Medicare IVIG Access Stakeholders' Principles

Patients, providers, home and specialty infusion pharmacies, and manufacturers of immunoglobulin have been working together to improve access to the Medicare Part B coverage of IVIG for beneficiaries with primary immunodeficiency (PI) diseases. The Medicare Modernization Act of 2003 included a medical benefit for patients with primary immunodeficiency diseases (PI) to receive IVIG in the home. However, this benefit proved to be incomplete, since reimbursement only covers the cost of the IVIG and does not cover the medically necessary professional services. As a result, most patients are not able to access their treatment in their home and are effectively denied coverage under this benefit.

Since that time, stakeholders have devoted their efforts to making the benefit complete by allowing for the reimbursement of all necessary supplies, equipment and services needed for home infusions. In 2012, Congress passed HR 1845, the Medicare IVIG Access Act, which authorized a demonstration project "to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency diseases."

The Centers for Medicare and Medicaid Innovations (CMMI) is responsible for the implementation of the demonstration established in the Medicare IVIG Access Act. As stakeholders committed to ensuring that PI patients have meaningful access to IVIG in the home, we have developed a set of principles that we believe are essential for the Demonstration Project to be successful. Our perspectives on the demonstration project reflect our vast experience in this area, and we urge CMMI to consider our views as it designs and works toward implementation of this project.

Our stakeholder group is committed to working with CMMI to help ensure the success of the Medicare IVIG Access Demonstration Project and is in agreement that the principles below should be a part of any polices and requirements developed for the Project.

- **The Project should adhere to standards of care for treatment of PI as outlined by American Academy of Allergy, Asthma and Immunology's AAAAI)** *Eight Guiding Principles for the Safe, Effective and Appropriate Use of IVIG for Primary Immunodeficiency.* http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf

- A **voluntary, rolling enrollment is needed due to the inherent** difficulty in enrolling 4,000 patients simultaneously at the start of the Demonstration Project. In addition, if patients voluntarily dis-enroll, we would like to see others have the opportunity to enroll in their place.

- **Registered Nurses with appropriate IVIG training should administer the infusion and remain with the beneficiary throughout the infusion**. According to the AAAAI's *Eight Guiding Principles for the Safe, Effective and Appropriate Use of IVIG for Primary Immunodeficiency*, adverse events can occur, many of which are acute and can include "thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome (ARDS), pulmonary edema, apnea and transfusion associated lung injury (TRALI)." Adverse reactions have occurred with all available immunoglobulin products and, while neither the occurrence nor severity of reactions can be reliably predicted for any given person, patients have been successfully managed in all care settings by trained health care professionals. IVIG has been administered in the home setting for more than a decade, and recently published outcomes data demonstrate the safety of this environment when the administration is performed by trained registered nurses.[i]

- **Pharmacies with staff trained in care coordination, clinical monitoring and administration of immunoglobulin based on the AAAAI's Eight Guiding Principles for the Safe, Effective and Appropriate Use of IVIG for Primary Immunodeficiency should be eligible to participate in the Demonstration Project.** Such pharmacies have demonstrated expertise in providing critical services to home infusion patients in the private insurance sector and experience serving PI patients.

- **The per visit payment amount for items and services should adequately reflect the cost of necessary registered nursing services for the safety of our patient population as well as the cost of collecting data for the project**. We recognize that the law directs the Secretary to establish a per visit payment amount for the in-home administration of IVIG based on, *not necessarily equal to*, the national per visit low-utilization payment amount under the home health services prospective payment system . Such rate also must reflect the appropriate treatment protocols for IVIG as outlined by AAAAI's Eight Guiding Principles and the unique needs of administering IVIG in the home for non-homebound PI individuals as well as ensure sufficient financial incentive for data collection within the demonstration.

- **From the full range of licensed IVIG products, patients must have access to the IVIG product most suitable to them as determined by their physician. IVIG products** are **not** interchangeable. The FDA requires that an individual clinical trial protocol is completed for each drug to receive licensure, even if it is from the same manufacturer. Manufacturing differences can, and do, affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy. Therefore patients must be able

to receive the product that is most suitable for them in order to maximize the potential for successful treatment and reduce preventable risks.

- **Data collection should represent outcomes relevant to various stakeholders, including patients, clinicians, and payors.** Data points collected for use in the demonstration report should include patient quality of life, ancillary cost savings to Medicare (both Part A and Part B), and clinical patient outcomes (frequency of infections, use of antibiotics, hospitalizations and ER visits).

The undersigned organizations pledge to work with CMMI to make this demonstration project successful and to provide accurate and complete recommendations to Congress.

Immune Deficiency Foundation
Accredo Health Group
Alternacare Infusion Pharmacy
American Academy of Allergy, Asthma and Immunology
AmerisourceBergen Corporation
ARJ Infusion Services
ASD HealthCare
Barnes Healthcare Services
Baxter Healthcare
BioFusion, LLC
Clinical Immunology Society
Coram Specialty Infusion Services
CSL Behring
Grifols
IgG America
Jeffrey Modell Foundation
National Home Infusion Association
Orsini Healthcare
Plasma Protein Therapeutics Association
US Bioservices
Vital Care, Inc
Walgreens

[i] Souayah N, Hasan A, Khan H, et al. The safety profile of home infusion of intravenous immunoglobulin in patients with neuroimmunologic disorders. *J Clin Neuromuscul Dis.* 2011;12(4 Suppl):s1-s10