Phosphate-Binder Use in US Dialysis Patients: Prevalence, Costs, Evidence, and Policies

Wendy L. St. Peter, Lori D. Wazny, and Eric D. Weinhandl

Medicare costs for phosphate binders for US dialysis patients and patients with chronic kidney disease enrolled in Medicare Part D exceeded $1.5 billion in 2015. Previous data have shown that Part D costs for mineral and bone disorder medications increased faster than costs for all Part D medications for dialysis patients. Despite extensive use of phosphate binders and escalating costs, conclusive evidence is lacking that they improve important clinical end points in dialysis patients or non–dialysis-dependent patients with chronic kidney disease. Using dialysis patient data from the US Renal Data System and laboratory information from the Centers for Medicare & Medicaid Services (CMS) CROWNWeb data, we update information on trends in phosphate-binder use, calcium and phosphorus values, and costs for Medicare-covered dialysis patients. We discuss these results in the context of evidence from clinical trials, meta-analyses, and observational studies evaluating phosphate-binder efficacy, safety, comparative effectiveness, and cost-effectiveness. Based on our analysis, we note a need for US Food and Drug Administration guidance regarding clinical evaluation of new phosphate binders, and we suggest that it would be in CMS' best interest to fund a clinical trial to assess whether lower versus higher phosphate concentrations improve hard clinical outcomes, and if so, whether particular phosphate binders are superior to placebo or other binders in improving these outcomes.

Complete author and article information provided before references.

Am J Kidney Dis. 71(2): 246-253. Published online November 28, 2017.

doi: 10.1053/j.ajkd.2017.09.007

Introduction

Medicare expenditures for phosphate binders for US dialysis patients and patients with chronic kidney disease (CKD) enrolled in Medicare Part D exceeded $1.5 billion in 2015.[1] We previously showed that phosphate binders are the most commonly used CKD–mineral and bone disorder (MBD) medications.[2] We also demonstrated that Part D costs for CKD-MBD medications (phosphate binders, vitamin D analogues, and cinacalcet) in dialysis patients increased faster from 2007 to 2010 than costs for all Part D medications, 36% versus 22%, despite relatively stable use within medication classes.[2] Phosphate binders represented 37% of total Medicare Part D spending for dialysis patients in 2014.[3]

The exploding costs of phosphate binders along with the lack of conclusive evidence from clinical trials evaluating their effects on hard clinical end points[4] stimulates several questions. Do phosphate-binder effects justify the costs to Medicare of this class of drugs in patients recieving dialysis? Should we continue to use a surrogate outcome (phosphorus reduction or control) as a primary end point to evaluate phosphate binders for regulatory approval? Which metrics should be considered for evaluating phosphate-binder effectiveness? To address these questions, in this Policy Forum article, we first use primary data to evaluate recent trends in phosphate-binder use and costs, as well as phosphorus and calcium concentrations, and subsequently review the literature on phosphate-binder effectiveness and cost-effectiveness.

Phosphate-Binder Use, Costs, and Phosphorus Control

The number of dialysis patients who were dispensed at least 1 Part D–covered phosphate binder increased from 204,208 in 2008 to 263,404 in 2013 (a 29% increase), while corresponding percentages of phosphate binder users were stable at ~76% (Table 1). Use of specific phosphate binders shifted over time. Calcium acetate use decreased from 38% in 2008 to 34% in 2013. Use of non–calcium-containing phosphate binders did not change, but sevelamer carbonate use inceased while sevelamer hydrochloride use decreased. By 2013, only 7% of dialysis patients with Medicare Part D receiving phosphate binders were dispensed sevelamer hydrochloride. Calcium carbonate is not covered by Part D and therefore is not included in analyses.

Annual Medicare costs for phosphate binders increased by $486 million between 2008 and 2013 (a 118% increase) (Box 1). Table 1 displays total Medicare costs, total costs per patient-year, and total costs per user-year for all phosphate binders and specific phosphate binders in 2008, 2010, 2011, and 2013. Sevelamer carbonate and sevelamer hydrochloride together accounted for $741 million

Policy Forum highlights aspects of nephrology relating to payment and social policy, legislation, regulation, demographics, politics, and ethics, contextualizing these issues as they relate to the lives and practices of members of the kidney community, including providers, payers, and patients.

in 2013, or 83% of Part D–covered phosphate-binder costs in dialysis patients. Percent changes in numbers of dialysis patients who were dispensed at least 1 Part D–covered prescription drug and Medicare costs of those prescription drugs are shown in Figure 1. From 2008 to 2013, total costs per user-year for phosphate binders increased from $2,221 to $3,716 (a 67% cumulative increase, or a 10.8% compound annual growth rate). In contrast, total costs per user-year for all other Part D–covered prescription drugs for dialysis patients cumulatively increased by 21% (a 3.9% compound annual growth rate) (Box 1). In 2013, lanthanum carbonate and sevelamer carbonate were the most costly per user-year at $4,924 and $4,470, respectively; calcium acetate was only $678. Between 2008 and 2013, total costs per user-year for calcium acetate and lanthanum carbonate cumulatively increased by 7% and 138%, respectively, while costs per user-year for sevelamer carbonate cumulatively increased by 284%.

