IMMUNE DEFICIENCY FOUNDATION

IDF Medical Advisory Committee Resolution Regarding Formulary Changes that Limit a Physician's Ability to Determine the Most Appropriate Immunoglobulin Replacement Therapy

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As immunologists responsible for treating patients who receive immunoglobulin (Ig) replacement therapy and as recognized experts in the field of immunodeficiency, we express our very serious concern regarding the recent development in which some health insurance providers have attempted to introduce new formulary policies that severely limit the physicians role in prescribing the most appropriate products for individual patients requiring immunoglobulin replacement therapy.   We believe that the policy to restrict access of subscribers to only one or two product/formulations of replacement immunoglobulin regardless of the particular product the patient may currently be receiving poses an <u>unjustified safety risk</u> for these patients. Several published reports have clearly demonstrated that a significant number of patients experience an adverse reaction associated with a change in immunoglobulin products.[1-5]   For example, the Immune Deficiency Foundation 2002 Patient Survey as quoted in Principle 8 of the AAAAI EIght Guiding Principles for Appropriate Use of IVIG for Primary Immunodeficiency Diseases found that 34% of all infusion related adverse events occur in the context of a product change.[1]

Some of the proposed new formulary policies appear to totally disregard the unique needs of patients who have specific medical conditions that impact their susceptibility to adverse reactions to certain Ig replacement products. By exposing all patients to a restrictive <u>fail-first</u> formulary policy, insurers are mandating that some of these often-frail patients will need to experience potentially life-threatening adverse reactions with <u>no medical justification</u> for exposing them to such risk. These reactions can include an anaphylaxis event, thrombosis, aseptic meningitis, stroke, seizure, loss of consciousness, and acute respiratory distress syndrome among others.[2]

We feel very strongly that patients who are stabilized on a particular product, whether intravenous or subcutaneous immunoglobulin, should <u>not be forced</u> to change outside of the decision of their treating physician. Under all circumstances, any change in Ig preparation must be carefully supervised by the patient's treating physician and not by someone unfamiliar with the complete medical status of the individual patient or whose involvement is just to oversee his/her Ig infusion.

In general there are slight efficacy or safety differences among the products in this class and all products are safe to administer in the home under certain conditions. However this statement only addresses half the story. Ig products are safe in general, but at the level of an individual patient some specific products may be safe and others unsafe. Adverse reactions have occurred with all available immunoglobulin products and unfortunately, neither the occurrence nor severity of reactions can be reliably predicted for any given patient.

For many individuals these products can also be safely administered at home, but there are many individuals for whom home infusion is potentially a very unsafe procedure and should never be attempted. There is no way to predict which patients will have an adverse event or how serious the adverse event will be when switching a patient to a product that they have never before used. Because of the potential severity of some adverse events, it is strongly recommended that Ig infusions involving transition to a different Ig product be carried out in a physician supervised medical facility and not in the patient's home until a patient's tolerance to the new product has been established. **The above is considered best practice by experts in the field when transitioning from one product to another.**

We urge all insurance providers to abandon policies that unnecessarily transition patients who are stabilized on a given immunoglobulin replacement product to another product, whether intravenous or subcutaneous immunoglobulin. The existing medical literature clearly indicates that significant adverse reactions do occur when patients switch products. There is no way to ensure that patients who are transitioned will not have adverse reactions and no way to determine when those reactions will be serious and life threatening. As you know, physicians are bound by the Hippocratic Oath to do no harm; we ask insurers to have policies that also follow this important principle.

References
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