to understand the utilization patterns and key mineral lab outcomes among patients initiating calcimimetic use in a real-world setting during the first 2 years of Medicare's Transitional Drug Add-on Payment Adjustment (TDAPA), an add-on payment for calcimimetics to Medicare's ESKD bundled payment for dialysis.

METHODS

1. **Persistent Sub-Cohort** defined as patients with continuous use of a single calcimimetic for 15 months of follow-up;
 2. **Treatment Change Sub-Cohort** defined as patients who changed from cinacalcet to etelcalcetide after ≥ 2 months on cinacalcet before changing and remained on etelcalcetide for ≥ 2 months after changing.
- The sample of patients changing from etelcalcetide to cinacalcet was too small for analysis.
 - PTH, phosphorus and corrected calcium levels were reported at baseline and for each month of follow-up as well as the proportion of patients in-target on PTH (<600 pg/ml) for each month of follow-up.
 - Calcimimetic doses were also calculated for each month of follow-up

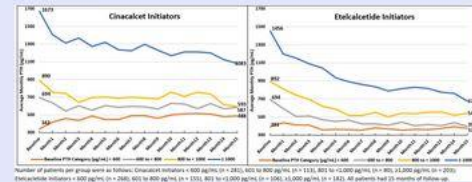
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RESULTS

Characteristic	Full Study Cohort: Initiators		Sub-Cohort: Persistent Users		Sub-Cohort: Change Cinacalcet to Etelcalcetide
	Cinacalcet	Etelcalcetide	Cinacalcet	Etelcalcetide	Cinacalcet to Etelcalcetide
Number of patients	677	711	222	424	183
Age, years, mean (SD)	61.6 (13.7)	63.4 (14.5)	62.0 (14.1)	63.7 (14.7)	60.1 (13.1)
Men, %	60%	55%	64%	55%	62%
Race, %					
White	32%	38%	32%	36%	29%
Black	49%	41%	41%	44%	57%
Other	13%	10%	19%	9%	10%
Missing	6%	11%	8%	11%	4%
Years on dialysis, mean (SD)	5.9 (4.5)	5.2 (4.4)	5.6 (4.4)	5.5 (4.4)	6.7 (5.1)
Baseline PTH (pg/mL), %					
<600	41%	38%	46%	37%	31%
600 to <800	17%	22%	19%	22%	15%
800 to <1000	12%	15%	8%	15%	16%
≥ 1000	30%	25%	27%	26%	38%
Mean (SD) Baseline Labs					
PTH (pg/mL)	864 (696)	804 (524)	767 (603)	825 (577)	1050 (784)
Phosphorus (mg/dL)	5.9 (1.6)	5.9 (1.6)	5.9 (1.5)	6.0 (1.6)	6.1 (1.7)
Corrected Calcium (mg/dL)	9.3 (0.8)	9.4 (0.6)	9.3 (0.8)	9.5 (0.6)	9.4 (0.7)
Average Weekly Dose (mg) Month 1 from Index Date	288.4	11.8	288.6	12.3	315.5

- For the full initiator cohort, all PTH sub-groups achieved average PTH <600 pg/mL by month 15 except for patients who initiated at PTH ≥ 1000 pg/mL (Figure 1).

Figure 1. Mean PTH by Month, by Baseline PTH Category and First Calcimimetic Used: Full Cohort



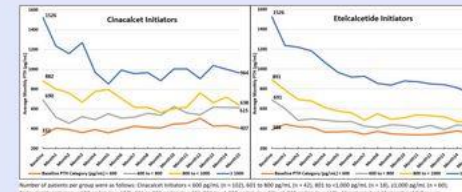
- By month 15 of follow-up, the proportion of initiators with baseline PTH ≥ 1000 who were in-target on PTH reached 58% for etelcalcetide and 41% for cinacalcet (Figure 2).
- The PTH ≥ 1000 sub-group had the poorest results on phosphorus and corrected calcium, with only 30%-45% of patients in target range of 3.5-5.5 mg/dL for phosphorus and 62%-81% of patients in target range of 8.4-10.2 mg/dL for corrected calcium each month (data not shown).

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RESULTS (continued)

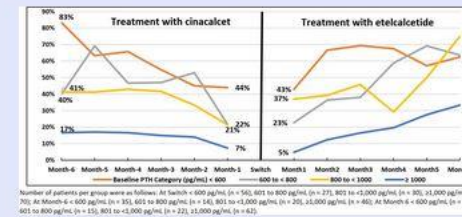
...with a 37% decline for cinacalcet patients and a 51% decline for etelcalcetide patients by month 15. (Figure 3).

Figure 3. Mean PTH by Month, by Baseline PTH Category and First Calcimimetic Used: Persistent Cohort



- Over 15 months of follow-up, the average calcimimetic doses were 48% higher for cinacalcet patients and 25% higher for etelcalcetide patients who started at baseline PTH ≥ 1000 when compared to patients started at baseline PTH 600 to <800 (data not shown).
- In the Treatment Change cohort, the percent of patients in target on PTH generally declined in the last 6 months on cinacalcet, but increased steadily after the change to etelcalcetide (Figure 4).

Figure 4. Proportion in Target for PTH (<600 pg/mL): Pre- and Post-Treatment Change (Cinacalcet to Etelcalcetide)



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DISCUSSION

- This study describes recent real-world use of calcimimetics in hemodialysis patients following the introduction of etelcalcetide and TDAPA reimbursement for calcimimetics in the US.
- This is the first study to report long-term follow-up (15 months) in a real-world cohort of etelcalcetide initiators.
- Regardless of calcimimetic used, patients initiating use at higher baseline PTH had poorer biochemical control than patients starting at lower PTH and required higher average calcimimetic doses, which translates to higher costs of managing SHPT than for patients initiated at lower baseline PTH.
- Patients whose treatment was changed from cinacalcet to etelcalcetide had improvements in PTH control post-treatment change, which may be

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CONCLUSIONS

- In small dialysis organizations, current management of SHPT with calcimimetics may be suboptimal especially for the 28% of patients initiating calcimimetics with PTH elevated above 1000 pg/mL.
- This situation may worsen in the near future with the recent reimbursement change for calcimimetics as they are now included in the Medicare PPS ESKD bundle rather than reimbursed on a fee-for-service basis as during this study.
- Real-world results reinforce the effectiveness of etelcalcetide for up to 15 months in all baseline PTH sub-groups.