IVIg Reimbursement Cuts Threaten Patient Access

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Physicians as well as patient and industry representatives say that a congressionally imposed reduction in Medicare reimbursement for intravenous immunoglobulin—when combined with several other factors—is having a devastating impact on access to the therapy, leading to more infections and serious illnesses among patients.

The payment scheme went into effect for physician offices in 2005 and for hospitals beginning in January, and was partly a reaction by the Centers for Medicare and Medicaid Services to rising intravenous immunoglobulin (IVIg) use, Bruce Kruger, director of practice and policy for the American Academy of Allergy, Asthma, and Immunology (AAAAI), said in an interview.

The immune therapy is approved for primary immunodeficiency, idiopathic thrombocytopenic purpura, Kawasaki disease, chronic lymphocytic leukemia, pediatric HIV infection, and allogeneic bone marrow transplantation. However, there has been increasing off-label use for infectious diseases; neurologic diseases such as myasthenia gravis, multiple sclerosis, and polymyositis; and hematologic diseases, allergies, and transplantation.

About 17% of the 50,000 people who receive IVIg for primary immune therapy are Medicare eligible and have been the first to start experiencing access issues, said Marcia Boyle, president of the Immune Deficiency Foundation (IDF). Ms. Boyle and Mr. Kruger said that private insurers are following Medicare's lead and also are starting to cut IVIg payments.

At the same time, supplies of the therapy, which takes up to a year to create, have tightened, partly because of rising demand.

From 2000 to 2005, manufacturers increased supplies by 60%, but it still was not enough, Julie Birkhofer, executive director, North America, of the Plasma Protein Therapeutics Association (PPTA), said in an interview.

Another problem: Much of the supply is tied up in physician offices, and they have stopped offering infusions because of the decreased payments.

In a study commissioned by the IVIg Summit Group (which includes the PPTA, IDF, several medical associations, and individual physicians), the Lewin Group found physicians are losing an average $400 per infusion, and losses pile up with increasing infusions. At 10 infusions, a physician would tally a $3,100 loss, according to Lewin.

The IDF and others say that patients have begun migrating to hospitals as physicians shut down infusion services, but that hospitals also are curbing IVIg infusions as the lower reimbursement hits them.

An IDF-funded study presented as a poster at the AAAAI's annual meeting in early March found that 39% of the 202 patients with primary immune deficiencies surveyed said they had problems in getting their IVIg therapy from June 2004 to June 2005, including postponed infusions, increased intervals between infusions, and being switched to a less-tolerated product.

The physician's office is a safer environment than a hospital for an immune-compromised patient. Infusions, usually given monthly, generally cost $5,000.

CMS has been reimbursing physicians for the average sales price plus 6%, and in 2006, added a $69-per-infusion payment to cover administrative costs. In 2005, CMS was paying hospitals 83% of the average wholesale price, which was a slightly higher reimbursement. But in 2006, hospitals also were moved to the average sales price plus 6% rate, which Lewin estimated as a 9% shortfall between the acquisition cost and the Medicare payment, said Ms. Birkhofer. Hospitals were also given an additional $75 for administration.

The PPTA, AAAAI, and others are seeking an add-on payment for the product and to assign Health Care Common Procedure Codes to each brand of IVIg. Currently, all 10 available brands are bundled under one code, giving physicians an incentive to prescribe the lowest-cost IVIg, said Ms. Birkhofer. That can affect patient access and care because not every patient can tolerate the same brand of IVIg, she said.

PPTA has received a legal opinion that CMS can adjust the payment through a rule or some other administrative mechanism.

Mr. Kruger said a payment add-on may be an interim solution, but long term, the demand issue should be addressed. "We're not so naïve to think that all therapy that was being provided was appropriate and necessary," he said. ■