Plasma Protein Therapeutics Association

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Ms. Tami Eide
Medicaid Pharmacy Supervisor
3232 Elder Street
Boise, ID 83705

Dear Ms. Eide,

The Plasma Protein Therapeutics Association would like to bring to your attention certain information about immune globulins (IG) before the drug class review of immune globulins at the November 15, 2013 Pharmacy and Therapeutics Meeting.

We have learned, Idaho's Pharmacy and Therapeutics Committee will review immune globulin in a few weeks. These reviews could lead to cost-containment strategies that may result in Medicaid recipients changing their current therapy. This would be contrary to the recommendations of experts in the field.

Specifically, the American Academy of Allergy, Asthma & Immunology developed Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency[1]. The eighth principle states, "IVIG is not a generic drug and IVIG products are not interchangeable. A specific IVIG product needs to be matched to patient characteristics to insure patient safety. A change of IVIG product should occur only with the active participation of the prescribing physician." While the principle states IVIG, the same holds true for subcutaneous immune globulin therapies as well.

The principles are based on studies that show IG therapies are not interchangeable. They are not pharmaceutically or therapeutically equivalent. Each IG therapy has been approved by the FDA for distinct clinical indications and each has distinct contraindications. Each has a different shelf life, and each is prepared and administered in a distinct manner. Storage requirements vary as does the sugar content.

Thus, patients can have varied responses to immunoglobulin therapy. There are a number of factors that impact how a patient will tolerate and respond to Ig treatment, including the patient's medical history, the volume that is delivered as well as the product's sugar content, IgA content, pH, route of administration and osmolality. Adverse reactions can range in seriousness from redness at the infusion site and severe headaches to anaphylaxis, kidney failure-and even in rare cases death.

[1] http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf

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Every IG therapy is unique and, because all therapies are biologics, each therapy reacts differently for each patient. Accordingly, it is essential that the choice of IG therapy be made collaboratively with the patient and healthcare provider in order to achieve the best possible health outcome for the patient. Therefore, it is critical that individuals have access to a diverse range of IG therapies, and that prescriptions for specific IG therapies are respected and reimbursed. Individuals who rely on IG therapies should have access to the full range of FDA licensed therapies.

"The goal of the Idaho Medicaid Pharmacy Program is to provide quality care to Medicaid participants with the most effective drug at the right price." PPTA supports that goal. We suggest that to meet that goal the Idaho Medicaid Pharmacy Program must maintain policies that allow participants access to the IG therapy that is most medically appropriate for them as decided by the participant in consultation with the physician.

I thank you for your attention to this matter and look forward to responding to any questions or comments you may have.

Best Regards,

Bill Speir, Director of State Affairs