August 10, 2004

SUBMITTED BY FACSIMILE

Mr. Michael Beebe
Director, CPT Editorial Information Services
American Medical Association
515 North State Street
Chicago, IL 60610

Re: Treatment of Intravenous Immune Globulin in Options A and B of the CPT Editorial Panel Workgroup Proposals for Discussion of Drug Infusion Administration

Dear Mr. Beebe:

On behalf of the Biotechnology Industry Organization ("BIO") and the Plasma Protein Therapeutics Association ("PPTA"), we appreciate this opportunity to comment on proposed changes to the Current Procedural Terminology ("CPT") codes related to the administration of drugs and biologicals. We strongly support efforts to ensure that the CPT codes for such services facilitate the establishment of appropriate payment levels; however, we are writing because of our concern that the proposed changes may defeat these goals with respect to intravenous immune globulin ("IVIG"). Specifically, we believe that it is inappropriate to consider infusion of immune globulin as a "low complexity" service akin to the administration of saline.

Options A and B that were presented at the June 21, 2004 CPT Public Session for Discussion of Drug Administration Procedures include separate codes for "low complexity" intravenous infusions and "high complexity" intravenous infusions. Under these options, "low complexity" infusions involve low patient risk, little special handling to prepare or dispose of the product, staff that do not require advance practice training, and less intensive monitoring. Conversely, "high complexity" infusions (i) require special considerations to prepare, dose, or dispose of the product; (ii) commonly entail significant patient risk; (iii) often involve intensive monitoring; and (iv) involve prolonged nursing time. As between these definitions, the administration of IVIG is inappropriately characterized as a "low complex infusion" in both Options A and B. For the reasons stated below, BIO and PPTA believe that IVIG administration meets all of the requirements for a "highly complex" infusion and should be characterized as such.

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IVIG Requires Special Considerations to Prepare, Dose or Dispose

IVIG involves the infusion of a large protein molecule and therefore requires special considerations to prepare, dose or dispose. Some IVIG therapies come in powder form in 5 or 10 gram vials and need to be reconstituted before administering. This involves an extensive process as needles, vial tops and any equipment that could contact the product must be sterile. The diluent needs to be brought to room temperature, 77 degrees Fahrenheit, and carefully mixed with the powder to prevent foaming. Before administering, the mixture must be visually inspected for particulate matter and coloration, cleaned with an alcohol swab and then transferred, via a special filter needle, into a sterile syringe for injection.

There are special storage considerations for certain IVIG products. Some products require refrigeration in special expensive refrigerators, while others must be kept at room temperature, which can be challenging in warmer climates. Disposal of excess product requires the institution to have a special system in place to dispose of biologicals. The preparation, dosing and disposal of IVIG requires special considerations and costs as compared to saline and should not be treated as such.

IVIG Commonly Entails Significant Patient Risk

Patients receiving IVIG therapy must be monitored for allergic reactions such as headaches, fever, chills, and in rare cases, anaphylactic shock. Adverse events are rare provided that the rate and the volume of the infusion are carefully controlled. In reality, it is the most sophisticated physician practices that infuse IVIG. Certain patients (*e.g.*, immunoglobulin A deficient, with a history of transfusion reactions) should receive their first few infusions in a hospital outpatient department to assure appropriate monitoring.

IVIG Often Involves Intensive Monitoring

IVIG is often administered over a multiple hour period requiring monitoring during this duration. The infusion rate often starts slowly and increases gradually over the course of the infusion. Allergic reactions could occur at any time during the administration because patient's tolerance levels vary widely. To adjust for this, physicians use the "Triple Escalation" technique—the rate is increased three times throughout the infusion—to monitor patient safety.

IVIG Involves Prolonged Nursing Time

Most institutions require nurses to fill out special forms after each infusion for physician review for appropriate patient monitoring. In general, nurses who infuse IVIG are specially trained, which involves a significant amount of time and expense. IVIG quality care requires institutional investment in nursing training and education. Because of the sophistication of administration and potential patient reactions, the administration of IVIG requires prolonged nursing time.

Conclusion

These facts alone demonstrate that IVIG should be considered a "high complexity" infusion. Clearly, IVIG infusions have a potential patient risk profile that cannot be said to be akin to saline infusions and other "low complexity" infusions. In addition, intensive monitoring is needed to ensure that adverse events do not occur during the infusion, as well as to increase the dose over time depending on the patient's tolerance. These are the types of judgments that could involve advance practice training to administer the product appropriately and significant amount of nursing time befitting a "high complexity" infusion under Options A and B.

For these reasons, we strongly urge you to remove the mention of immune globulin from the parenthetical listing of products that exemplify "low complexity" infusions. Based on the definition of that phrase, IVIG does not qualify as a "low complexity" infusion. As others have noted in this code revision process, the creation of "low complexity" and "high complexity" codes could create disputes regarding where particular therapies should be categorized. In our view, it is not productive to have to engage in such disputes in the development of revised codes and code language, and listing a product that does not clearly fit within either category as an example needlessly focuses on the validity of the classification of a drug rather than the propriety of the language that differentiates the types of infusions. Accordingly, removing IVIG from the parenthetical in Options A and B would allow the focus to be where it should be – on the code descriptions.

We hope that you consider our recommendation seriously as the process moves forward. If you have any questions concerning this matter or if we can be of further assistance, please contact Michael Werner at 202-962-9200 or Julie Birkofer at 202-789-3100.

Sincerely,

/s/

Julie Birkofer
Deputy Executive Director, North America
Plasma Protein Therapeutics Association

/s/

Michael Werner
Chief of Policy
Biotechnology Industry Organization