Orals in the Bundle: A Policy Framework

Rachel L. Feldman, Mark P. Desmarais, and James S. Muller

Summary
Oral prescription drugs for treatment of bone and mineral disorders (phosphate binders and calcimimetics) in patients undergoing dialysis (i.e., those with ESRD) will be integrated into the Medicare Part B ESRD bundled payment system in 2016. Payment will be denied under Medicare Part D. Integrating Part D drugs into Part B payment at this level of scale lacks any policy precedent. Providers and patients have serious concerns about the potential for inadequate funding, and the Centers for Medicare & Medicaid Services (CMS) has been silent about the methods and other critical policy used to guide its decisions. We believe an adequate policy framework to support valuation of the targeted oral drugs depends on use of the most recent available Medicare Part D data, measurement of mean utilization for all target drugs based on a minimum of 6 months of complete data for prescriptions and dialysis treatments, use of appropriate price proxies to monetize drug volume to dialysis provider acquisition cost, adjustment to account for change in adherence due to change in patient out-of-pocket expenses, inclusion of valuation for dispensing and administrative cost, and a mechanism for adjusting payment to future changes in adherence.


Introduction
Medicare pays for most renal dialysis in the United States, and, in 2011, changes mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (1) were implemented in the prospective payment system (PPS) for ESRD. In the federal regulations released in August 2010 that set forth these changes (2), the Centers for Medicare & Medicaid Services (CMS) integrated items that had historically been separately paid into a single bundled payment per dialysis treatment (the bundle). Before these changes, payment for dialysis consisted of a case-mix–adjusted rate per treatment, inclusive of a list of drugs and laboratory tests, while intravenous drugs and a variety of other laboratory tests and supplies were billed and reimbursed separately (Figure 1). As of January 1, 2011, historically separately paid items are included in an expanded base rate that is adjusted for geographic wage differences, case-mix variables, low-volume facilities, and for treatments during the first 120 days of dialysis. Dialysis providers bear the risk for managing all services within “the bundle.” The services that had historically been separately paid were redefined as “dialysis services” and for Medicare payment purposes were no longer considered to be drugs, laboratory tests, or supplies. MIPPA provided for a 4-year transition to fully implement the new PPS.

In 2011 proposed rule-making, CMS communicated its intent to include historically separately paid prescription oral drugs (paid under Medicare Part D) in the bundle. It identified the oral drugs that were equivalents to separately paid (Part B) intravenous drugs (e.g., oral vitamin D) and estimated the value of these products using Medicare Part D data. These products were primarily used by patients receiving home dialysis, approximately 8.4% of patients with ESRD (3). CMS also identified two classes of oral drugs that are prescribed for most dialysis patients to manage bone and mineral disorders—phosphate binders and calcimimetics—and explained its plan to redefine these drugs as “dialysis services” to be added to the bundle (4). Phosphate binders include brand-name and generic calcium acetates and several other non–calcium-based brand-name drugs. The only calcimimetic product to be included is cinacalcet, a very expensive sole-source brand-name drug (Sensipar).

In final 2011 rules, CMS reviewed many comments objecting to the inclusion of these oral drugs into the bundle in 2011 (5). CMS had estimated the value of these oral drugs to be in the range of $14 per treatment (6), and commentators widely objected to this amount as inadequate, providing a range of methodologic critiques and alternative estimates for their value. CMS acknowledged the validity of some methodologic critiques and concerns about inadequate time to prepare for implementation and deferred inclusion of these drugs in the bundle until the transition is complete in 2014. On January 2, 2013, Congress deferred inclusion of these drugs into the bundle to 2016, as part of the American Taxpayer Relief Act (7). To date, regulations have not specified or signaled how CMS will approach the valuation of these products for inclusion in the bundle. Before Congress deferred inclusion of oral agents into the bundle, CMS was, by its own statements in meetings with industry representatives, working with contractors to prepare for release of rules in 2013 that would set forth its approach (one author was present during this meeting).
This paper explores the decisions CMS must make to incorporate Part D drugs into the Medicare Part B ESRD PPS in 2016. Methodologic choices will determine the ultimate value attributed to these products, and several policy decisions will have far-reaching consequences for dialysis facilities, prescribing physicians, patients, and future efforts to integrate Part D products into Part B programs (Table 1). Although this paper does not address the quality issues associated with the use of these drugs, it is important to note that reaching consensus on quality measures for bone and mineral metabolism has been difficult.

