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Calcimimetic Use in Dialysis-Dependent Medicare Fee-for-Service Beneficiaries and Implications for Bundled Payment

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Abstract

Background Patients who are dialysis dependent and have secondary hyperparathyroidism (SHPT) may require calcimimetics to reduce parathyroid hormone levels to treatment goals. Medicare currently uses the Transitional Drug Add-on Payment Adjustment (TDAPA) designation under the ESKD Prospective Payment System ("bundled payment") to pay for calcimimetics (the first products eligible for the adjustment); this payment designation for calcimimetics is expected to conclude after 2020. This study explores variability in calcimimetic use across key patient characteristics and its potential effect on policy options for incorporating calcimimetics permanently into the bundle.

Methods This descriptive analysis used the 100% sample of Medicare FFS Part B (outpatient) 2018 claims to describe national-, regional-, and patient-level variation (including race, dual eligibility, and dialysis vintage) in calcimimetic use among beneficiaries who are dialysis dependent.

Results A total of 373,874 beneficiaries were analyzed, 28% had ≥90 days of calcimimetic use during 2018. At the national level, the proportion of patients on dialysis using calcimimetics was roughly 80% higher in Black versus non-Black patients on dialysis, 30% higher in patients on dialysis who were dual eligible versus non–dual eligible, and three times higher in patients with a dialysis vintage ≥3 years versus <3 years (all results unadjusted). Calcimimetic use was similar across census regions, however, substantial variation in calcimimetic use was observed at the facility level. Medicare spending for calcimimetic therapies as a proportion of total Medicare dialysis spending was >10% in approximately 20% of dialysis facilities.

Conclusions Although less than a third of beneficiaries use calcimimetics, certain patient-level characteristics are associated with higher rates of maintenance calcimimetic use. Due to the financial pressure many dialysis facilities face, how calcimimetics are incorporated into the bundle may have a direct effect on facility reimbursement for, and patient access to, therapy. Careful consideration will be required to ensure patients who are vulnerable and require treatment for SHPT do not face barriers to appropriate care.

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Introduction

As implemented by the Centers for Medicare and Medicaid Services (CMS) in the 2011 Medicare Program ESKD Prospective Payment System (PPS) Final Rule, Medicare provides a bundled payment to dialysis facilities for patients receiving maintenance dialysis (1). Unlike other outpatient Medicare payment systems that are on the basis of provider costs that are routinely calibrated to ensure payment rates are aligned relative to costs, Congress directed CMS to create a single, bundled, ESKD PPS payment for dialysis care that is updated only for market-basket adjustments through the CMS rulemaking cycle each year. This bundled payment includes most renal dialysis services furnished to ESKD beneficiaries receiving outpatient maintenance dialysis. The ESKD PPS is designed to mitigate potential disparities across the population of patients on dialysis and dialysis facilities *via* a patient- and facility-adjusted payment per treatment, which covers the cost of most drugs, laboratory services, supplies, and capital-related costs related to furnishing maintenance dialysis.

To account for new and innovative therapies within the bundled-payment system, in 2016 Medicare established a new temporary payment adjustment to the ESKD bundled rate for qualified, newly approved drugs and biologics—the Transitional Drug Add-on Payment Adjustment (TDAPA)—that would be

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applicable for a minimum of 2 years, or until sufficient cost and utilization data would be available for Medicare to incorporate it into the ESKD PPS payment (CMS 2015) (2). In the 2019 rulemaking cycle, CMS expanded TDAPA eligibility to include new renal dialysis drugs within existing functional categories. Calcimimetics, the first drugs to be eligible for TDAPA, are a class of drugs indicated for the treatment of secondary hyperparathyroidism (SHPT) associated with CKD. This includes orally administered cinacalcet (approved in 2004) and intravenous (IV)-based etelcalcetide (approved in 2017), which have been eligible for the TDAPA since 2018 (3). At the time the ESKD PPS payment was implemented in 2011, only oral cinacalcet was available. It was excluded from the ESKD PPS at the time because it did not yet have an IV equivalent. Following the Food and Drug Administration (FDA) approval of IV-based etelcalcetide, calcimimetic products were included in ESKD PPS, starting in January 2018, with CMS granting the TDAPA to both products for a minimum of 2 years. Generic cinacalcet was approved by the FDA in 2018 and has been eligible for TDAPA since entering the market.

