Plasma Protein Therapeutics Association

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Mr. Andy Vasquez
Deputy Director
Medicaid/CHIP Vendor Drug Program
Health and Human Services Commission
Braker Center, Building H
11209 Metric Boulevard
Austin, TX 78758-4021

Dear Mr. Vasquez:

The Plasma Protein Therapeutics Association would like to bring to your attention certain information about immune globulins (IG) before the drug class review of IG at the Pharmacy and Therapeutics Committee Meeting on April 11, 2014. We are concerned that the review could lead to cost-containment strategies which may result in Medicaid recipients being required to change their current therapy. This would be contrary to the recommendations of leading 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 ensure 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.

These 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 IG 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 of fluid that is delivered as well as the product's sugar content, IgA content, and route of administration. Adverse reactions can range in seriousness from redness at the infusion site and severe headaches to anaphylaxis, kidney failure, and even death in rare cases.

[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. Therapies should be administered based upon what is medically appropriate and determined by a physician in consultation with the patient, not dictated by payers. This approach is consistent with the mission of the Texas Medicaid program to improve health of Texans by: emphasizing prevention; promoting continuity of care; providing a medical home for Medicaid recipients; and ensuring that each recipient can receive high quality, comprehensive health care services within the recipient's community

The Texas Medicaid mission of emphasizing prevention is furthered by allowing the medically appropriate IG therapy to be determined by a physician in consultation with the patient. This is shown by the results of a 2008 study that concluded that attempting to impose a universal therapeutic trough level leads to patients becoming ill and needing expensive hospital treatment[2]. Such adverse events could be prevented by allowing Medicaid recipients to continue with their current treatment regimens.

Permitting Medicaid recipients to continue with their current IG therapy would clearly also meet the continuity of care portion of the agency's mission. . It would also allow those Medicaid recipients infusing at home to receive high quality care in the community since a product change necessitates hospital-based infusion to establish safety.

Therefore, Texas Medicaid can further its mission and adhere to the best practices outlined by leading immunologists by establishing a policy that does not require Medicaid recipients to change IG therapy because of the preferred drug list. 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

cc: Texas Pharmaceutical and Therapeutics Committee Members

[2] Bonagura et al J Allergy Clin Immunol. 2008 Jul;122(1):210-2. Biologic IgG level in primary immunodeficiency disease: the IgG level that protects against recurrent infection.