Inclusion of Oral Drugs in the Bundled Payment System for ESRD

July 22, 2009

Agenda

- Precedent-Setting Decision for Bundling of Medical Services
- MIPPA Requires Inclusion of Oral Drugs Used to Treat ESRD
- Inclusion of Oral Drugs will Improve Quality and Ensure Access
- Inclusion of Oral Drugs will Reduce Medicare Spending
- Providers Can and Must Comply with Inclusion of Oral Drugs

Precedent-Setting Decision for Bundling of Medical Services

- Robust bundle for dialysis services is precedent-setting
- Efforts to unbundle specific items and services will continue
- Robust bundle ensures all relevant items and services are on an equal playing field

MIPPA Requires Inclusion of All Oral Drugs Used to Treat ESRD

- Section 1881(b)(14)(B)(iii) requires inclusion of "any oral equivalent form" of current separately billable drugs used to treat ESRD
- Section 1881(b)(14)(B)(iv) requires inclusion of "other items and services" used to treat ESRD
  - Certain drugs without Part B equivalent are used to treat ESRD
- W&M Health Subcommittee Chairman Stark said Congress's intent was to include "all oral dialysis-related drugs in the bundle, including calcimimetics and phosphate binders." (Congressional Record, June 24, 2008)
- Clarifying language regarding orals in the bundle included in House Health Care Reform bill

Including Oral Drugs will Improve Quality and Ensure Access

- According to MedPAC, including existing Part D-covered drugs "might help insure that beneficiaries receive appropriate care and that providers do not substitute Part D drugs for drugs that are covered under the broader dialysis bundle."
- MedPAC continued: Including these drugs "might help ensure that beneficiaries receive appropriate care. The decision making process would be based on what is best for the patient. Incentives to substitute a Part D drug for a service covered under the bundle, which might not result in the best care, would be eliminated."
- Including oral drugs under the Part B bundle will ensure that all patients with ESRD have access to them

Including Oral Drugs will Reduce Medicare Spending

- Unbundling oral drugs will incentivize higher utilization under Part D
- According to MedPAC, including these drugs in the bundle "would prevent providers from cost shifting by substituting Part D drugs for services covered under the payment bundle."
- CBO scores inclusion of these oral drugs in the bundle as a substantial savings to Medicare

Risk of Cost Shifting is Real

- Vitamin D and calcimimetics both used to treat bone and mineral metabolism
- Standard of Care is use of both drugs in some ESRD patients
- Recent manufacturer-funded studies promote using less Vitamin D and more calcimimetics earlier in the diagnosis of SHPT
- Leaving calcimimetics outside bundle would create financial incentive to prescribe drug in certain circumstances
- Increased use of calcimimetics and decreased use of Vitamin D would increase Part D spending and potentially result in adverse outcomes for patients, which is contrary to intent of bundle

Providers Can and Must Comply with Inclusion of Oral Drugs

- Mandatory inclusion of oral equivalent forms of Vitamin D and iron are not disputed
- Providers are required to make available all items and services in the bundle to qualify for the bundled payment
- A variety of options are available to providers to comply with delivery of these drugs to patients
- According to MedPAC, if these orals are included, "providers could furnish all of the drugs that were necessary to treat ESRD-related comorbidities at the facility."

Summary

- Including all IV and oral ESRD drugs in the bundle was the intent of MIPPA and is good public policy

- Including all IV and oral ESRD drugs used to treat patients in the bundle will:
  - Ensure optimal patient care and compliance and thus outcomes
  - Reduce costs to the Medicare program