In the 2020 rulemaking cycle, CMS confirmed that the calcimimetic therapies would be eligible for a third year of TDAPA (*i.e.*, for 2020) (4). CMS has indicated that it will use the TDAPA period to collect data on use, payment patterns, and beneficiary cost-sharing amounts of both oral and IV forms of calcimimetics. CMS plans to use these data to inform incorporation of calcimimetics into the bundle, including adjusting the base rate of the ESKD PPS bundle to include calcimimetics (2). On July 6, 2021, CMS released the 2021 ESKD PPS proposed rule, which proposes to end the TDAPA designation for calcimimetic therapies and incorporate these drugs into the bundled-payment base rate, beginning on January 1, 2021 (5). However, concerns among stakeholders exist regarding disparities in calcimimetic usage and how the drug class will be accounted for in the ESKD bundled rate after the TDAPA concludes (6,7).

To explore the potential implications of incorporating the calcimimetic therapies currently eligible for TDAPA into the ESKD bundled payment for specific facilities and patient populations, this analysis evaluated a national snapshot of variation in calcimimetic use in Medicare Fee-for-Service (FFS) beneficiaries receiving maintenance dialysis in 2018. Based on this analysis, we consider potential challenges to incorporate calcimimetics into the ESKD PPS bundle.

Materials and Methods

Data Source and Variables

A 1-year, unadjusted, descriptive analysis was performed using the 100% sample of Medicare FFS enrollment and Part B medical claims from 2018. Criteria for inclusion were as follows: (*1*) beneficiary was enrolled in Medicare FFS in 2018, and (*2*) beneficiary received maintenance dialysis at any time during 2018 (dialysis services identified from Part B claims, using facility and type of services codes to differentiate between dialysis place of service [facility, home based] and dialysis type [hemodialysis, peritoneal dialysis]). Baseline demographics and maintenance dialysis history were obtained using the Medicare Beneficiary Summary File and 100% FFS Part B claims. This analysis is not a clinical research study, as defined in 21 Code of Federal Regulations (CFR) Part 50, and institutional review board approval is not required. The study databases were de-identified before their release to study investigators. The study databases have been evaluated and certified by an independent third party to be in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 statistical de-identification standards and to satisfy the conditions set forth in Sections 164.514 (a)–(b)1ii of the HIPAA Privacy Rule regarding the determination and documentation of statistically de-identified data. Use of the study databases for health services research is, therefore, fully compliant with the HIPAA Privacy Rule and federal guidance on Public Welfare and the Protection of Human Subjects (45 CFR 46 §46.101).

The primary measure of interest for this study was maintenance use of a calcimimetic during 2018. For patients with ESKD, clinical guidelines recommend monitoring parathyroid hormone (PTH) levels every 3–6 months (8). More frequent monitoring may be required for patients with SHPT who are treated with calcimimetics to reach their target maintenance dose (9). Maintenance use of a calcimimetic was defined as a beneficiary having medical claims reflecting at least 90 days of calcimimetic use (on the basis of service dates), with a gap of no more than 60 days between any consecutive administrations in 2018. Calcimimetics were identified using Part B medical claims containing Healthcare Common Procedure Coding System code "J0606" (injection, etelcalcetide, 0.1 mg) or "J0604" (cinacalcet, oral, 1 mg [for ESKD on dialysis]). PTH levels were not captured in the claims.

Patient characteristics that have previously been identified in the literature as showing an association with calcimimetic use included age (categorized as <65 years of age or ≥ 65 years as of January 1, 2018); patient race (Black versus other); and dialysis vintage (defined as duration of time beneficiary qualifies for Medicare under the ESKD benefit [aged with ESKD, disabled with ESKD, or ESKD only] before 2018 and stratified by <3 or ≥ 3 years). Dialysis vintage for all qualifying patients on maintenance dialysis in 2018 for this analysis was computed using the Medicare Status Code from the Medicare Enrollment File; patients who have at least 36 months of enrollment in Medicare with Medicare Status Code values of 11 (aged with ESKD), 21 (disabled with ESKD), and 31 (ESKD only) between 2015 and 2018 are classified as patients with a dialysis vintage of >3 years in 2018. An additional baseline measure included dual eligibility for Medicare and Medicaid (as a proxy for socioeconomic status) (10,11).