Adjusted for relative phosphate-binding capacity, costs of calcium acetate, lanthanum carbonate, and sevelamer carbonate in 2013 were $0.79, $4.67, and $4.85, respectively, per one calcium carbonate–equivalent gram (Fig 2). Thus, to achieve an equal degree of phosphorus control in a typical patient, Medicare expended about 5 times as much on sevelamer carbonate and lanthanum carbonate as on calcium acetate in 2013.

Serum phosphorus and calcium distributions trended upward between 2012 and 2014. Phosphorus control slightly worsened between 2012 and 2014; 12.8%, 57.6%, and 29.6% of dialysis patients had serum phosphorus concentrations ≤ 3.5, 3.6 to 5.5, and >5.5 mg/dL, respectively, in December 2012 versus 11.2%, 55.5%, and 33.3% in December 2014. In the same months, serum calcium concentrations (corrected for albumin) trended upward: 27.5%, 49.1%, 19.7%, and 3.7% had serum calcium concentrations ≤8.4, 8.5 to 9.2, 9.3 to 10.2, and >10.2 mg/dL, respectively, in December 2012 versus 23.4%, 50.5%, 22.0%, and 4.1% in December 2014.

Regulation of Phosphate Binders

Percentages of Medicare Part D–covered dialysis patients using phosphate binders remained steady from 2008 through 2013, but patient prevalence grew, so the increase

Table 1. Number and Percentage of Medicare Part D–Covered Dialysis Patients Who Were Dispensed Phosphate Binders and Total Costs Per Patient-Year and Per User-Year, Overall and by Phosphate Binder, in 2008, 2010, 2011, and 2013

Statistic	2008	2010	2011	2013
No. of Part D–covered dialysis patients	294,779	322,540	337,959	384,464
Follow-up time, patient-y	228,430	251,425	265,333	304,962
Phosphate-binder users[a]				
Any phosphate binder	204,208 (76.8%)	222,021 (76.3%)	232,230 (75.8%)	263,404 (75.5%)
Calcium acetate	100,082 (37.6%)	107,334 (36.7%)	110,493 (36.0%)	120,163 (34.3%)
Lanthanum carbonate	27,374 (10.8%)	23,363 (8.4%)	20,037 (6.9%)	17,129 (5.2%)
Sevelamer carbonate	14,349 (5.5%)	112,337 (39.7%)	129,556 (43.2%)	167,056 (48.7%)
Sevelamer hydrochloride	120,210 (46.3%)	49,062 (17.2%)	31,877 (10.4%)	17,249 (4.9%)
Total costs, millions				
Any phosphate binder	$411.5	$496.0	$597.6	$897.3
Calcium acetate	$58.1	$60.7	$65.5	$75.3
Lanthanum carbonate	$53.6	$69.4	$69.7	$80.9
Sevelamer carbonate	$15.9	$261.2	$377.0	$694.9
Sevelamer hydrochloride	$283.9	$104.7	$85.5	$46.2
Total costs per patient-y				
Any phosphate binder	$1,706	$1,869	$2,136	$2,805
Calcium acetate	$238	$225	$231	$233
Lanthanum carbonate	$223	$262	$251	$255
Sevelamer carbonate	$64	$987	$1,350	$2,176
Sevelamer hydrochloride	$1,182	$394	$304	$142
Total costs per user-y				
Any phosphate binder	$2,221	$2,449	$2,817	$3,716
Calcium acetate	$633	$614	$642	$678
Lanthanum carbonate	$2,065	$3,106	$3,646	$4,924
Sevelamer carbonate	$1,164	$2,487	$3,125	$4,470
Sevelamer hydrochloride	$2,553	$2,286	$2,915	$2,891

Note: Abbreviated methods: we analyzed US Renal Data System Standard Analysis Files to identify dialysis patients who were enrolled in Medicare Part D prescription drug plans. Each line of Part D data includes the date on which a prescription drug was filled, branded and generic names of the prescription drug, number of tablets or capsules that were dispensed, and Medicare payment for each prescription drug. We assessed calcium acetate, lanthanum carbonate, sevelamer carbonate, and sevelamer hydrochloride. Calcium carbonate was not assessed because it is an over-the-counter medication; thus, it is not covered by Part D. Neither ferric citrate nor sucroferric oxyhydroxide were assessed because they were not available until after 2013. We tabulated the number and percentage of patients who were dispensed each phosphate binder at least once during a calendar year. For each phosphate binder, we calculated total Medicare payments per patient-year (ie, costs among all patients) and per user-year (ie, costs only among users). Detailed methods are included in Item S1.
[a]Count (proportion of Part D–covered dialysis patients, weighted by follow-up time per patient).