

# REIMBURSEMENT MATTERS

## Medicare and Immune Globulin

By Alma Lucy Morales

When Linda Swim had to wait nearly two months for her routine treatment of immune globulin, and her doctor's office was forced to postpone her regular treatments, she knew her condition would worsen. Previously, Swim's life had significantly improved since she had started immune globulin therapy in 1996, and she feared what would happen if she were unable to obtain her scheduled infusions. "Before I began my IVIG treatments, my condition was so severe that I was in bed all the time. I was so weak that I could not get out of bed except to go to the bathroom. I had to stop working. I could not do anything for myself. It was terrible."

Swim's situation is an example of how changes in Medicare reimbursement for the administration of immune globulin have unintentionally jeopardized the health of patients who rely on this lifesaving therapy.

According to the Centers for Medicare & Medicaid Services (CMS), the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) was created to "modernize the Medicare program" and improve access to care. In theory, the MMA was supposed to save tax dollars while allowing those in need to receive proper treatment. In practice, however, in many cases, patients have been denied care in their traditional settings. The reason is purely economic.

The January 1, 2005, congressionally mandated reduction in Medicare Part B reimbursement rates and the two-tier rates for liquid and lyophilized (powdered) immune globulin, implemented on April 1, 2005, established two different rates for administering immune globulin to patients, depending on where the treatment is received: in the physician office and at home or in the hospital outpatient setting. The new reimbursement methodology significantly lowered the rate paid to physician offices and homecare companies for immune globulin infusions—at a time when immune globulin prices were rising and supplies of immune globulin products were tightening.

The combination of reduced reimbursement, rising prices and tightening supply created a dangerous situation



in which seriously ill, low-income patients with primary immune deficiencies or neuropathies were struggling to maintain access to care. In many cases they were unable to access treatment, causing their health to deteriorate.

By May of 2005, the reduced rate at which physicians' offices were being reimbursed was so devastating that many physicians had no choice but to refer their patients elsewhere. These patients had to resort to receiving treatment in a hospital, where their co-pays were as high as \$649 per treatment and their exposure to infection was increased.

"It is an intolerable position to be in, when we cannot receive reimbursement for the services we have provided for our patients, reimbursement that will allow us to at least cover our own cost for the products administered. All of us at our office simply want to care for our patients in a compassionate and effective manner, and not be forced into positions that compromise our quality of patient care and the health of the people we serve!" said Dr. Robert Dracker of Syracuse, New York.

What many people predicted as the worst-case scenario happened in September 2005 when one patient who was unable to receive his regular immune globulin treatments died. Although Lawrence Michalski's official cause of death was cardiorespiratory disease, some doctors believe the inability to receive routine immune globulin therapy contributed to his death.

"The predictable consequences of the Medicare Modernization Act and the Part B rate reduction are due

to the unique nature of the human plasma products market and a lack of policymakers' understanding of product supply dynamics," said Patrick M. Schmidt, president and CEO of FFF Enterprises, the nation's largest distributor of immune globulin.

In this critical life-and-death environment, while Congress continues to make decisions about reimbursement, industry, patient advocacy organizations and healthcare professionals strive to improve future reimbursement decisions for the benefit of the patients.

### Working Toward a Solution

"The industry has come together to work toward a solution to the current problems with reimbursement," said Schmidt. The newly formed group comprises most of the industry's major constituents, including the Immune Deficiency Foundation, the Jeffrey Modell Foundation, The Neuropathy Association, primary channel distributors, such as FFF Enterprises, and immune globulin manufacturers, such as Baxter, Grifols, Octapharma, Talecris and ZLB Behring. The group is also working closely with the Plasma Protein Therapeutics Association, as, together, they are addressing immune globulin issues and building awareness about these issues in Congress and at CMS. "There is no easy or quick fix," Schmidt explained, "but we are working together to find a way to make things better for patients."

Educating Congress on the importance of immune globulin access for patients with primary immune diseases and neuropathies is the primary focus for this group. The combined forces are also researching legislation that can affect access to care for immune globulin consumers.

An encouraging development occurred in November 2005 when CMS responded to the need for a change in the reimbursement rates in the hospital outpatient setting. CMS established an add-on payment to cover the additional preadministration-related services required to locate and acquire adequate immune globulin product and prepare for an infusion of immune globulin in outpatient settings and physician practices. While this change temporarily addresses the issue for some patients, reimbursement for the homecare setting still needs adjustment—and the add-on is only temporary.

This series of reimbursement changes is believed by many to be likely to cause unforeseen repercussions throughout the community of immune globulin users, regardless of their health insurance provider. Because private insurers typically follow Medicare's lead, the reduction in Medicare reimbursement will likely impact private pay patients who depend on immune globulin infusions. In fact, private insurance changes have already

occurred: Two of the nation's largest private insurance companies dropped their immune globulin reimbursement rates by nearly 20 percent within the last year, and industry watchers expect other companies to follow suit.

### What You Can Do to Help

A leading organization for people with primary immune deficiencies, the Immune Deficiency Foundation (IDF), encourages immune globulin consumers to become advocates in the effort to inform Congress about the challenges of reimbursement and access to care. "Visit your local Congress members' offices and let them know how these changes have affected you," recommends Michelle Vogel, director of government affairs for IDF. "It is important for patients to share their stories with their representatives and to let them know how changes in reimbursement impact the entire immune globulin community."

Patients and national patient advocacy groups have played a key role in the improvements that have been made to reimbursement rates so far. "Putting a face on primary immune deficiency and neuropathy patients has been a driving force for Congress to get involved," says Vogel.

In recent months patient advocacy has clearly begun to have a positive effect. Representatives Jim McCrery (LA) and Steve Israel (NY), upon learning from patients about how the reimbursement reductions were impacting their quality of care, spearheaded an effort to build awareness of the importance of having access to immune globulin. The effort is ongoing and will likely become more successful as additional U.S. representatives and senators get involved.

The chain of events since the first Medicare rate reductions demonstrates that consumers can make a difference in the congressional decision-making process by simply getting involved. Calling on your U.S. senators and representatives' offices, writing letters to them, and participating in patient advocacy groups are just a few of the ways you can make a difference in the future of reimbursement and access to immune globulin therapy. As Michelle Vogel advises, let your voice be heard; you can be part of the solution! ■

#### Get Involved Today!

Contact your representative by visiting the U.S. House of Representatives website and entering your state and zip code at <http://www.house.gov/writerep/>

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