

# HealthAlliance**MEDICARE**

## **PURPOSE OF THE POLICY**

To establish guidelines for coverage of Vivaglobin®.

## **STATEMENT OF THE POLICY**

Vivaglobin® will be covered when the following criteria are met and applies to new starts only for Medicare Part D Members

## **PROCEDURES**

### **1. FDA approved indications under Part D**

### **2. 3mo approval at a time**

### **3. Exclusions**

- 3.1 Administration of IgG by the subcutaneous route has not been studied in conditions like ITP and neuropathies in which large doses are usually given to block Fc receptor function, complement deposition or other immunomodulatory effects. Since the pharmacokinetics of subcutaneous IgG differ so markedly from those of large IV doses, the efficacy of subcutaneous IgG in those conditions cannot be predicted, and additional studies will be necessary before that can be recommended

### **4. References**

- 4.1 Use of immune globulin in primary immunodeficiency; 2007 UpToDate
- 4.2 Vivaglobin [product labeling]. ZLBBehring, January 2006.