A Policy Framework

No explicit policy framework exists to guide the decisions CMS will have to make. The only historical precedent for incorporating Medicare Part D products into Part B programs is the outpatient hospital prospective payment system (OPPS). However, the OPPS methods cannot be applied to the ESRD PPS without major changes to the ESRD claims and cost report infrastructure, which are not anticipated.

A policy framework must address both the valuation of the products to be included in the bundle and modifications to the PPS to accommodate a broadened bundle. It also needs to realistically consider implementation challenges. Lacking a precedent, CMS must make many policy and methodologic decisions to determine the dollar value for the drugs to be included in the bundle in 2016.

- What definition and metric to use for “utilization”;
- What data source to use as the basis to measure historic “utilization”;
- What year to use as the base year to estimate utilization;
- How best to represent estimated utilization as dialysis facility “acquisition cost”;
- How to account for dispensing and administrative costs;
- How utilization is affected by differences in patient out-of-pocket costs when moving from Part D to Part B.

Monetizing Utilization

Under 2011 rules, CMS used 2007 Part D claims data, recognizing that only about two thirds of Medicare patients with ESRD had Part D plans. Although Part D claims data represent the largest data set for the relevant products, no information exists to determine how different the drug utilization might be for patients without Part D plans. CMS did recognize that it would be covering all Medicare patients for these drugs under Part B and must account for those with no Part D history.

CMS also used the Part D data to identify dollars paid on behalf of patients with ESRD that are associated with the specific products. Part D dollars fall into quite a few categories, including Medicare payments to plans for

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**Figure 1.** Composite rate system (prior to 2011) and bundled payment system (2011 to present).

<table>
<thead>
<tr>
<th>Composite Rate System (Prior to 2011)</th>
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<tbody>
<tr>
<td>Bundled Services</td>
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<td>18 Routine Lab Tests</td>
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<td>Certain Routine Drugs</td>
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<td>Routine Supplies</td>
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<td>Staff Time</td>
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<td>Machine and Overhead Costs</td>
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<th>Bundled Payment System (2011 to present)</th>
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<tr>
<td>Bundled Services</td>
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<tr>
<td>All ESRD-Related Lab Tests</td>
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<td>IV Drugs</td>
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<td>Supplies</td>
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<td>Staff Time</td>
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<td>Machine and Overhead Costs</td>
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**Table 1.** Drugs under Medicare Part B and Part D

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<thead>
<tr>
<th>Drugs under Medicare Part B</th>
<th>Drugs under Medicare Part D</th>
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<tr>
<td>Typically administered by physician</td>
<td>Typically obtained from pharmacy</td>
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<tr>
<td>One benefit design for all patients</td>
<td>Patients choose different benefit designs</td>
</tr>
<tr>
<td>Coverage of drugs determined by Medicare</td>
<td>Coverage of drugs determined by plan formulary</td>
</tr>
<tr>
<td>20% patient copayment</td>
<td>Copayment based on plan design</td>
</tr>
<tr>
<td>Reimbursement paid by Medicare to the facility</td>
<td>Reimbursement paid by Medicare to plan</td>
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ingredient and various administrative activities, beneficiary copayments and payments for drugs when they are in the coverage gap (otherwise known as the “donut hole”), subsidies, and premiums that are not specific to any drug. Subsidies and beneficiary cost-sharing are scheduled to change each year as a result of the Affordable Care Act provisions to close the donut hole by 2020. Subsidies cover a sliding scale of premiums, copayments, and drugs in the coverage gap (8). Part D dollars associated with specific drugs represent, to some extent, the acquisition costs of prescription drug plans that purchase hundreds of drugs in volume through mechanisms that will be different from those available to dialysis facilities. Nowhere does CMS explain its methods for calculating these amounts.

