IMMUNE DEFICIENCY FOUNDATION COMMENTS

TO CMS PROPOSED RULE ON CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (CMS-1471-P)

RECOMMENDATION: CMS should amend the definition of "blood and blood products" to include IVIG which is manufactured solely from human plasma to recognize the need to provide continuing access for chronic, life-threatening conditions and diseases, such as primary immune deficiency.

The Immune Deficiency Foundation (IDF), a national organization providing service to patients and family members affected by primary immune deficiency diseases appreciates this opportunity to comment on the proposed rule published by CMS on August 12, 2003. In the proposal CMS neglected to reclassify IVIG into the category for "blood and blood products," inappropriately excluding the chronic use population of primary immune deficiency patients. IVIG is prepared solely from pooled human plasma of donors by modification and refinements of the cold ethanol method of Cohn fractionation and should therefore be classified in the category of "blood and blood products."

IDF has serious concerns that the CMS approach to paying for IVIG as a biologic and not as a blood product may impact patient access to care by refusing to protect reimbursement rates under the dampening effect. As a result, we believe the policy will have the harmful outcome of forcing hospitals to reassess the economic feasibility of continuing to make these therapies available.

Primary immune deficiency diseases are disorders in which part of the body's immune system is missing or does not function properly. The World Health Organization recognizes nearly 100 primary immune deficiency diseases. Many of these disorders are caused by intrinsic or genetic defects in the immune system, which require chronic replacement therapy comprised of intravenous gamma globulin infusions to protect from frequent life-threatening infections and debilitating illnesses. Most primary immune deficiency patients do not have an alternative therapeutic option; therefore survival depends on access of IVIG.

Patient access to care is essential as IVIG is life-saving, as well as life-sustaining. Hospitals will not administer IVIG at a loss, which will affect access to care for primary immune deficient patients. Most Medicare patients receive IVIG in the hospital outpatient setting due to medical necessity and lack of coverage for alternative sites. Currently, CMS does not provide for home infusions of IVIG for primary immune deficiency patients, which further reduces their treatment options if hospital benefits are reduced.

The Department of Health and Human Services' (HHS) very own advisory committee on Blood Safety and Availability has called for the reclassification of IVIG. Most recently, on May 2, 2003, the committee endorsed a resolution stating the following:

> *Intravenous Immune Globulin (IGIV) is derived from pooled human plasma; is used to treat chronic diseases; and is fractionated from the same source material used to produce human derived clotting factor for the treatment of hemophilia.*
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> *Therefore; the advisory committee recommends that with regard to the Medicare Hospital Outpatient Prospective Payment System, CMS amend the definition of blood and blood products to include all plasma products used to treat life threatening conditions for which there is the need to provide continuing access to plasma based therapies used to treat chronic diseases and life threatening conditions, specifically including IGIV.*

We hope that HHS will accept and implement the recommendation of its own experts in the final rule.

As a result of inadequate reimbursement rates individuals with primary immune deficiency diseases will encounter serious problems in obtaining access to the life-sustaining or life-saving therapies they need. We wish to completely avert a regretful and avoidable outcome such as hospitals discontinuing service to primary immune deficiency patients. We strongly request CMS to act now to reclassify IVIG as a "blood or blood product" to avoid patients being confronted with denial of access.

If there is any additional information you need, please do not hesitate to contact Michelle Vogel, Director of Government Affairs, at (800) 296-4433 or (410) 321-6647.

Thank you for your kind consideration.