

IVIG Reimbursement Woes Limit Access

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Physicians as well as patient and industry representatives say 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.

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 increasing off-label use for infectious diseases; neurologic diseases such as myasthenia gravis, multiple sclerosis, and polymyositis; 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 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 offering 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 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 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 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.

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.

AAAAI's Primary Immunodeficiency Committee has assembled a review of evidence supporting IVIG use in various conditions. The panel reviewed 80 indications, said Dr. Jordan S. Orange of the University of Pennsylvania, Philadelphia, and lead author of the review (*J. Allergy Clin. Immunol.* 2006;117:S525-53).

The paper aims "to emphasize the importance of selecting patients for immunoglobulin very carefully," said Dr. Orange. "Pushing the boundaries of indications is going to lead to increased usage of a scarce product," and those uses may not always be effective, he said.

Dr. Orange helped design and analyze a new unpublished AAAAI/Immune Deficiency Foundation survey of specialists who treat primary immune deficiency. One of the questions asked members about the impact of the CMS reimbursement. Ninety-five percent said the current policy represented some risk to their patients, Dr. Orange said. ■

In a new survey of specialists who treat primary immune deficiency, 95% said the current policy posed some risk to their patients.

POLICY & PRACTICE

Charity Health Care Declines

The decade-long decline in the proportion of physicians providing charity care continued in 2004-2005, according to a study by the Center for Studying Health System Change. The percentage of physicians providing any free or reduced-fee care decreased to 68% in 2004-2005, down from 72% in 2000-2001. "Declines in charity care were observed across most major specialties, practice types, practice income levels, and geographic regions," study authors Peter J. Cunningham, Ph.D., and Jessica H. May wrote. "Increasing financial pressures and changes in practice arrangements may account in part for the continuing decrease in physician charity care." More than 70% of physicians providing charity care reported that they typically did so in their own practice, while 14% provided it while on call in a hospital emergency department and 6% in another practice or clinic. The researchers noted that surgical specialists were the most likely among specialty physicians to provide charity care, probably because many are required to be on call at hospitals and therefore have less choice about whether to treat uninsured patients. Pediatricians were the least likely to provide charity care, which perhaps reflects the fact that more children than adults have public health coverage, they said.

Cigarette Smoking Rate Stubbed

The number of cigarettes sold in the United States in 2005 dropped just over 4% from 2004, the largest 1-year percentage decrease in sales since 1999, according to figures compiled by the Treasury Department. "We are pleased to see that the long decline of cigarette consumption is continuing," Cheryl Heaton, Dr.P.H., president of the American Legacy Foundation, said in statement. "We also know that for the first time in the United States, there are more former smokers than current smokers." The National Association of Attorneys General also applauded the numbers, noting that the drop continues "the unprecedented long-term decline in cigarette smoking that began with the settlement of lawsuits" brought by state attorneys general against the major tobacco companies.

Paxil Class-Action Suit Hits GSK

Families of adolescents who took paroxetine (Paxil) and attempted suicide have filed suit against GlaxoSmithKline in federal court, claiming that the drugmaker "defrauded the medical profession, the Paxil patient population, and the general public." The suit alleges, among other things that GlaxoSmithKline "hired doctors to present 'posters' around the world at medical conferences which claimed, falsely, that Paxil was effective and safe for the treatment of depression with children and adolescents." In one case that spurred the suit, a pediatrician prescribed Paxil for an 11-year-old boy

to treat separation anxiety disorder, according to plaintiff's attorneys. The boy "immediately began having difficulty sleeping and had angry outbursts while on Paxil, but his family did not make the connection between his deteriorating behavior and the drug," according to the suit. One month later, he hanged himself with the dog's leash in the family laundry room. The boy's mother filed the class-action suit in March in Philadelphia. The complaint notes that although the drug has never been approved for use in pediatric patients, GlaxoSmithKline "has conducted a number of clinical trials involving the use of Paxil with pediatric patients ... GSK's own documents admit that the results of these clinical trials did not show a statistically significant benefit over placebo," the plaintiffs claimed.

Bush Whacked in Health Care Poll

Americans have a low level of trust and confidence in President Bush when it comes to improving the U.S. health care system, a Wall Street Journal Online/Harris Interactive poll found. Only 25% of adults are "confident or very confident" that the president can reduce the percentage of Americans without health insurance, according to the online survey of more than 2,400 adults. About half (49%) of Republicans expressed this level of confidence, compared with 7% of Democrats and 19% of Independents. Respondents expressed somewhat more trust in the Democrats (45%) and potential 2008 Democratic presidential candidate Sen. Hillary Clinton (D-N.Y.) (41%) to improve the health care system than in the Republicans (31%) and President Bush (30%).

Cancer Site Targets Asian Speakers

A searchable online database of cancer material in 12 Asian languages is now available. The Asian American Network for Cancer Awareness, Research, and Training Web tool (www.aan-cart.org/apicem) is designed to help Asians and Pacific Islanders with limited English-speaking abilities gain access to information about reducing their risk for cancers of the breast, cervix, colon, lung, and stomach. The effort, unveiled at the annual meeting of the Asian American Network for Cancer Awareness, Research and Training (AANCART), is supported by the American Cancer Society and the National Cancer Institute. The new database catalogs and provides links to print materials written in the following languages: Khmer, Chamorro, Chinese, Hawaiian, Hmong, Ilokano, Korean, Samoan, Tagalog, Tongan, and Vietnamese, as well as English-language materials culturally tailored for Native Hawaiian populations. Additional languages and topics will be added as more materials become available, according to AANCART.

—Nancy Nickell