Amgen Submits Testimony to House Ways & Means Committee

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Amgen Cites Evidence that Majority of EPOGEN(R) Use Has Been Appropriate Over Time and Shares New Data Showing More Conservative Dosing in Response to Updated CMS Policy and Product Labeling

Company Says Data Shows No Compelling Rationale for Congress to Mandate Untested Changes to Payment System

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--June 26, 2007--Amgen (NASDAQ:AMGN) today submitted testimony for the record of the House Ways & Means Subcommittee on Health hearing on "Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care."

Amgen cited data in its testimony showing that the majority of EPOGEN(R) (Epoetin alfa) use in dialysis has been and continues to be appropriate. When examined over time, 83 percent of patient hemoglobin excursions above 12 g/dL fall below 12 g/dL within three months.

Amgen also highlighted new analyses of U.S. dialysis data showing that physicians are using EPOGEN even more conservatively since the Centers for Medicare & Medicaid Services (CMS) announced the Erythropoietin Monitoring Policy (EMP) in November 2005 and the U.S. Food and Drug Administration (FDA) made changes to the product labeling for Erythropoiesis Stimulating Agents (ESAs), including EPOGEN, in March 2007.

"Amgen is committed to the highest standards of patient safety. The well-being of patients is Amgen's top priority as is the appropriate use of all of our products," said Joshua Ofman, M.D., M.S.H.S., vice president of Global Coverage and Reimbursement at Amgen. "Based on the best available scientific evidence and utilization data, there does not appear to be a compelling policy or clinical rationale to immediately make fundamental, untested changes to the dialysis payment system."

Current Utilization Data

The new analyses cited in Amgen's testimony are based on dialysis data collected through April 2007, representing approximately 80 percent of all U.S. dialysis patients. This data indicates:

-- The percentage of patients with hemoglobin levels between 11-12 g/dL is increasing (from 26.3 percent in January 2007 to 27.7 percent in April 2007).

-- The percentage of patients with hemoglobin levels greater than 13 g/dL is declining (from 26 percent in January 2007 to 23.6 percent in April 2007).

-- Physicians are decreasing EPOGEN doses more frequently in response to elevated hemoglobin levels. (In April 2007, 81 percent of hemoglobin excursions above 13 g/dL were followed by a physician reducing ESA dose within 30 days, compared to 72 percent in November 2005 when the EMP was announced. In April 2007, 49 percent of hemoglobin excursions between 12 g/dL and 13 g/dL were followed by a physician reducing ESA dose within 30 days, compared to 37 percent in January 2007).

"When considering the impact of current reimbursement policies and revised product labeling on patient care it's important to look at data collected after current changes were made and communicated to the community," explained Robert Brenner, M.D., executive director, Nephrology Medical Affairs at Amgen. "Although these policies have only been in effect for a short period of time, we're seeing early indication that changes in clinical practice patterns are underway. The full impact has not yet been determined."

Patient Risks, Financial Costs of Underutilization

Citing documented risks to patients and potential increased healthcare costs associated with dialysis patient hemoglobin levels below 11 g/dL, Amgen cautioned Congress against changing Medicare ESA payment policy using untested mechanisms that could have the harmful consequence of negatively impacting the quality of care for Medicare beneficiaries receiving dialysis.

Hemoglobin levels less than 11 g/dL are associated with increased hospitalization, mortality and healthcare expenditures. CMS has an established Clinical Performance Measure (CPM) for all dialysis clinics that evaluates the percentage of patients with hemoglobin levels above 11 g/dL, and publishes this data on its web site for patients and providers to monitor clinical performance.

Amgen's testimony notes that Medicare per unit expenditures for EPOGEN have decreased over time, from $10 per 1,000 units in 1994-2004 to $9.10 per 1,000 units in July 2007. Since the reimbursement method for EPOGEN switched to average sales price (ASP) +6 percent in 2006, per unit Medicare payments for EPOGEN have decreased by almost 7 percent.

Amgen addressed concerns about rising total CMS expenditures for EPOGEN. The testimony notes that increased overall expenditures are a consequence of steady growth in the dialysis patient population, meaningful improvement in meeting CMS' quality standards on dialysis patient health, and an increasingly sicker dialysis population with higher EPOGEN requirements.

Science-Based, Patient-Focused Reimbursement Policy

"Amgen believes that any changes considered to the dialysis payment system should have a strong policy or clinical rationale, promote access and quality of patient care, and be financially viable for dialysis providers, patients and taxpayers," explained Ofman.

One potential change to reimbursement involves a new payment system that would bundle government payment for dialysis services with separately billable dialysis drugs. According to Amgen's testimony, bundled payment systems create powerful financial incentives to save money by underutilizing and withholding needed medical services. Bundling methodologies should be balanced with a robust and clinically valid risk-adjustment system, as well as an agreed-upon set of quality safeguards, or they may result in the under-treatment of vulnerable dialysis patients.

Amgen points to the potential for serious unintended consequences to specific dialysis populations, in particular those patients who are treated by smaller, independent dialysis facilities, including in rural areas and centers located in underserved urban areas. Amgen cites these potential consequences of a fully bundled system in urging Congress to wait for the results of a demonstration project to test a bundled system in dialysis, as currently mandated by the Medicare Prescription Drug, Modernization, and Improvement Act (MMA).

Appropriate Anemia Management

Before the advent of EPOGEN, physicians had few options for treating anemia in dialysis patients and had to rely on blood transfusions. Unfortunately, chronically administered blood transfusions put patients at risk for complications such as blood-borne infections and antibody responses that limit the chances for a successful kidney transplant.

On March 9, 2007, the FDA and Amgen announced that a black box safety warning was being added to all ESA labels, including new guidance for dosing and administration. The updated label states physicians should use the lowest dose of EPOGEN that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions and not to exceed 12 g/dL.

According to Amgen's testimony, the nephrology community consensus is that a hemoglobin target range of 11 to 12 g/dL minimizes risk and maximizes benefit in dialysis patients, but due to the severity of additional disease burden and inherent natural hemoglobin variability, dialysis patients are very difficult to consistently maintain within this relatively narrow hemoglobin range.

The testimony also underscores that when used as directed by the FDA-approved package insert, EPOGEN has been shown to be safe and effective in multiple clinical trials, and has over a decade and half of safety monitoring in real-world use in almost 1.4 million dialysis patients for a total exposure of approximately 3.8 million patient-years.

U.S. Dialysis Patient Population

The U.S. Renal Data System reports that prevalent dialysis patients have more than doubled since 1988. About one-third of U.S. dialysis patients are African-American and one in seven is Hispanic. Dialysis patients typically carry a heavy burden of other medical conditions, including high blood pressure, diabetes, heart disease and anemia.

Some members of Congress have raised questions about differences in ESA utilization between the United States and Europe. Amgen's testimony states that the differences in ESA dose across world regions can be explained in part by differences in patient co-morbidities, race and dialysis vascular access type, as well as hemoglobin outcomes.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

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