Considerations for New End Stage Renal Disease Payment System

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Key Points

- Scope of Bundle
  - Oral-only calcimimetics and phosphate binders are not included under MIPPA definition of renal dialysis services
  - Adding oral-only drugs like calcimimetics to dialysis bundle is contrary to the public interest
    - Increases Medicare program spending by shifting costs from private sector to Medicare
    - Creates complexity for CMS, dialysis facilities, and patients
- Other Bundling Issues
  - Per treatment unit of payment is clinically appropriate and aligns incentives
  - Quality improvement program and payment adjusters are complementary tools for ensuring appropriate anemia management under bundled payment

Oral-Only Calcimimetics and Phosphate Binders are Not Included Under MIPPA Definition

- MIPPA bundles payment for items and services provided by dialysis facilities under Medicare Part B
- Drugs included in the MIPPA dialysis bundle:
  - Intravenous and injectable drugs that are currently separately billable by dialysis facilities[1]
  - Oral equivalent forms of intravenous and injectable drugs that are currently separately billable by dialysis facilities
- Oral-only calcimimetics and phosphate binders are not equivalent to any Part B intravenous or injectable drugs
- Therefore, oral-only calcimimetics and phosphate binders are not included under MIPPA definition

1. CMS indicated in the CY 2009 proposed rule that the following intravenous/injectable drugs represented 99.7 percent of total expenditures for separately billable drugs in dialysis in calendar year 2007: EPO, Paricalcitol, Sodium-ferric-glut, Iron-sucrose, Levocarnitine, Doxercalciferol, Calcitriol, Iron-dextran, Vancomycin, Alteplase, Aranesp (73 Fed. Reg. 38,502, 38,528, Jul. 7, 2008).

Oral-Only Calcimimetics Not Equivalent to Any Intravenous or Injectable Part B Drugs

- Sensipar® (cinacalcet) is the only calcimimetic on the market
- It is an oral drug and there are no intravenous or injectable equivalent forms
- Currently, Medicare beneficiaries receive calcimimetics through Part D plans and private prescription drug coverage
- Sensipar® is indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma
- There are other classes of drugs for the manifestations of secondary HPT, but these are not clinically equivalent to calcimimetics

Adding Oral-Only Drugs to Dialysis Bundle Will Increase Medicare Program Spending

- Almost a third of Medicare beneficiaries on dialysis have oral drug coverage outside of Medicare Part D[1]
- If these drugs are put into Part B, then their cost is shifted to Medicare and Medicare's costs are increased
- Calcimimetics example:[2]
  - $75 million in 2011
  - $800 million over ten years
  - This amount is for only the third of Medicare beneficiaries on dialysis who have oral drug coverage outside of Medicare Part D
  - For dialysis beneficiaries with Part D, the cost of calcimimetics would be shifted from Medicare Part D to Medicare Part B

Needlessly increasing Medicare program expenditures, especially by shifting costs from private plans to the federal government, is contrary to the public interest

1. Analysis based on IMS Lifelink and MedPAC March 2009 Report to Congress 2. Analysis based on IMS Lifelink, MedPAC March 2009 Report to Congress, Amgen 2008 Annual Report, USRDS ADR 2008, and 2008 HHS Report to Congress.

Dialysis Bundle is Complex to Implement and Adding Oral-Only Drugs Could Harm Patient Access

- CMS, Part D, and other Payers
  - Lack of dialysis facility data for utilization and cost for CMS to set bundled rate
  - Implications for access to the drug (s) for non-dialysis uses under prescription benefits
- Facilities
  - Would need to take on new function of dispensing oral drugs for home use
  - Would likely involve obtaining State pharmacy licenses or pharmacy contracts and working with Part D and private plans to coordinate provision of drugs
- Patients
  - Confusion as to which payer covers their oral medications for home use
  - Could lose benefits afforded by a single pharmacy provider dispensing drugs for home use (e.g. monitoring for drug interactions)
- Clinical
  - Oral-only calcimimetics and phosphate binders taken daily with food and therefore cannot be taken during dialysis treatment

Renal Community Consensus for Per Treatment Unit of Payment

- The unit of payment in the bundle could be made per treatment, per week, or per month
- Per treatment unit of payment is clinically appropriate, aligns incentives for quality care, and is least operationally burdensome
- Dialysis patients miss a significant number of dialysis sessions
- A monthly or weekly unit of payment would result in greater complexity and could harm patient access
  - Less flexibility for patients who need dialysis away from home
  - More complex accounting for missed treatments including hospitalizations

Bundled Rate Will Reflect Recent Improvements in Anemia Management

- MIPPA directs CMS to base the bundled payment on utilization from 2007, 2008, or 2009 - whichever is lowest
- Changes in anemia management that occurred in response to 2007 erythropoiesis stimulating agents (ESA) label changes and 2008 CMS ESA Monitoring Policy (EMP) revisions will be reflected in rate[1]
  - More patients in Hb range of 10 - 12 g/dL
  - Almost equal reduction in Hb above 12 and 13 g/dL
  - Small increase in Hb below 10 g/dL

1. FDA approved labeling for ESAs in chronic renal failure (CRF) revised in 2007. Among the changes, physicians instructed to "individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL" and a hyporesponse definition and dosing instructions were added. Labeling for ESAs in CRF does not specify a maximum dose

Quality Program Will Help Ensure Appropriate Anemia Management Under Bundled Payment

- Bundling creates incentives to be efficient, however, incentives for under-treatment also inherent in bundled payment systems
- The Quality Incentive Program (QIP) will help to mitigate this risk
- Anemia management quality indicator is required under MIPPA as part of the QIP
- Given poor outcomes associated with low Hb levels:
  - Anemia quality indicator should focus on minimizing Hb levels below 10 g/dL
  - Anemia management should be given sufficient weighting within the QIP composite score
  - Tracking performance should begin before bundling to establish baseline

Payment Adjusters Will Need to Address Variable Patient Requirements

- Patient response to ESAs varies dramatically
  - Phase 3 studies show 40-fold variation in ESA dose requirements[1]
  - Factors associated with ESA dose requirements
    - Hospitalizations[2]
    - Race[3]
    - Inflammatory conditions[4]
    - Weight[5]
    - Missed dialysis sessions[6]
- To ensure patients can receive necessary care MIPPA includes several approaches for payment adjusters
  - Outlier adjustments, case-mix adjusters, other facility adjusters

1. Eschbach JW, Abdulhadi MH, Browne JK *et al*. Recombinant human erythropoietin in anemic patients with end-state renal disease: results of a phase III multicenter clinical trial. Ann Intern Med 1989; 111: 992–1000. 2.Solid et al. Perihospitalization hemoglobin-epoetin associations in U.S. hemodialysis patients, 1998 to 2003. Hemodial Int. 2007 Oct;11(4):442-7. 3. Lacson et al. The association of race with erythropoietin dose in patients on long-term hemodialysis. Am J Kidney Dis. 2008 Dec;52(6):1104-14 4. Bradbury et al. Impact of elevated C-reactive protein levels on erythropoiesis- stimulating agent (ESA) dose and responsiveness in hemodialysis patients. Nephrol Dial Transplant. 2009 Mar;24(3):919-25 5.Chan et al. Facility factors dominate the ability to achieve target haemoglobin levels in haemodialysis patients. Nephrol Dial Transplant. 2008 Sep;23(9):2948-56. 6. Bradbury et al. Exploring relative mortality and epoetin alfa dose among hemodialysis patients. Am J Kidney Dis. 2008 Jan;51(1):62-70