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IDF Medical Advisory Committee Resolution on Product Choice for Immunoglobulin Replacement Therapy

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The Medical Advisory Committee of the Immune Deficiency Foundation (IDF) is concerned about policies that interfere with a physician's ability to select the most appropriate immunoglobulin replacement therapy (IG therapy) for each patient or require a patient to switch from an existing treatment without a compelling medical reason. The information below represents the consensus of the Medical Advisory Council on the coverage of immunoglobulin therapies. The physicians who make up this body are internationally regarded as experts in the research and care of individuals with primary immunodeficiency disorders. Issues that mandate flexibility in choosing immunoglobulin products are:

- Immunoglobulin therapies are not generic. 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.¹ Manufacturing differences can, and do, affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy.² Furthermore, some patients do not tolerate intravenous administration and require subcutaneous administration and vice versa. The products for the different types of administration are not interchangeable.
- A policy that provides access to alternate therapies only after a patient has suffered an adverse event or other harm is unacceptable. A number of factors impact how a patient will tolerate and respond to a particular brand of immunoglobulin, including the patient's medical history and the product's characteristics such as the volume delivered, sugar content, IgA content, pH, route of administration and osmolality.^{3,4} Physicians are in the best position to select the most appropriate product for their patients.
- The incidence of adverse reactions increases when a patient changes therapies.⁵ A policy that requires patients to switch to the insurer's current preferred product puts patients at risk and will require additional infusion time and patient monitoring due to the heightened risk of reactions.
- Not all brands of immunoglobulin will always be immediately available to all providers at all times due to product allocation and/or withdrawals. A major immunoglobulin withdrawal was initiated as recently as 2010. The product was withdrawn as a result of reports of increased thromboembolic events.⁶ There have been a number of market events that have caused delays and withdrawals from varying manufacturers over the past several years. This has led to periods in which some or all IG therapies have been subject to allocation.^{7,8} Therefore, restricting physicians to a single approved product could lead to delays in treatment.

The Medical Advisory Committee of the Immune Deficiency Foundation recommends with the strongest conviction that physicians be allowed flexibility to select appropriate products for patients.

Citations

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5. Immune Deficiency Foundation. Treatment Experiences and Preferences among Patients with Primary Immunodeficiency Diseases. *National Survey of Patients* 2008. Accessed August 17, 2010 at http://www.primaryimmune.org/publications/surveys/2008_treatment_report_06_08_09.pdf.
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7. US Department of Health and Human Services, Office of the Assistance Secretary for Planning and Evaluation. Analysis of Supply, Distribution and Access Issues Associated with Immunoglobulin Intravenous (IGIV). February 2007.
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