Across all Medicare payment systems, policies for reimbursement and valuation of drugs are based on the concept of “acquisition cost,” which varies according to the purchasing power of different classes of trade. Use of Part D dollars to value the drugs for inclusion in the bundle would not represent dialysis facility acquisition cost, nor would it represent acquisition costs for the types of pharmacies with which dialysis facilities will likely contract to provide drugs for their patients. Therefore, one important criterion for the policy framework will be that valuation of the drugs incorporated into the bundle represents a reasonable acquisition cost for dialysis facilities.

The 2011 ESRD PPS regulation referred to valuation of the oral drugs at “98 percent of the estimated total amount of payments that would have been made under this title if the ESRD PPS were not implemented” (9). There is some room to interpret what this means. CMS’s initial interpretation was the Part D dollars identified as associated with patients with ESRD and the targeted drugs based on 2007 claims data. Another interpretation of “payments that would have been made” could refer to utilization, which would be consistent with the language in MIPPA. “Utilization” can be understood as the volume of drugs used by patients with ESRD expressed on a per treatment basis and monetized according to historical reimbursement, at Average Sales Price (ASP) plus 6%, which is how these drugs are reimbursed in physician offices under Part B policies (10).

ASP is defined as an acquisition cost for physician offices and is also used in OPPS reimbursement. In these policies, ASP is a “price proxy” for acquisition cost that is directly tied to drug volume. There is no ASP for Part D drugs. However, other price proxies are available for consideration. Wholesale acquisition cost, for example, is a real price reported publicly on a regular schedule to the government by manufacturers, and it provides an accurate historical proxy for branded drugs purchased by retail pharmacies (10). Other price proxies are available to the government but may not be publicly reported for individual products.

A further interpretation for “payments that would have been made” could refer to what would have been spent to provide these drugs had they been delivered to patients under Medicare Part B. Patient out-of-pocket costs will vary considerably from Part D to Part B. In Part D, patients are responsible for about 25% of drug costs, but many patients with ESRD have subsidies that reduce that cost burden. Under Part B, patients are responsible for about 20% of drug costs. Patients who did not have subsidies under Part D may have supplemental insurance that covers their coinsurance responsibility for Part B drugs, whereas many of those with subsidies under Part D will have no subsidy under Part B. Drug utilization can be expected to change in relation to patient sensitivity to these costs (11). Dialysis facilities will, assuming responsibility to provide these drugs, feel obligated to fill prescriptions that patients might not have filled on their own (12). (The authors conducted interviews with medical and renal pharmacy directors at dialysis companies and renal pharmacies that participated in the studies during 2011. These expert interviews explored the range of issues involved in patient compliance with these particular drugs.) Therefore, criteria for the policy framework will need to ensure that valuation of the drugs is adequate to capture the actual volume and mix of products that must be purchased by facilities for all Medicare patients with ESRD, taking these sensitivities and shifts in costs into account.

The 2011 regulations relied on 2007 claims data based on requirements of MIPPA. Legal advisors for the industry associations have provided extensive legal analyses to CMS, arguing that it should use the “best available data” and that such data would be the most recent available data. MIPPA’s specifications did not refer to any year after 2011. A further criterion for the policy framework would require that CMS use data to estimate utilization that reflects the most current practice for which data are available, which will likely be 2013 or later, for 2015 rule-making.

The critical policy distinctions between valuation based on historical Part D dollars versus drug volume monetized using a price proxy are as follows: (1) Using Part D dollars does not represent an acquisition cost for facilities or the pharmacies they contract with, and (2) Part D dollars are available only for the original valuation because Part D will cease to cover these drugs. Subsequent monitoring for adequacy of treatment, changes in practice patterns, and inclusion of these products in the ESRD-PPS outlier payment policy will rely on drug volume in claims data. Part D dollars will not describe the drug mix, dosing, or practice patterns for comparison purposes going forward.

In bundled payment, the risk that requires monitoring is underutilization. Comparisons year to year will become important to explain quality outcomes as well as to assess adequacy of payment.

