

Amgen Position and Recommendation Regarding Oral Drugs without Intravenous Equivalents and the End-Stage Renal Disease Prospective Payment System

BACKGROUND

- Medicare currently pays dialysis facilities for certain items and services used to treat patients with end-stage renal disease (ESRD) under a composite rate system. In this system, one payment is made for each dialysis treatment that includes items and services that are considered to be part of the composite rate. In addition to the composite rate, Medicare also pays dialysis facilities separately for certain drugs and biologicals¹ and laboratory services.²
- Legislation enacted in 2008 mandated that the Centers for Medicare & Medicaid Services (CMS) establish a new bundled payment system for dialysis services effective January 1, 2011.³
- Under the new system, referred to as the ESRD Bundled Prospective Payment System (PPS), a single payment will be made for “renal dialysis services,” which includes (i) items and services in the composite rate as of December 31, 2010; (ii) erythropoiesis stimulating agents and any oral form of such agents; (iii) other drugs and biologicals furnished for the treatment of ESRD for which payment was (before the start of the new payment system) made separately and any oral equivalent form of such products; and (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of ESRD.⁴
- Sensipar[®] (cinacalcet) is a calcimimetic; it is currently the only such product on the market. It is an oral drug with no injectable equivalent form and is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma. Sensipar[®] is typically taken daily (i.e., more frequently than the usual three dialysis sessions per week). Sensipar[®] is not included in the ESRD composite rate, it is not paid as a separately billable drug, it is not an oral equivalent of a separately billable drug, and it is not otherwise paid for under Part B.
- Currently, Medicare beneficiaries receive almost all oral drugs, including Sensipar[®], through Part D plans or private prescription drug coverage. Many Medicare beneficiaries with ESRD also take other oral drugs that do not have injectable equivalents – such as phosphate binders – that are currently covered exclusively under Part D or private prescription drug coverage. In addition, many take numerous other oral drugs for the treatment of co-morbid conditions and complications associated with ESRD (e.g., oral anti-hypertensive medications). These, too, are either paid for under private prescription drug coverage or Part D. Patients receive these medications at commercial pharmacies, not at dialysis facilities.
- CMS has proposed to include some, but not other, oral-only Part D drugs in the definition of “renal dialysis services” such that these products would be included in the new ESRD PPS bundled payment

¹ These are known as “separately billable drugs.” See Medicare Benefit Policy Manual, Ch. 11, § 30.4.2.

² The statutory provisions governing the current payment system are largely in Sections 1881(b)(12) and (b)(13) of the Social Security Act (SSA).

³ See Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. No. 110-275, § 153 (adding SSA § 1881(b)(14)).

⁴ The precise definition of “renal dialysis services” is in SSA § 1881(b)(14)(B).

and paid under Part B rather than Part D. CMS has provided little rationale for its proposal to include certain drugs, as opposed to others, in the payment bundle. However, oral-only products that CMS proposes to include in the bundle do not fall within the statutory definition of “renal dialysis services,” and any other reading of the statute is flawed on both legal and policy grounds.

- Amgen appreciates the goals of Congress in enacting, and CMS in implementing, a new bundled payment system for ESRD. We support efforts to enact payment policies that improve the quality and efficiency of health care delivery. At the same time, we recognize that the powerful financial incentives inherent in bundled payment systems necessitate having strong quality of care standards in place along with a sound understanding of implementation details to avoid potential unintended consequences for patients. CMS appears to have understood these needs as the Agency carefully studied the bundling of separately billable Part B drugs in the ESRD payment system over almost a decade.
- Inclusion of some oral drugs in the bundle fundamentally changes the bundle that has been under study by CMS for so long. Such a dramatic change requires careful study and adequate data to assess the potential for unintended consequences to this fragile and highly vulnerable Medicare population, which may include significant access issues and risks to the quality of care. The inclusion of oral-only Part D drugs in the payment bundle has not been adequately studied or addressed with the nephrology community and potential risks to beneficiaries have not been analyzed.
- Amgen urges CMS to recognize that it has proposed to take a precedent-setting step by including oral-only Part D drugs in the new payment bundle. It would be unfortunate if insufficient planning, shortcomings in implementation or regulatory over-reaching resulted in poor patient care and reduced support for future payment reform efforts. If the agency ultimately adopts its proposal to include oral-only Part D drugs in the ESRD PPS payment bundle, it must ensure that it has the data needed both to meet the statutory requirements in setting the PPS payments and to prevent adverse impacts on beneficiary access to and quality of care.
- Congress has recognized the potential for significant risks to ESRD patients under this proposal and included a provision in the Patient Protection and Affordable Care Act (PPACA) requiring the Government Accountability Office (GAO) to analyze dialysis facilities’ ability to comply with state pharmacy regulations and furnish oral-only drugs that beneficiaries currently obtain at commercial pharmacies. The PPACA provision also requires GAO to study whether appropriate quality measures exist to safeguard ESRD patients being furnished oral-only drugs and report on Medicare beneficiary access to high-quality dialysis services⁵.

