Update on IVIG

Update on Immune Globulin Intravenous (IGIV)

The Committee finds that:

- Since our prior recommendations of January 2005, there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients' lives at risk (e.g., patients with immunodeficiency).
- Changes in reimbursement of IGIV products under MMA since January 2005 have resulted in shortfalls in the reimbursement of IGIV products and their administration.
- Immediate interventions are needed to protect patients' lives and health.

We therefore urge the Secretary:

- to declare a public health emergency so as to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule for IGIV products, and
- otherwise to assist CMS to identify effective short and long term solutions to the problem of unavailability of and access to IGIV products in all settings.

Update on Immune Globulin Intravenous (IGIV)

- Distributors
- Plasma Protein Therapeutic Association
- CMS
- Immune Deficiency Foundation
- Providers
- Pharmacist
- Patients

Status on Immune Globulin Intravenous (IGIV)

- **Providers indicate difficulty in obtaining specific brands of IGIV for some patients**
  - **Privately insured**
  - **Medicare**
- **Shift in treatment location**
- **Hospitals have reported difficulty in obtaining physicians' IGIV product of choice for patient**
- **Upward trend in price, most notably in the secondary market**

Findings on Immune Globulin Intravenous(IGIV) Availability

- **Increase in off-label use of IGIV**
- **Industry**
  - **Consolidation**
  - **Changes in business practice**
  - **Market correction**
  - **Reduction in inventory**
  - **Smaller number of distributors**
- **Medicare Modernization Act effective January 2005 changed the Medicare Part B to 106 percent of the manufacturers' average sales price.**
  - **Medicare payment rate is updated quarterly**
  - **Increased 9% for lyophilized IGIV as of July 2005**

Findings on Immune Globulin Intravenous (IGIV) Availability

- **Sufficient supply of IGIV for patients who need treatment**
- **Suggest that under the manufacturers' allocation process, physicians might best serve patients by communicating their supply needs directly to manufacturers.**
- **Ensure that IGIV treatment is prioritized toward FDA labeled use and those diseases or clinical conditions that have been shown to benefit from IGIV based on evidence of safety and efficacy.**

Advisory Committee on Blood Safety & Availability

Action Plan

- **Web Posting – www.hhs.gov/bloodsafety**
  - **Report denial of treatment, delay of treatment, forced reduction in dosage**
  - **FDA**
    - **CBER Product Shortage Number 800-835-4709**
    - **CBERProductshortages@cber.fda.gov**
  - **CMS**
    - **1-800-MEDICARE**
- **Supply Channel and Emergency Reserve**
  - **Discussions with PPTA and manufacturers**
  - **Hotline established**
- **Evidence Based Study -TBD**
- **CMS Reimbursement**
  - **Monitor cost**
  - **IG assistance**

Advisory Committee on Blood Safety & Availability

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

AUG - 8 2005

Mark Brecher, M.D.
Chair, Advisory Committee on Blood Safety and Availability
1101 Wootton Parkway, Suite 250
Rockville, MD 20852

Dear Dr. Brecher:

Thank you for your letter summarizing the topics discussed at the May meeting of the Advisory Committee on Blood Safety and Availability. I am encouraged by the progress reports on standardization of protocols for the detection of bacterial contamination and the extension of platelet product dating. This is an excellent example of the private sector and the Department working together to increase product safety and efficacy.

The Committee's continued evaluation of strategies for vigilant detection and management of emerging or re-emerging infectious diseases is a necessary first step toward the goal of reducing the risk of transfusion-transmitted diseases. Your work has potential impacts on blood and blood products as well as other vital products such as bone marrow, progenitor cells, tissues, and organs. Please continue your discussions and deliberations on this important issue.

We have investigated the current status of IVIG highlighted in your comments. After extensive discussions we have concluded that at this time there are sufficient supplies available to patients. However, there do appear to be ongoing marketplace adjustments related to how manufacturers and distributors are managing their respective inventories, and we will continue to monitor the situation.

Our examination of the allocation process indicates that physicians and providers might best serve their patients by communicating supply needs directly to manufacturers and distributors. Review of the current utilization of IGIV also indicates that there is increased use of this product for off-label uses that may also be increasing pressure on supplies. Therefore, we believe that physicians should ensure that priority be given to IGIV treatment for FDA labeled uses and those diseases or clinical conditions that have been shown to benefit from IGIV based on evidence of safety and efficacy.

While HHS has no control over the prices manufacturers or product distributors may charge, the Centers for Medicare and Medicaid Services (CMS) will continue to monitor the average sales price on a timely basis, as mandated by Congress, to ensure that the reimbursement reflects 106 percent of manufacturers' average sales price.

Thank you for your dedication, and please express my appreciation to the Committee.

