KIDNEY CARE PARTNERS

Delay Incorporating Oral-Only Drugs into the ESRD PPS

Complex Nature of Administering Phosphate Binders/Lowering Drugs and Concerns about MA Plans Adjusting Reimbursement Make Their Inclusion Premature

KCP asks Congress to delay the inclusion of oral-only drugs in the ESRD PPS. CMS plans to add oral phosphate binders/lowering drugs to the ESRD bundle, moving them out of the Part D program beginning January 1, 2025. Yet, dispensing and administering these drugs present unique challenges for patients and dialysis providers that are unlike those facilities have overcome to provide other oral products through Part B. Given the volume of pills and variability in patient response to the many available products, pharmacies are better suited to distribute these drugs under Part D to ensure that people living with kidney failure continue to have access to the individualized care they need. Congressional action is needed to pause the inclusion of these drugs.

Medicare policy should make sure patients receive services from the provider best suited to provide that care. In the case of phosphate binders/lowering drugs, pharmacies through Part D are the best situated to provide access for individuals who require dialysis. Phosphate binders/lowering drugs are necessary to treat hyperphosphatemia, which occurs in nearly all individuals who receive dialysis treatments. If not treated, hyperphosphatemia can increase mortality, vascular calcification, and cardiovascular events.

- For most of these patients, the starting dose is typically 7.5 pills daily or more than 200 pills each month. If an average dialysis facility treats 100 patients in total, it would have to find a way to obtain, store, and distribute more than 20,000 pills each month.

- There are multiple types of phosphate binders/ lowering drugs from which physicians and patients must select to get the right outcomes for an individual patient. Because of this fact, facilities would have to manage even more pills to ensure they are appropriately stocked for the products being prescribed. Products vary in efficacy, tolerability and safety for each patient. Moreover, physicians report that a patient's dose and type of product can change often through their time on dialysis.

- Not all facilities have the infrastructure or resources to support these additional administrative challenges. This is a particular concern for small to mid-size independent dialysis facilities serving patients in rural communities.

- In order for phosphate binders/lowering drugs to be effective, they must be taken multiple times per day, with all phosphorus-containing meals and snacks, rather than once during a dialysis session.

Placing phosphate binders/lowering drugs into the ESRD PPS will place patient access at risk because many Medicare Advantage plans have refused to implement the Medicare payment policies that support adding new products to the bundle. More than 40 percent of Medicare beneficiaries requiring dialysis have chosen to enroll in MA plans and that percentage is growing.

- While MA plans offer many important services not available through traditional Medicare, many plans unfortunately have relied on a loophole that allows them not to reimburse dialysis providers for the cost of providing new products to patients or to recognize the costs when those produces are added to the bundle.

- Because all individuals receiving dialysis require phosphate binders/lowering drugs, a plan's policy to withhold adequate funding for these products would be devastating for patients.

Congress can support individuals receiving dialysis to obtain optimal care with phosphate binders/lowering drugs by further delaying their inclusion in the bundle, retaining their coverage under Part D. Both Congress and CMS have delayed the inclusion of these drugs multiple times due to operational, clinical, and administrative concerns with implementation. In last year's rulemaking, CMS indicated it would not exercise its authority to further delay their inclusion.

- KCP asks Congress to act expeditiously to further delay adding oral-only drugs to the bundle until the earlier of January 1, 2033, or such time as intravenous options are approved.

- Historically, CBO has indicated that keeping oral-only drugs in Part D will generate savings; KCP believes that the savings generated by a further delay should be invested back to support kidney community policy priorities.