⁵ P.L. 111-148, §10336.

ANALYSIS

Including Oral-Only Part D Drugs in the Payment Bundle Would Be a Precedent-Setting Decision and Result in Poor Medicare Policy

- Sensipar[®] (cinacalcet) and phosphate binders are important treatments for secondary hyperparathyroidism (HPT), a progressive and insidious disease with long term consequences when there are treatment delays and under-treatment including: bone pain, bone loss, skeletal fracture, cardiovascular (CV) calcification, hospitalizations, CV disease, surgical parathyroidectomy, and increased mortality rates.⁸
 - Bundled payment systems have an inherent incentive for under-treatment. Secondary HPT patients are particularly vulnerable because the short-term consequences of under-treatment are mild and asymptomatic, although the long-term consequences are serious and potentially irreversible.
 - When changes in payment systems occur quality monitoring is fundamental to safeguarding patient care, yet CMS did not propose any quality monitoring related to outcomes in secondary HPT in the proposed rule – despite the fact that MIPPA specifically identified bone mineral metabolism (i.e. secondary HPT) for inclusion in the Quality Improvement Program to the extent such measures are feasible.
 - CMS does not currently have outcomes-based quality measures in this area and as such does not have baseline data under the current system to track performance against under the new PPS.
- CMS has not sufficiently evaluated the inclusion of Sensipar[®] (cinacalcet) and phosphate binders in the ESRD PPS and lacks the data to do so.
 - CMS recognized that careful evaluation and testing are critical components for safeguarding patient access and quality of care when it spent years analyzing how to bundle separately billable Part B drugs, including working with the University of Michigan’s Kidney and Epidemiology Cost Center (UM-KECC), issuing two reports to Congress, and working with an advisory committee. However, the same level of rigor and analysis has not been performed for oral-only drugs.
 - CMS lacks the necessary data on utilization of oral-only Part D drugs. The Part D data used in CMS’s analysis only represents utilization of 53.26 percent of ESRD beneficiaries in contrast to the full data set CMS has for separately billable Part B drugs and it cannot be assumed that Part D utilization is representative of Medicare patients with coverage outside of Part D. In addition, only 2 years of Part D data are available and the data are too new to determine whether the results seen in these data are stable.

⁸ Ganesh SK, Stack AG, Levin NW, et al., Association of elevated serum PO(4), Ca x PO(4) product, and parathyroid hormone with cardiac mortality risk in chronic hemodialysis patients J Am Soc Neph 2001; 12: 2131-8. Marco MP, Craver L, Betriu A, et al., Higher impact of mineral metabolism on cardiovascular mortality in a European hemodialysis population. Kidney Int Suppl 2003; S111-4.

- CMS needs complete, stable, multi-year aggregated patient-level data to properly determine case-mix implications.
- Changing the site of service by making dialysis facilities responsible for furnishing these drugs results in inadequate protections for patients and significant operational complexities for providers and payers.
 - ESRD patients commonly take many oral medications, and under this proposal they may be required to go to different pharmacies to obtain their medications. This could put patients at higher risk of drug to drug interactions because patients will no longer benefit from drug interaction monitoring that is required under Part D.
 - If patients have to travel to multiple pharmacies and /or they lose geographic access protections under Part D, patients may simply choose not to take their medications; this could have a negative impact on compliance and thus long-term clinical outcomes.
 - The shift in site of service also will be operationally difficult and costly for dialysis facilities which have never been responsible for the provision of oral-only drugs.
 - If facilities choose to act as a pharmacy and provide drugs directly, in virtually all states they will need to be licensed as a pharmacy which will be a costly undertaking. It requires pharmacy staff, physical space requirements, and pharmacy systems.
 - The other option for facilities is to provide drugs under arrangement but this also will result in extra costs in terms of staff time and expertise to negotiate and manage contracts, and information systems.

