IVIG Reimbursement Woes inhibit Access

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Physicians as well as patient and industry representatives say a congress’ bills for reducing 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.

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, said Bruce Kruger, director of practice and policy for the American Academy of Allergy, Asthma, and Immunology (AAAAI).

The immune therapy is approved for primary immunodeficiency, idiopathic thrombocytopenic purpura, Kawasaki disease, chronic lymphocytic leukemia, pediatric HIV infection, and allogeneic bone marrow transplantation. There also has been increased use of IVIG for infectious diseases; neurologic diseases such as myasthenia gravis, multiple sclerosis, and polymyositis; hematologic disorders, 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 hard-to-make therapy—it 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 infusions because of the decreased payments.

In a study commissioned by the IVIG Summit Group (which includes the PPTA, the IDF, several medical associations, and individual physicians), the Lewin Group found that physicians are losing an average $400 per infusion, and that the 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 reduce IVIG infusions, 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 99% 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 considered 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 to $775 for administration.

The PPTA, the 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, which gives 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.

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The suit alleges, among other things, that Paxil was effective and safe by the American Legacy Foundation, said Mr. Kruger. "Paxil's own documents lend support to the plaintiffs' arguments. One month late-