The dialysis facility identifier listed on each beneficiary's first observed maintenance dialysis claim in 2018 was captured from the Part B claims and crossreferenced to the current CMS Dialysis Facility Compare public-use files (12). For each dialysis provider, the following measures were calculated for 2018: (*1*) number of patients on maintenance dialysis; (*2*) number/percentage of patients on maintenance dialysis by race (Black versus non-Black), age <65, dual eligibility for Medicare and Medicaid, and dialysis vintage (<3 years on maintenance dialysis, ≥ 3 years); (*3*) number/percentage of patients on maintenance dialysis receiving calcimimetics; (*4*) number/percentage of patients on maintenance dialysis receiving calcimimetics by race, age <65,

dual eligibility for Medicare and Medicaid, and dialysis vintage; and (5) Medicare payments for calcimimetics as a percentage of total Medicare payment for maintenance dialysis. Payments for calcimimetics were derived from Part B claims that included a physician-administered calcimimetic. Facility characteristics included geographic location, defined by US Census region, metropolitan statistical area (MSA; defined as metropolitan and micropolitan), and dialysis chain size ("large," "medium," "small and other"). For the purpose of determining dialysis chain size, large dialysis providers represent DaVita or Fresenius facilities; medium represents Dialysis Clinic Inc., US Renal Care, American Renal Associates, and Satellite Healthcare facilities; and the remainder of facilities are classified as small and other. Facility results were aggregated by MSA and US Census region. MSA and Census region was derived from the facility five-digit zip code and mapped to US Census definitions (13). This analysis highlights the facility-to-facility variation in calcimimetic utilization, in the three MSAs with the highest rate of calcimimetic use, for the total maintenance dialysis population, to demonstrate variation of calcimimetic use within a specific MSA. The analysis reports calcimimetic utilization at the facilities with the highest and lowest use of calcimimetics within each of these identified MSAs; facility-level variation in calcimimetic use was further explored by race, dual-eligible status, and dialysis vintage. The analysis was limited to dialysis facilities located in the continental United States and Alaska and Hawaii. Beneficiary counts represent unique, nonduplicated patients.

Unadjusted, descriptive results are reported at the national, census region, and facility level. Facility-level variation in calcimimetic use within an MSA was calculated as the intra-MSA percentage-point difference between maximum and minimum use for MSAs with two or more facilities. Facility-level variation in payment for calcimimetics as a proportion of total Medicare spending for maintenance dialysis was stratified by the percentage of patients using calcimimetic. Hypothesis testing and statistical comparisons were not performed as part of this analysis.

Results

There were 374,874 Medicare beneficiaries who were dialysis dependent in 2018 that qualified for analysis. Approximately half were dual eligible for Medicare and Medicaid, half were located in the southern region of the United States, and half had been receiving dialysis for ≥3 years. Black patients and patients <65 years comprised 35% and 52% of patients, respectively. The majority of patients received care from a large dialysis organization (71%). See Table 1 for general characteristics.

At the national level, 119,546 beneficiaries had evidence of any calcimimetic use during 2018, of which 105,517 (28% of beneficiaries who were dialysis dependent in 2018) met the definition of maintenance calcimimetic use (*i.e.*, had at least 90 days of calcimimetic use, and no gaps >60 days between any consecutive administrations) (Table 1). Maintenance calcimimetic utilization was consistent at the US Census Region level, ranging from 23% in the West Census Region

Table 1. Characteristics of Medicare FFS beneficiaries receiving maintenance dialysis, 2018

Characteristics	Unique Beneficiaries, *n* (%)	Beneficiaries with ≥90 d of Calcimimetic Use, *n* (row %)
Beneficiaries who were dialysis dependent (2018)	373,874 (100)	105,517 (28)
Age		
Age <65 yr	194,356 (52)	62,629 (32)
Age ≥65 yr	179,518 (48)	42,888 (24)
Dual-eligible status		
Dual eligible for Medicare and Medicaid	182,364 (49)	58,343 (32)
Not dual eligible for Medicare and Medicaid	191,510 (51)	47,174 (25)
Dialysis vintage		
Dialysis dependent for at least 3 yr	189,254 (51)	79,143 (42)
Dialysis dependent for <3 yr	184,620 (49)	26,374 (14)
Race		
Black race	131,617 (35)	52,040 (40)
Non-Black race	242,257 (65)	53,477 (22)
US Census Region[a]		
Midwest	75,257 (19)	18,311 (24)
Northeast	61,978 (16)	16,804 (27)
South	182,617 (46)	54,256 (30)
West	75,876 (19)	17,823 (23)
Size of dialysis provider chain[b]		
Large	284,746 (71)	87,878 (31)
Medium	43,115 (11)	11,283 (26)
Small and other	73,060 (18)	17,083 (23)

Calcimimetic use is defined as having at least 90 d of calcimimetic use, without a gap of no more than 60 d between any consecutive administrations. FFS, Fee-for-Service.
[a]The sum of patients for "US Census Region" and "size of dialysis provider chain" is greater than the total unique beneficiaries because certain patients were treated in multiple census regions and types of dialysis facilities over the course of the claims data period.
[b]Large dialysis provider chain comprises DaVita or Fresenius facilities; medium comprises Dialysis Clinic Inc., US Renal Care, American Renal Associates, and Satellite Healthcare facilities; remainder of facilities are classified as small and other.

to 30% in the South Census Region. For the three variables associated with calcimimetic prescriptions, more patients with those characteristics were calcimimetic users. Patients younger than age 65 used calcimimetics at a higher proportion versus patients age 65 and older (32% versus 24%, respectively). Of the patients receiving dialysis for ≥3 years, 42% were calcimimetic users compared with 14% for those receiving dialysis for <3 years. For Black patients, 40% were calcimimetic users compared with 22% for non-Black patients.