It is contrary to the statute and Congressional intent to include oral-only Part D drugs in the ESRD PPS beginning January 1, 2011

- Amgen believes that Congress never intended to include oral-only Part D drugs in the ESRD PPS when MIPPA was passed. There was significant debate on the issue when MIPPA was being negotiated in 2008 and the Senate Finance Committee, which crafted MIPPA with input from CMS and other legislative advisory bodies, included specific definition criteria for renal dialysis services in the statute.
 - The statutory definition of “renal dialysis services” at Section 1881(b)(14)(B) contains four clauses. An item or service must fall within one of these four clauses to be included in “renal dialysis services” and thereby in the new ESRD PPS bundle which includes (i) items and services in the composite rate as of December 31, 2010; (ii) erythropoiesis stimulating agents and any oral form of such agents; (iii) other drugs and biologicals furnished for the treatment of ESRD for which payment was (before the start of the new payment system) made separately and any oral equivalent form of such products; and (iv) diagnostic

laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of ESRD.⁷

- Oral-only Part D drugs like Sensipar[®] (cinacalcet) are (i) not included in the current composite rate, (ii) not erythropoiesis stimulating agents, (iii) have never been considered separately billable drugs and they are not the oral equivalent form of such drugs, and (iv) are not laboratory tests and other items and services.
 - In their 2008 Report to Congress, CMS explained that the items and services that might be added to an ESRD PPS bundle would be such things as supplies and blood products.⁸ Most significantly, oral-only Part D drugs are not mentioned in this report.⁹
 - Furthermore, in a 2006 GAO report to Congress on bundling Medicare's payment for drugs, the report discusses the inclusion of Part B drugs but only references Part D drugs to explain that they are not part of the subject matter of the report.¹⁰
- Recent legislative proposals provide further support that oral-only Part D drugs were not intended by Congress to be included in the ESRD PPS.
 - Two legislative proposals - Section 1232 of H.R. 3200, America's Affordable Health Choices Act and Section 1232 of H.R. 3962, the Affordable Health Care for America Act - if enacted, would have modified MIPPA to include, "oral drugs that are not the oral equivalent of an intravenous drug (such as oral phosphate binders and calcimimetics)." The Congressional Budget Office (CBO) estimated that the proposal, in combination with a provision to extend coverage of immunosuppressive drugs, would result in changes to baseline spending for the Medicare Program.¹¹ This analysis indicates that the CBO believes these drugs are not currently included in the ESRD PPS.

⁷ The precise definition of "renal dialysis services" is in SSA § 1881(b)(14)(B).

⁸ HHS Report to Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System (February 2008).

⁹ This may reflect the fact that CMS understood the scope of a new bundled payment for dialysis services to be limited to items and services covered under Parts A and B of Medicare. Section 1881(a) of the SSA sets the parameters for what is paid under § 1881(b), and the focus is on Part A and Part B benefits. Because oral-only Part D drugs are not covered under Medicare Part A or B, they are not items and services paid under SSA § 1881, and therefore they would not be within the new ESRD payment bundle.

¹⁰ US Government Accountability Office (GAO) Report to the Chairman, Committee on Ways and Means, "End-Stage Renal Disease – Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility". Available at www.gao.gov/cgi-bin/getrpt?GAO-07-77.

¹¹ H.R. 3200 Subtitle C, Section 1232 <http://www.cbo.gov/ftpdocs/104xx/doc10464/hr3200.pdf>

At a Minimum, CMS Must Delay Inclusion of Oral-Only Part D Drugs in the ESRD Payment Bundle

- Amgen maintains that there is no compelling policy rationale, given the potential for adverse consequences for patient care and the lack of adequate data or study to assess predictable or unintended consequences, to include oral drugs that do not have an intravenous equivalent in the ESRD PPS payment bundle.
- Layered on top of these concerns is the absence of a transition for oral-only Part D drugs. Congress understood that dialysis facilities need time to adjust to a new payment rate and in Section 1881(b)(14)(E)(i) of MIPPA explicitly directed the Secretary to provide a four-year phase-in period offering a payment rate that blends rates under the current system with the new rates under the PPS. However, providers do not have this choice with oral-only Part D drugs.
- If, despite the legal and policy issues, CMS remains intent on including Part D drugs in the ESRD payment bundle, the agency should do so only after the four-year transition period and the GAO is able to study and report on the implications of such policy as directed by Congress.
- After completion of the GAO study, CMS should incorporate appropriate findings of the GAO report in its implementation of the bundle as well as include appropriate safeguards to protect quality patient care.
- Given the inevitable complexity of issues for many facilities during the four-year transition period, Amgen believes that CMS should address all implementation, legal, and policy concerns before including oral-only Part D drugs in the payment bundle at the conclusion of the transition period. This will allow time for ESRD providers to develop the capabilities and infrastructure necessary to comply with any changes made to the broad payment bundle.
- CMS has the legal authority to delay inclusion of oral-only Part D drugs in the payment bundle. During the period of the delay, these drugs would continue to be covered and paid for under Part D because of the statutory definition of “covered Part D drug” in the Social Security Act.

