
From: Charlotte Cunningham-Rundles
Sent: 14 June 2007 22:22
To: emlsecretariat
Subject: EML list, Subcutaneous Immune Globulin Therapy
Follow Up Flag: Follow up
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Dr Sue Hill
Department of Medicines Policy and Standards (PSM)
Health Technology & Pharmaceuticals
World Health Organization CH-1211 Geneva 27

Dear Dr Hill,

Polyvalent Human Immunoglobulins for intravenous use have been included in the World Health Organization (WHO) Model List of Essential Medicines for life-long replacement therapy individuals with primary & secondary immune deficiencies. I know that an application for Polyvalent Human Immunoglobulins for subcutaneous use to be included in the EML for Children, is now being made and will be discussed in a July meeting of the WHO.

I am a Clinical Immunologist in the United States and have been working in the field of primary immune deficiency for 30 years. I performed some of the first licensing trials of IVIG in the United States and have used basically all products that have come into use. I treat both adults and children with primary immune defects and am responsible for the direct care of about 200 or more immune deficient subjects who require Ig replacement, in the United States. As you are aware, subcutaneously delivered immune globulin has been used in some situations since first described in 1970 and more recently widely in England and Scandinavia. Due to these studies and the absolute need for more flexible and equally effective and safe therapy, CSL Behring conducted a trial of this method in the United States, using a preparation suited to this use. Based on the results of this trial, this product was licensed by the FDA and has now growing use in the US for children and adults.

My own use of subcutaneous immune globulin goes back 15 years, using Ig preparations in standard doses, for subjects with poor venous access, intolerance of intravenous formulations, or the greater flexibility afforded by this therapy. We are now using the new licensed product and find that it is very satisfactory, well tolerated, efficacious, and leads to very good levels of immune globulin in the blood. This method can easily and safely be given in the home, as has been amply shown by a number of studies. This therapeutic alternative is important for busy families, children, students and many other patients.

It is very important that the use of subcutaneous immune globulin be endorsed as an Essential Medication.

Of other specific information is required, I would be happy to provide it.

Sincerely yours,

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