At the national level, the median facility-level percentage of patients on maintenance dialysis who were using calcimimetics was 22% for large-dialysis-organization (LDO) facilities, 22% for medium-dialysis-organization (MDO) facilities, and 18% for small-dialysis-organization (SDO) and other unspecified facilities; the interquartile range (i.e., the difference between the 25th and 75th percentiles) for those facility types were 13%, 17%, and 20%, respectively. See Table 2 for the variation in calcimimetic use among patients who are dialysis dependent across the United States by dialysis facility chain size.

Whereas calcimimetic use was consistent at the US Census Region level, greater variability was observed at the MSA level. For example, the proportion of patients on dialysis using calcimimetics varied substantially at the facility level within those MSAs with the greatest percentage of total patients on dialysis using calcimimetics. Among the three MSAs with the greatest proportion of patients on dialysis using calcimimetics, each had >47% of all patients on dialysis using calcimimetics. However, within the MSAs, differences in calcimimetic utilization rates at the facility with the greatest calcimimetic utilization rate and the facility with the lowest utilization rate was substantial. For example, in the Killeen–Temple, Texas MSA, there was a 64%-point difference between the calcimimetic utilization rates at the facility with the highest calcimimetic utilization and the facility with the lowest calcimimetic utilization (73% and 9%, respectively; see Table 3).

Further, this intra-MSA, facility-level variation in calcimimetic use was present in the three patient-level characteristic and demographics analyzed in the claims analysis. Across the three MSAs with the greatest proportion of total patients on dialysis using calcimimetics for ≥90 days, substantial differences in the percentages of calcimimetic utilization in Black patients (Figure 1A), dual-eligible patients (Figure 1B), and patients with dialysis vintage ≥3 years (Figure 1C) were observed between the facility with the greatest overall calcimimetic utilization rate and the facility with the lowest overall calcimimetic utilization rate within the MSA.

Beyond patient- and intra-MSA, facility-level variation in calcimimetic utilization, this analysis explored the variation in the proportion of total Medicare payment to facilities due to calcimimetics. We found that, as a percentage of those facilities' total Medicare payment, 1304 facilities (19% of all dialysis facilities) had at least 10% of total Medicare payments for maintenance dialysis associated with payment for calcimimetic therapies; those 1304 facilities treated 26% of all calcimimetic users in 2018 (see Table 4). Medicare spending for calcimimetic therapies as a proportion of the total Medicare payment to the facility was >10% at roughly 20% (1304) of all dialysis facilities in the United States.

Discussion

We analyzed Medicare FFS ESKD claims data in 2018, the most recent full calendar year period available, to identify the specific demographics and characteristics of patients on maintenance dialysis, with a focus on those patients using calcimimetics during the first year that these therapies were eligible for TDAPA. At the aggregate level, the patient characteristics and demographics considered included race, dual-eligible status, and dialysis vintage; the claims

Table 2. Median facility-level percentage of patients using calcimimetics by region and facility type, 2018

Geography	Facility Type	Number of Facilities	Median Facility-Level Percentage of Patients Who Are Dialysis Dependent and Using Calcimimetics	Interquartile Range (%)
United States	LDO	5267	22	13
	MDO	768	22	17
	SDO and other	1219	18	20
Midwest Census Region	LDO	1264	20	13
	MDO	101	19	17
	SDO and other	317	19	18
Northeast Census Region	LDO	635	25	15
	MDO	128	19	14
	SDO and other	229	19	21
South Census Region	LDO	2504	24	14
	MDO	390	24	17
	SDO and other	425	19	25
West Census Region	LDO	864	19	11
	MDO	149	20	17
	SDO and other	248	17	14

Calcimimetic use is defined as having at least 90 d of calcimimetic use, without a gap of no more than 60 d between any consecutive administrations. LDO facilities represent DaVita or Fresenius facilities; MDO facilities represent Dialysis Clinic Inc., US Renal Care, American Renal Associates, and Satellite Healthcare facilities; remainder of facilities are classified as SDO and other. LDO, large dialysis organization; MDO, medium dialysis organization; SDO, small dialysis organization.