CONCLUSION

Sensipar[®] (cinacalcet) is a product that treats a severe illness in ESRD patients. It has no injectable equivalent and was never intended to be included in the new ESRD PPS payment bundle. Amgen believes that CMS should delay the inclusion of oral-only Part D drugs in the ESRD bundle until the findings from the GAO report are fully explored and integrated into the policy-making process. If after that time, the agency decides to move forward with the inclusion of these therapies into the PPS, it should do so only after the four-year transition period given the inevitable legal and policy complexities inherent in implementation of the PPS.



Pioneering science delivers vital medicines™

Oral Drugs without Intravenous Equivalents and the End-Stage Renal Disease (ESRD) Bundled Prospective Payment System (PPS)

May 19, 2010

Key Points

- Amgen supports payment policies that reinforce comprehensive patient management, require evidence-based best practices, and align incentives for efficient care with improved outcomes
 - ESRD Bundled PPS has the potential to promote quality and efficiency, but also can have serious unintended consequences
- The Office of Management and Budget (OMB), other authoritative bodies, recognize ESRD Bundled PPS requires study and evaluation before implementation due to the inherent complexity

AMGEN'S RECOMMENDATION

- Delay inclusion of oral-only Part D drugs that do not have injectable equivalents in the ESRD Bundled PPS
 - Adequate evaluation and patient safeguards needed
 - US Government Accountability Office (GAO) required to study feasibility by March 2011¹

Access to Secondary HPT Therapies is Important

- Secondary hyperparathyroidism (HPT) is a progressive disease²
- Few short-term consequences, disease can be asymptomatic until advanced stages
- But long-term consequences of treatment delays are serious and potentially irreversible
- African Americans disproportionately impacted by secondary HPT, with higher parathyroid hormone (PTH) levels at dialysis initiation and greater utilization of Sensipar[®] (calcimimetics)³

Secondary HPT is a serious condition; Payment policies that jeopardize patient access to secondary HPT therapies could reduce disease control and may place patients at risk for poor long-term outcomes.

Insufficient Patient Safeguards Exist to Protect Access to and Quality of Care

- Dialysis providers would not be at risk for the cost of consequences of under-treatment since hospitalizations are not included in the proposed bundle
 - Appropriate consensus-driven and proven outcomes measures for secondary HPT should be in place before oral-only secondary HPT drugs are included in the bundle, with baseline data to track performance and changes in quality of care
- Patients would lose important protections available under current pharmacy benefit
 - Drug utilization review
 - Geographic access standards and requirements
 - Medication therapy management programs
 - Possible requirement to use multiple pharmacies which could potentially increase rates of non-compliance

Congress remains concerned about patient impact. PPACA requires GAO to study and report on, by March 2011, whether appropriate quality measures exist in this area, and the impact on access to care by including oral-only drugs in the ESRD Bundled PPS. *

Insufficient Analysis and Data for Oral-Only Drugs will Place Facilities and Ultimately Patients at Risk

- Years of study for separately billable Part B drugs with no comparable analysis for oral-only drugs
 - Part D data incomplete, does not represent total ESRD per-patient utilization
 - Data should capture full utilization of oral drugs by Medicare Part B beneficiaries at the patient-level, be linked to outcomes data, and be stable over at least a three-year time horizon
- Facilities will incur costs beyond the medication cost due to new infrastructure and staffing needs
 - Facilities opting to dispense will have to comply with state pharmacy laws (hiring dedicated pharmacy staff, ensuring appropriate space, etc)
 - Facilities opting to contract with pharmacies will incur costs related to managing that activity, both staff and information systems
 - The proposed rate per-treatment is insufficient to cover drug cost let alone the non-drug costs associated with the proposed policy change.
- Lack of transition for oral-only drugs is contrary to statute and congressional intent
 - Oral drugs are among the items for which a transition is most necessary since dialysis facilities have never been responsible for the provision of such drugs. The absence of a transition exacerbates the disincentive to make clinical decisions based on best therapy.