Measuring Utilization

The Part D claims data represent the largest and most representative source for data to measure utilization. CMS currently limits access to these data to academic and certain nonprofit research organizations. The Kidney Care Council, the industry association that represents many of the larger and medium-sized dialysis companies, funded a study by the authors to investigate what CMS would be likely to learn by analyzing the Part D claims data. Using pharmacy data donated by three dialysis companies that operate renal pharmacies and dialysis treatment data for the same patients receiving drugs through these pharmacies, and having reviewed in detail the specifications for the Part D claims data, the authors explored the possible methods for measuring utilization for...
the target drugs. The study was performed twice using 2010 and 2011 data sets.

A thought experiment was performed using the Part D data specifications to develop alternative analysis plans that CMS might use. The examination of Part D dollars could not be tested in the study data, but other approaches were tested. Study data were not statistically representative of the national dialysis population but included 25,000–35,000 patients receiving dialysis for 12 months and patients whose drugs were covered by Medicare Part D with and without low income subsidies, by Medicaid and by commercial insurance. The thought experiment resulted in recommendations to CMS for its contractors on alternative methods for use of Part D data in valuation of the target drugs. The data analyses focused on measuring variation in drug utilization on a per treatment basis.

Key methodologic considerations that lead to different calculations of utilization were identified:

- Prescriptions are filled at variable increments ranging up to 90 days. Therefore, accurate estimation of volume per treatment should be based on patients receiving dialysis for periods of 6 months or longer.
- Drug volume needs to be calculated in relation to treatments received by the same patients over the defined time period so that the numerator of drug volume and denominator of treatments are correctly matched—this was not done in CMS’s 2010 analyses.
- The National Drug Codes for different versions of a single product sold in different doses need to be rolled up together and converted to milligrams.
- Once volume of each drug is calculated on a per treatment basis, it is monetized by applying the most appropriate price proxy. The authors used 2010 and 2011 wholesale acquisition cost for branded drugs and a blended acquisition cost reported by pharmacies that donated data for generic calcium acetates. The monetized volume per treatment is summed across all products to produce the total ingredient valuation per treatment for the mean utilization.

This approach to calculation of utilization should produce an accurate estimation for the average volume of drugs that facilities will need to purchase. An estimation of administrative cost per filled prescription needs to be added to the ingredient cost per treatment to account for the costs that facilities will be charged by pharmacies for dispensing the drugs and for other costs involved in monitoring patient drug use. No historical data are available to estimate these administrative costs. Estimates from various sources range from low dispensing fees paid by state Medicaid programs in the $5–$10 range to higher fees paid by commercial insurers in the $10–$20 range. It is not clear at this time how physicians conferring with facilities will adjust prescriptions. Facilities that can closely monitor and handle patients’ drugs as permitted by some state laws may choose shorter prescription lengths, whereas others may use longer prescription lengths while using other mechanisms to interact with patients around their drug use. Facilities will have the incentive not to waste product unnecessarily, and patients at higher risk may need to receive more frequent prescriptions for shorter-duration utilization. These practices need to be considered in valuing the administrative costs.

Adherence

Adherence is the concept that describes the extent to which patients actually consume drugs according to the physician prescription. Adherence for the target drugs is known to be complicated (14,15): Some pills are large, are difficult to swallow, and are prescribed in multiples; certain pills are prescribed to be taken with meals, but patient appetites and meal frequency may not conform to the prescription; patients may ration pills because of overall pill burden and overall out-of-pocket costs across all of their medications (11,15). The study data show that 20%–40% of patient months include no drug utilization depending on level of out-of-pocket costs to patients. This can mean that patients spread out their drugs over a longer period than specified in the prescription, taking fewer pills per day than prescribed. It can also mean that patients were not filling prescriptions or that some patients are not prescribed any combination of these medications.