Table 3. Facility-level variation of calcimimetic utilization for all patients on dialysis within Metropolitan Statistical Areas with the highest rates of calcimimetic use, 2018

Metropolitan Statistical Area	Patients Using Calcimimetics at All Facilities (%)	"Maximum Facility" Calcimimetic Utilization (%)[a]	"Minimum Facility" Calcimimetic Utilization (%)[b]	Intra-MSA Percentage Point Difference between Maximum and Minimum Utilization
Killeen-Temple, Texas	50	73	9	64
Reading, Pennsylvania	48	51	29	23
Williamsport, Pennsylvania	47	50	34	17

MSA, Metropolitan Statistical Area.
[a]Maximum facility refers to the facility within the MSA with the greatest proportion of all patients on dialysis using calcimimetic therapies.
[b]Minimum facility refers to the facility within the MSA with the lower proportion of all patients on dialysis using calcimimetic therapies.

analyses also considered variation of calcimimetic use at the MSA and facility level, and calcimimetic payment as a proportion of total Medicare reimbursement. These data are at an aggregate level of all patients on dialysis in the 50 states and District of Columbia; these data do not necessarily hold true at the MSA level or facility level. This analysis focused on variation in use of calcimimetics for Black patients compared with non-Black patients (as opposed to a comparison across all races) due to the existing literature that has identified the association of higher calcimimetic utilization and Black race (10,11). Because age is one of the existing patient-specific case-mix adjusters as part of the ESKD PPS, the variation in calcimimetic utilization on the basis of this patient-level characteristic was not included as part of this analysis. Further, although studies have investigated the association between socioeconomic status and use of calcimimetic therapies (*e.g.*, low-income subsidy) (14), previous research has not investigated such an association between dual-eligible status and utilization of such therapies; as such, dual-eligible status was included as a baseline characteristic in this analysis. Finally, this analysis considered variation in calcimimetic use on the basis of patients' dialysis vintage (*i.e.*, ≥3 or <3 years), given previous research that has identified an association between vintage and cinacalcet utilization (10). Although prior studies have identified an association between these baseline characteristics and calcimimetic use, this analysis is (to our knowledge) the first time the 100% sample of the Medicare Part B claims has been used (*1*) to describe variation in both cinacalcet and etelcalcetide utilization, and (*2*) to assess utilization patterns of calcimimetics in the Medicare population during the TDAPA period for both these therapies.

Whereas the bundled-payment system seeks to incentivize provider efficiency in treating patients with ESKD, the ESKD PPS accounts for the variation in patients receiving maintenance dialysis through a number of patient-level case-mix adjusters, including: patient age, body surface area, low body mass index, two acute comorbidities, two chronic comorbidities, and the onset of renal dialysis (*i.e.*, the first 120 days of dialysis) (1). Beyond patient-level case-mix adjustments, CMS also adjusts the bundled payment for additional facility-level characteristics (*i.e.*, rural facilities, low-volume facilities, and area wage levels), home-based training, and outlier payments for patients with costs above specific thresholds (15).

Policymakers should evaluate whether the method to account for calcimimetics in the bundled-payment rate may affect facilities after the conclusion of the TDAPA, given the substantial variability in (*1*) calcimimetic utilization patterns associated with patient characteristics and demographics at the aggregate level, and (*2*) facility-level rates of calcimimetic utilization on the basis of these patient characteristics and demographics. Specifically, there is a risk of creating unintended financial disincentives for facilities to appropriately treat patients with SHPT and, with this, the potential to increase clinical risk to those patients where maintenance of PTH levels is critical to avoid complications associated with SHPT and hypercalcemia. Understanding the opportunities and challenges of various methods by which calcimimetics might be accounted for in the bundled payment will be a key consideration for policymakers, with potential implications for providers and patients.

On July 6, 2020, CMS published the Calendar Year 2021 ESKD PPS notice of proposed rulemaking (NPRM), which included a proposed methodology for incorporating the calcimimetic therapies into the payment system's base rate beginning January 1, 2021 (5). In the NPRM, CMS proposes to end the TDAPA status for the calcimimetics and to include their costs in the bundle by adding $12.06 to the per-patient, per-treatment base rate. CMS calculated this amount by dividing the total calcimimetic expenditures for 2018 and 2019 by the total number of paid hemodialysis-equivalent treatments in those years. To determine the calcimimetic expenditures (*i.e.*, the numerator), CMS used the total number of units that were identified in the National Claims History file and multiplied the total number of units over the 2-year period for cinacalcet and etelcalcetide by their respective Average Sales Price (ASP) listed in the most recently released ASP file (*i.e.*, the second quarter 2020 ASP file). This calculation was then reduced by 1% to account for the outlier payment, because calcimimetic therapies would become eligible outlier services once incorporated into the base rate. CMS also proposed to use more recent ASP data for the final policy (*i.e.*, the fourth quarter 2020 ASP file), which is expected to result in an amount that is lower than the $12.06 included in the NPRM.