Inclusion of oral-only Part D drugs in the new payment system fundamentally changes the bundle that has been under study by CMS for close to a decade. Such a dramatic change requires careful study and adequate data to assess the potential for unintended consequences to this vulnerable Medicare population.

The Nephrology Community is United On the Potential Risks and Clinical Consequences

- The Kidney Care Partners, as well as patient groups, physicians groups, and other ESRD stakeholders all raised significant concerns over the oral-only Part D drug bundling proposal

“The lack of data for both utilization and outcomes for oral drugs, coupled with an inadequate proposed payment, could worsen quality and ultimately harm patients.” ¹

“...There are currently few appropriate clinical metrics in place to monitor impacts of changes in drug regimen on patients.... We believe that it could pose a threat of unintended consequences which could be detrimental to patient outcomes.” ²

“Disparities in care will increase. Nephrologists may be placed in the untenable position of determining not which medications are most appropriate for a patient, but which patients within the facility are most deserving or have the greatest need for certain medications.” ³

- At a minimum, many of these groups advocate for a delay in including oral-only Part D drugs in the bundle until these concerns can be addressed

Amgen Recommendation for Oral-Only Drugs

- Oral-only drugs should not be considered for inclusion in ESRD PPS bundle until findings from the GAO report are appropriately incorporated into the decision-making process and patient safeguards are in place to ensure that:
 - Patients will receive appropriate care for secondary HPT
 - Quality metrics, with baseline data, are incorporated
 - Patients, providers, and payers can implement and operationalize the shift in site of service
 - Reimbursement is based on accurate data and includes appropriate case-mix adjusters for variation in secondary HPT medication requirements
- Amgen believes that delaying the inclusion of oral-only part D drugs in the ESRD bundle is a prudent policy change that CMS should make in the forthcoming Bundled PPS Final Rule. If, after appropriately addressing the findings of the GAO report, the agency decides to move forward with the inclusion of these therapies into the PPS, it should do so only after the four-year transition period.

End Notes

1. P.L. 111-148, Section 10335
2. Goodman WG. *Semin Dial.* 2004;17:209-216., 2. Goodman WG, Quarles LD. *Kidney Int.* 2007;74:276-288., 3. Moe SM, Sprague SM. *The Kidney.* 8th ed. Philadelphia, PA: Saunders Elsevier; 2008:1784-1813., 4. Block GA, et al. *J Am Soc Nephrol.* 2004;15:2208-2218., 5. Kalantar-Zadeh K, et al. *Kidney Int.* 2006;70:771-780., 6. Danese MD, et al. *Clin J Am Soc Nephrol.* 2008;3:1423-1429.7. Danese CJASN 2008, 8. Ganesh SK, et al. *Clin J Am Soc Nephrol.* 2001, 9. Marco MP, et al. *Kidney Int. Suppl* 2003.
3. Wolf M, Betancourt J, Chang Y, et al., Impact of activated vitamin D and race on survival among hemodialysis patients. *J Am Soc Nephrol* 2008;19:1379-1388. St. Peter, WL, Li Q, Liu J, et. al. Cinacalcet use patterns and effect on laboratory values and other medications in a large dialysis organization. *CJASN* 2009;4:354-360.
4. P.L. 111-148, Section 10335
5. Kidney Care Partners (KCP) is an association of patients, physicians, nurses, dialysis providers, and manufacturers. KCP letter to the Centers for Medicare and Medicaid Services (CMS) on the End-Stage Renal Disease Prospective Payment System Proposed Rule dated December 11, 2009.
6. American Kidney Fund (AKF) is charitable health organization serving the kidney disease population through financial assistance, education, and community service programs. AKF letter to CMS on the End-Stage Renal Disease Prospective Payment System Proposed Rule dated December 14, 2009.
7. Forum of End Stage Renal Disease Networks (ESRD Networks) is an association that advocates for the organizations that monitor the quality of chronic kidney disease, dialysis and kidney transplants in the U.S. ESRD Networks letter to CMS on the End-Stage Renal Disease Prospective Payment System Proposed Rule dated December 15, 2009.