Although CMS could examine the difference in adherence that is associated with patient out-of-pocket expenses associated with these drugs in Part D data, no information is available to predict how provider behavior may change or how such change might affect patient adherence, and indirectly increase or decrease the cost of drugs to dialysis providers. CMS can develop a demand elasticity measure to adjust valuation of the drugs from Part D to Part B adherence on the basis of differences in out-of-pocket expenses observed in Part D claims data. Change in adherence due to new provider behaviors, however, will not be seen until providers assume responsibility for payment in 2016. A critical part of the policy framework will be whether, under what circumstances, and how frequently CMS will reevaluate utilization for changes in adherence or provider practice.

Valuation of historic average drug volume, although consistent with Medicare PPS practice, will freeze the historic mix of products and adherence rates. Bundled payment creates an incentive for providers to limit utilization wherever possible and to substitute lower-cost for higher-cost products. Study data for 2011, while not statistically representative of the national ESRD population, showed that 20%–30% of patient months included some use of cinacalcet, the most expensive of these drugs, depending on patient out-of-pocket costs. Cinacalcet accounted for about one third of the estimated mean value for the oral drugs to be included in the bundle. Dialysis provider behavior could increase utilization by filling more prescriptions and encouraging compliance with physician orders. It could also discourage the use of cinacalcet and the more expensive phosphate binders.

Quality measures and penalties for not meeting them represent the only real check on provider response to financial incentives. A policy framework that adapts to change in practice could encourage best practice to improve patient outcomes over short-term financial incentives because providers would expect future payments to reflect changes in their utilization, catching up to increased, and presumably improved utilization. Failure to provide a mechanism for
future adjustment, however, will leave providers uncertain as to future payment, and behavior can be expected to be cautious and aligned with financial incentives.

Implementation Issues
Contracting with pharmacies and developing plans and protocols to take responsibility for the provision of these drugs remain hostage to uncertainty, until CMS releases more information about its plans. Without explicit information about the valuation of these drugs for inclusion in the PPS, providers have limited information with which to negotiate with pharmacies. In many states, ESRD providers cannot dispense drugs because of state pharmacy laws. As a result, many providers will have to contract with pharmacies to deliver drugs to patients by mail order or other means, precluding the facility handling the drug. Contracting options will also be different for different classes of dialysis providers: Hospital-based providers will be able to use hospital pharmacies; large dialysis organizations either operate and can expand or may develop renal pharmacy subsidiaries; whereas most small independent dialysis organizations will have to explore developing pharmacy capacity in their facilities, state laws permitting, or developing contracts with clinical pharmacies. Small organizations will have little leverage in negotiating price.

Providers have other decisions to make: how to balance waste against efficiency by encouraging longer or shorter prescriptions, how much effort and cost to invest in and how best to promote patient compliance, and what type of patient education and compliance monitoring to use. Quality measures require the provider to attest to monthly laboratory testing for serum calcium and serum phosphate. Laboratory tests are included in the bundle, and historic testing for parathyroid hormone was performed approximately quarterly (12). Increased attention to the mix of these drugs may require more frequent parathyroid hormone testing for some patients, which will increase provider costs (this is one of the most expensive laboratory tests included in the bundle). In general, providers will be exploring how to maximize use of lower-cost drugs while managing patient condition as measured by lab values and clinical evaluation.

At the same time CMS develops its policy framework for valuation of oral drugs, it will need to reevaluate other components of the PPS, including how the oral drugs will affect outlier payment policy; case-mix, comorbidity, and wage adjustments to the base rate per treatment; the market basket; and the structure of the base rate itself. The recent congressional action mandated that the base rate be “re-based” to account for observed decreased utilization of intravenous drugs since the bundle was implemented. This re-setting of the base rate will decrease bundled payments and will be explained in 2013 proposed rules for 2014 payments. At this time, the methodology and scope for re-basing are unknown.

Conclusion
Bone and mineral disorders associated with ESRD involve complex clinical decision-making, adjustments to mix and dose of oral drugs, dietary counseling, and attention to adherence to drugs and diet to prevent significant morbidity and adverse events (12,14,15). CMS’s valuation of the oral drugs used to manage these conditions in an adjusted bundle in 2016 will create incentives that will make improving quality of care easier or more difficult, depending on the comprehensiveness of the policy framework that guides these decisions.

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