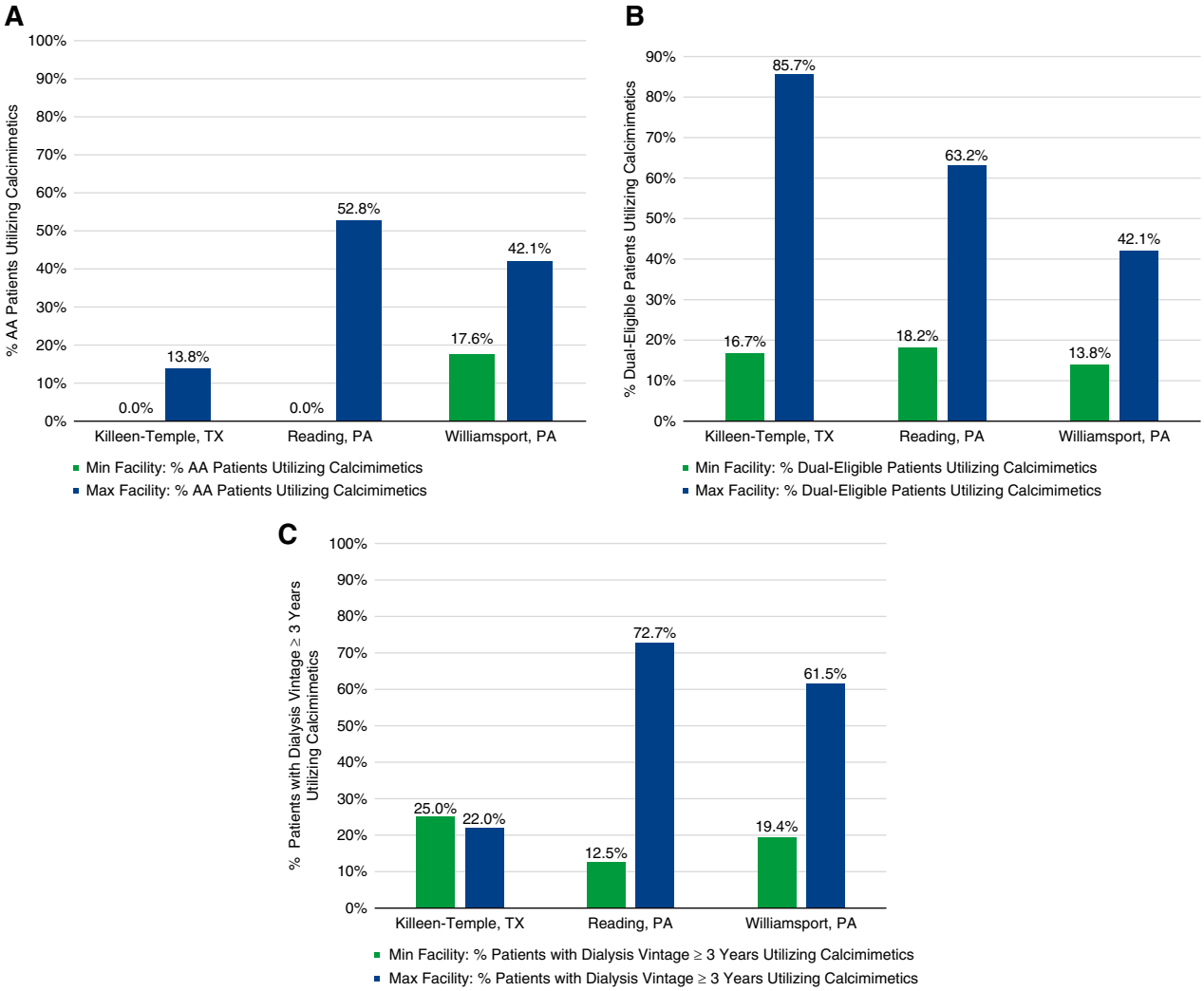

Figure 1. | 2018 claims analysis demonstrates variations in calcimimetic utilization across patient characteristics and demographics at the facility-level within MSAs. (A) Intra-MSA variability in facility percentage of calcimimetic use among Black patients in three MSAs with highest rates of calcimimetic use, 2018. (B) Intra-MSA variability in facility percentage of calcimimetic use among patients who were dual eligible in MSAs with highest rates of calcimimetic use, 2018. (C) Intra-MSA variability facility percentage of calcimimetic use among patients with dialysis vintage >3 years in MSAs with highest rates of calcimimetic use, 2018. AA, African American; min, minimum; max, maximum; MSA, metropolitan statistical area.