Sincerely yours,

Cristina V. Beato M.D.

Cristina V. Beato, M.D.
Acting Assistant Secretary for Health

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Advisory Committee on Blood Safety and Availability

Status of Immune Globulin Intravenous (IGIV) Products

In the last few months, the Department of Health and Human Services (HHS) and its agencies, the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS), have received several reports that some health care providers have had difficulty obtaining Immune Globulin Intravenous (IGIV), a.k.a. IVIG, products. HHS is actively working with manufacturers, health care providers, patient groups, and other government entities to better understand the present situation and to assess potential actions. Although there are reports from some health care providers of difficulties with IGIV product distribution and pricing, we do not find evidence of an overall shortage of IGIV at present, or indicators of an impending shortage.

Reports from providers indicate that they have encountered problems obtaining specific brands of IGIV for some patients, including privately insured patients and those covered by Medicare. In some cases treatment locations have reportedly shifted from physician offices to hospital settings. Some hospitals have reportedly experienced difficulty in obtaining the physicians' IGIV product of choice for the patient. At the same time, prices for IGIV have been on an upward trend, most notably in the secondary (or resale) market. From discussions with stakeholders, it is clear that a number of changes have been occurring in the marketplace; however,

their relationship to the issues reported by some providers is not fully understood, but will be monitored;

- Providers vary in the scope of indications for which they prescribe IGIV. Some providers have reported that the majority of their IGIV use is for off-label indications. Off-label use may have increased, contributing to rising demand. (Current label indications include: Primary Humoral Immunodeficiency, acute and chronic Idiopathic Thrombocytopenia Purpura, B cell Chronic Lymphocytic Leukemia, Kawasaki Syndrome, Pediatric HIV, and Bone Marrow Transplantation.)
- Industry consolidations and other business practice changes that apparently have been intended to improve efficiencies may have reduced historic inventory levels. For example, some manufacturers have been allocating products to a smaller number of distributors combined with a reduction in the size of their inventories. Although fewer products were distributed in the last twelve months than in the previous twelve months, the smaller inventories may not reflect a shortage if manufacturers can supply additional inventories as needed. Manufacturers and distributors have reported that any supply chain issues should be resolved soon.
- The Medicare Modernization Act, effective January 2005, changed the Medicare payment for IGIV administered in physician offices and the home to be 106 percent of the manufacturer's average sales price. The Medicare payment rate is updated quarterly and has been increased nine percent for lyophilized IGIV as of July 2005.

We are working with stakeholders to further assess the evolving marketplace. At this time, we believe there is sufficient supply of IGIV for patients who need it. Under manufacturers' allocation processes, physicians might best serve their patients by communicating their supply needs directly to manufacturers and by ensuring that IGIV treatment is prioritized toward FDA labeled use and those diseases or clinical

conditions that have been shown to benefit from IGIV based on evidence of safety and efficacy, and for which safe and effective alternative therapies are not available.

It is a HHS goal to work with partners in the marketplace to help prevent or alleviate shortages of medical products, including IGIV. We are seeking additional information on the current availability of IGIV products. We are asking health care providers and patients who experience difficulty obtaining IGIV to report their experiences (e.g. denial of treatment, delay of treatment, forced reduction in dosage, etc.) by sending an email to FDA at CBERProductshortages@cber.fda.gov. Those without email access may call (800) 835-4709. Reports related to Medicare-related coverage and access to care should call 1-800-MEDICARE.

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www.hhs.gov/bloodsafety

Blood Safety & Availability

CMS Regulations

Name of regulation	Type of rule		Date of Publication	
2006 acute hospital inpatient payment system	Final rule	FR	August 12, 2005	IP
2006 hospital outpatient prospective payment system (HOPPS)	Proposed rule	FR	July 25, 2005	Comments due Sept 16, 2005
2006 hospital OPPS	Corrections	FR	August 26, 2005	Comments due by Sept 16, 2005
2006 Physician Fee Schedule	Proposed	FR	August 8, 2005	Comments due by Sept 30, 2005
2006 Physician Fee Schedule	Corrections	FR	Sept 1, 2005	Comments due Sept 30, 2005

CMS Regulations

These documents are on the **CMS website** for Providers:

www.cms.hhs.gov/providers/

- Note: Click on “Provider Type” icon for either “Hospitals” or “Physicians” and follow the links to the specific payment system.

The **Federal Register** website is:

www.gpoaccess.gov/fr/index.html

- Note: These documents may be lengthy and would require a high speed printer.

Payment for Part B drugs (including updates for Average Sales Price (ASP) data and the Competitive Acquisition Program (CAP) is on the Medicare Fee-For-Service Part B Drugs website:

www.cms.hhs.gov/providers/drugs/default.asp