

October 12, 2007
Reference No.: SASC07058

Via U.S. Mail

Ms. Peggy King
Pharmacy Director
Office of Pharmacy Services
350 Capitol Street, Room 251
Charleston, West Virginia 25301-3707

Re: Reimbursement for Alpha-1 Proteinase Inhibitors Products

Dear Ms. King:

I am writing to you on behalf of the Plasma Protein Therapeutics Association (PPTA). PPTA represents the leading producers of plasma protein therapies for individuals with bleeding disorders, primary immune deficiencies and alpha-1 antitrypsin deficiency. Plasma protein therapies are not interchangeable, and there are no generic substitutes. Individual therapies are approved by the Food and Drug Administration (FDA) for specific clinical indications. The needs of each patient are unique, and patients respond to the same treatment differently. The ability to tolerate a specific treatment over time may also change. Accordingly, patients, with the support of their physician, must have access to the full range of plasma protein therapies to assure proper patient care and treatment.

We are concerned about West Virginia's reimbursement of alpha-1 proteinase inhibitors (A1PI) at the generic rate of AWP -30%. Section 5A-3C-3 of the West Virginia Code defines a generic drug as a multiple-source drug that is not an innovator drug. I would suggest to you that the therapies in question are innovator drugs and not multiple-source drugs.

A multiple-source drug according to paragraph 6 of section 5A-3C-3 is a drug for which there are two or more drug products which are rated as therapeutically equivalent under the Food and Drug Administration's (FDA) Orange Book and are determined by the FDA to be pharmaceutically equivalent and bioequivalent.

There are currently three A1PI products: Prolastin, Zemaira, and Aralast. None of these products are listed as therapeutically equivalent under the FDA's most recent publication of the Orange Book. The FDA has not determined these products are pharmaceutically equivalent and bioequivalent. Therefore, these products they do not meet the plain language definition of a "generic drug" pursuant to West Virginia law.

The same section of West Virginia law states that an innovator drug will be referred to as a "brand." The term "innovator drug" means a drug which is produced or distributed

under an original new drug application approved by the food and drug administration. These products are biologicals and pursuant to federal rules are approved under a biologics license application, not a new drug application. However, FDA form 356h is used for both submissions, and therefore the biologics license application is the equivalent of a new drug application. Based on the fact that these products are approved pursuant to an application that is the equivalent of a new drug application, it would be appropriate to designate these products as innovator drugs pursuant to West Virginia law.

Accordingly, because these products are brand and not generic pursuant to West Virginia law, we would recommend that you begin paying for them at the brand rate of AWP -15%.

Our concern at PPTA is that the generic rate may have a negative impact on patient access. There may be cases where the acquisition costs for the therapies are greater than the reimbursement levels. It is only a matter of time before some affected providers refuse to furnish recipients with their needed therapies. Because time is of the essence, we would ask that you make this change as soon as possible.

We thank you for your consideration of this important matter that may have serious implications for patient access to life-saving therapies. I would like to meet with you about this matter if possible. Should you have any questions, or if you require additional information, please do not hesitate to contact me.

Sincerely,



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