An "agnostic" incorporation (*i.e.*, one that does not account for a patient's use of calcimimetic therapy) of the dollars used for calcimimetics *via* the TDAPA into the bundle on a per-patient, per-treatment rate (as CMS used in the rebasing of the bundle after the American Taxpayer Relief Act of 2012) may present the most straightforward approach for CMS, but this will likely create significant risks (as demonstrated in this analysis) to certain patients and facilities. For example, this analysis found (*1*) the proportion of Black patients using calcimimetic therapies was roughly

Table 4. Payment for calcimimetics as a percentage of total Medicare payment for maintenance dialysis, 2018

Payment for Calcimimetics as a Proportion of Total Medicare Spending for Maintenance Dialysis	No. of Dialysis Facilities	Percentage of All Dialysis Facilities	Percentage of Calcimimetics Users Served
<5%	2982	43	32
≥5% to <10%	2638	38	42
≥10%	1304	19	26
Total	6924	100	100

80% higher than the proportion of non-Black patients using calcimimetics; (2) the proportion of patients who were dual eligible and using calcimimetics was roughly 30% higher than the proportion of patients who were non–dual eligible and using calcimimetics; and (3) the proportion of patients with a dialysis vintage ≥3 years who were using calcimimetics was nearly three times the proportion of patients with a dialysis vintage <3 years who were using calcimimetics.

If the dollars used to treat SHPT with calcimimetics in this population were spread across all dialysis treatments, it would result in modest increases in payment for all treatments, but this increase would likely be insufficient to account for the costs of calcimimetic treatments in patients actually using these therapies. Based on the methodology of the Calendar Year 2021 proposed rule, CMS proposes to add $12.06 to every treatment for every patient to account for the calculated costs associated with calcimimetic therapies using 2018 and 2019 calcimimetic utilization data, the most up-to-date ASP for each product, and the number of hemodialysis-equivalent treatments for that time period. For an MDO facility at the 75th percentile for any calcimimetic use in 2018 (36% of patients using the therapy), with patients prescribed a regimen of a 30 mg cinacalcet tablet per day, that facility would see an estimated 4% reduction in Medicare payment under the proposed update to the bundled-payment rate (versus separate TDAPA payment). Alternatively, for an MDO facility at the 25th percentile for any calcimimetic use (17% of patients using the therapy), with patients prescribed this same daily dose of cinacalcet, the facility would see a 0.8% increase in Medicare payments under the updated bundled-payment rate. Understanding the narrow margins under which dialysis facilities operate, a reimbursement reduction of the magnitude in the first scenario could present a significant financial burden for such dialysis facilities.

For facilities with a large share of patients using calcimimetics and small chain facilities that are less able to absorb financial losses, this policy could create disincentives to use this therapy to maintain appropriate PTH levels and create potential access challenges for patients. As this claims analysis identified, payment for calcimimetics as a proportion of the total Medicare payment to the facility was >10% at roughly 20% of dialysis facilities. On the basis of these data, one in five dialysis facilities would face substantial negative effects if calcimimetics are included in the bundle on a per-patient, per-treatment basis for all dialysis treatments (regardless of calcimimetic utilization). A policy that does not account for the differences in calcimimetic use across different patient populations may disproportionately affect vulnerable patient populations such as Black beneficiaries, dual-eligible beneficiaries, and those with a dialysis vintage >3 years.

As noted, the ESKD PPS has several patient-level case-mix adjustments to account for variation in the patient costs. Of the existing case-mix adjusters, age (specifically, patients <65 years old) has been identified with higher calcimimetic utilization (10). The introduction of new patient-level case-mix adjustments to account for patient-level characteristics associated with greater use of calcimimetics (*i.e.*, Black patients, dual-eligible patients, and patients with a dialysis vintage ≥3 years) could potentially address some of the variability in calcimimetic utilization, however, it could also introduce new challenges to implement and would not necessarily accurately account for variation in calcimimetic use across facilities. In particular, as demonstrated by the variation in calcimimetic use by patients within these subgroups from facility to facility, compared with the actual rate of calcimimetic use by the full patient population, an agnostic or "blanket" adjuster tied to any one, or all, of these patient characteristics or demographics could inaccurately over- or under-compensate facilities. For example, whereas patients with Black race showed greater use of calcimimetics overall, the analysis demonstrates only adjusting payment for calcimimetics on the basis of race would not appropriately account for the calcimimetic utilization at specific facilities.

