

October 13, 2006

Ayesha Berlind
Senior Economist
Eastern Research Group, Inc.
110 Hartwell Avenue
Lexington, MA

Re: IVIG Meeting Comments

Dear Ms. Berlind:

These comments are submitted by the American Society of Clinical Oncology (ASCO), which is the national organization representing physicians who specialize in the treatment of cancer. We are responding to the notice on the Public Meeting on Patient and Physician Concerns in Access to Intravenous Immunoglobulin (IVIG) issued by the Department of Health and Human Services. Our comments are an expansion of comments made at the public meeting on September 28, 2006.

The Food and Drug Administration has approved various brands of IVIG for different indications. IVIG is typically used by oncologists as a supportive care drug to reduce the infection risk in patients with chronic lymphocytic leukemia who have low immunoglobulin levels. It is also used, among other indications, to treat idiopathic thrombocytopenic purpura when a rapid rise in the patient's platelet count is needed and following bone marrow transplantation to prevent the risk of graft-versus-host disease and infections.

In response to the notice of the meeting, ASCO conducted an informal survey of its members to identify access and health problems related to IVIG. 81 primarily office-based oncology practices responded to the survey. Of those respondents, 11 practices said they have not administered IVIG in their practice setting in the past six months. 70 oncology practices that reported administering IVIG over the last six months responded and provided information that we believe usefully identifies some of the current issues. A compilation of the survey responses is attached, and the broad results can be summarized as follows:

First, there continues to be a shortage of IVIG, and over 40% of the survey respondents reported that in recent months their practices have not been able to purchase the full quantity of IVIG that they needed to treat their patient population. In addition, most respondents experienced significant delays in obtaining IVIG. Most respondents have been unable to obtain the same IVIG product consistently but instead have been compelled to switch from brand to brand depending on availability.

Second, inadequate Medicare reimbursement for IVIG is a serious problem. Our survey revealed a wide range of prices paid for IVIG, with those prices generally substantially in excess of the Medicare payment amount. The average price paid by survey respondents in the last six months was about \$40 per 500 milligrams of lyophilized IVIG and \$49 for non-lyophilized IVIG. These prices compare to the current Medicare payment amounts of about \$25 for lyophilized IVIG and

\$30 for the non-lyophilized version. Our survey indicates that the add-on payment that Medicare makes for IVIG acquisition has not been a solution for most practices.

Third, as a result of the inadequate Medicare payments, many physicians are referring patients to hospitals for IVIG treatment to avoid out-of-pocket losses. About half of the survey respondents stated that they take this approach. Some referrals to hospitals require patients to travel long distances.

Fourth, the shortage of IVIG has altered treatments. 47% of respondents said that they give patients less than a full dose, and 31% said that they give IVIG patients fewer treatments. A significant number of practices have combined IVIG products from different manufacturers to make up a full dose.

Finally, our survey found a number of adverse effects on patient health resulting from the IVIG situation:

- Delayed treatment has resulted in increased bleeding episodes, bruising, infections, and hospitalizations.
- The intermittent availability of IVIG has led to increased transfusions and splenectomies.
- Because of the shortage problems, patients sometimes must be switched from one manufacturer's IVIG to another's, and side effects including allergic reactions that did not occur with the initial IVIG result from the different version.

In analyzing the survey results, we compared the responses of smaller practices (1-10 physicians) with those of larger practices (11+). The responses were essentially the same, thus indicating that the identified problems with IVIG are not related to practice size but rather appear to be universal among oncologists.

Thank you for the opportunity to submit these comments. Please do not hesitate to contact me if you have additional questions.

Sincerely,

Joseph S. Bailes, MD
Co-Chair, Government Relations Council

cc: Amber Jessup