Another potential option to account for the variability in calcimimetic utilization and reduce potential disincentives to appropriately treat patients with SHPT would be to develop an adjustment similar to the existing ESKD PPS outlier payment adjustment. To maintain a budget-neutral outlier payment policy, CMS currently reduces the per-treatment base rate payment by 1% to account for the estimated total payments under the PPS that are outlier payments; qualifying outlier services are then paid from this reserve of funds withheld from each treatment (16). Given the utilization patterns and costs associated with calcimimetic therapies in 2018, better understanding the expected costs for patients' calcimimetic needs in the post-TDAPA years will be necessary. This could represent a payment option with minimal disruptions, while ensuring facilities with higher rates of calcimimetic utilization are reimbursed adequately for these additional costs.

There are limitations to consider in interpretation of these findings. First, this analysis used CMS-sourced beneficiary medical claims data. Claims data are captured for the purpose of provider billing and reimbursement, and there is the possibility of errors or misclassification of medical conditions and drug use. Further, complete medical history was not evaluated, limiting the ability to determine the exact date of dialysis initiation. Additionally, the 2018 data represent the first year by which cinacalcet claims were submitted under the medical benefit and paid under TDAPA, and the first year that IV etelcalcetide was commercially available. The 2018 data could represent lower calcimimetic utilization than subsequent years. The analysis also focused on patients receiving maintenance calcimimetics, which was defined as patients having at least 90 days of calcimimetic use during 2018, with a gap of no more than 60 days between any consecutive administrations. Of note, this definition of calcimimetic use would exclude some patients who initiated a calcimimetic in the last quarter of 2018 and reached the end of the follow-up period before qualifying under this definition of maintenance calcimimetic use. Clinical values, including PTH levels, were not captured in the data, therefore, appropriateness of calcimimetic therapy was not evaluated. Finally, this study demonstrates the variability in baseline characteristics and healthcare resource utilization across dialysis facilities. Because the goal of the analysis was to highlight this variability, we did not adjust the cost metrics or perform statistical comparisons. As additional claims history on IV calcimimetics become

available, future results could be adjusted to account for differences in patient- and facility-level characteristics.

In summary, this analysis of calcimimetic utilization in Medicare FFS beneficiaries who were dialysis dependent in 2018 found variations in the use of calcimimetic therapies by both (*1*) patient demographics and characteristics, and (*2*) facility geography and characteristics. The analysis demonstrated greater rates of calcimimetic utilization in patients with certain characteristics—Black race, dual-eligible status, and dialysis vintage ≥3 years—compared with patients without those characteristics. However, given the variation in calcimimetic use by patients with these characteristics at the facility level compared with the calcimimetic use of the facility's full population, a patient case-mix adjuster alone would likely not adequately account for the increased likelihood and costs of calcimimetic utilization after the TDAPA period. The variation in the need for calcimimetic treatment for SHPT presents a challenge for CMS and policymakers to develop methods to appropriately account for these therapies in the ESKD bundled rate after the TDAPA. Incorporation of calcimimetics into the bundle rate that does not appropriately account for these variations in utilization could disproportionately affect vulnerable patients who most need treatment.

Disclosures

P. Desai and H. Owens are employees at Amgen, Inc. and own Amgen stock. J. Fagan, M. Gooding, M. Kambhampati, Z. Levine, A. Petrilla, and J. Young are employees at Avalere Health, an Inovalon company. R. Rubin is a consultant to Amgen, Inc.

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Author Contributions

P. Desai, M. Gooding, H. Owens, A. Petrilla, R. Rubin, and J. Young conceptualized the study; M. Gooding and A. Petrilla were responsible for investigation; P. Desai, M. Gooding, M. Kambhampati, H. Owens, A. Petrilla, and J. Young were responsible for methodology; J. Fagan, M. Gooding, and Z. Levine were responsible for project administration; P. Desai, M. Gooding, H. Owens, A. Petrilla, and R. Rubin provided supervision; J. Fagan, M. Gooding, M. Kambhampati, Z. Levine, and A. Petrilla wrote the original draft; P. Desai, J. Fagan, M. Gooding, Z. Levine, H. Owens, and R. Rubin reviewed and edited the manuscript; P. Desai and H. Owens were responsible for funding acquisition; M. Kambhampati and A. Petrilla were responsible for data curation; and M. Kambhampati, A. Petrilla, and J. Young were responsible for formal analysis.

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