



## Summary of Response to OIG Survey on IVIG

### **IVIG Acquisition Information**

As a group purchasing organization (“GPO”), Premier enters into group purchasing contracts on behalf of its members which set forth the terms and conditions under which the members have the right, but not the obligation, to purchase products and services. Premier has group purchasing contracts with each of the Intravenous immune globulin therapy (IVIG) manufacturers for a specified annual volume of IVIG which is made available for purchase by Premier members. As a GPO, Premier does not purchase any IVIG. Premier members that wish to purchase IVIG under Premier contracts purchase the IVIG directly from the manufacturers, or our contracted distributor. 97 percent of Premier’s contracted IVIG volume is sold by Premier’s contracted manufacturers to Premier’s contracted distributor (FFF Enterprises). FFF Enterprises distributes the contracted IVIG to Premier members. Baxter BioScience distributes the remaining 3 percent of Premier’s contracted IVIG to Premier members that have selected Baxter BioScience for direct distribution. The total volume of contracted IVIG is allocated to Premier members through an internal allocation process.

### **IVIG Contract Pricing**

All of the IVIG contracted volume covered by Premier’s manufacturer contracts is sold to Premier members at the contracted price. IVIG purchased by Premier members under Premier contracts is for the members’ “own use” and not for resale.

### **IVIG Purchase Methods Used by Premier Members**

IVIG is purchased by Premier members directly from contracted manufacturers or from Premier’s contracted distributor which purchases only from the contracted manufacturers. Premier enters into group purchasing contracts with each of the IVIG manufacturers which set forth the terms and conditions (including price) under which Premier’s members may purchase IVIG. As stated above, members are not permitted to resell IVIG purchased under Premier group purchasing contracts. However, if a Premier member were to breach this requirement, the member’s ability to participate under the applicable manufacturer’s IVIG contract would be terminated and the member’s account at the contracted distributor would be closed. In addition, each manufacturer’s contract for IVIG states that all IVIG sold to Premier members is sold at the contracted price. Premier’s manufacturer contracts provide that the manufacturers may increase IVIG prices. Three of the four contracts set the maximum increase at 10 percent per year, the fourth contract allows for increases consistent with market conditions.

### **Distribution Information**

The movement of available IVIG into our contracted supply that is available to Premier members is accomplished by a unique method of allocation of IVIG product.

In some distribution models outside of Premier once the customer’s monthly allocation of IVIG is purchased the customer is prevented from ordering any additional IVIG until the following

month. Likewise if the full allocation of IVIG is not purchased under this same model, the product may go un-used for that month and will eventually lead to a permanent decrease in that customer's allocation.

In Premier's distribution model, our contracted distributor, FFF Enterprises has an extensive staff of field-based and phone-based sales representatives who spend several hours a day managing the movement of allocations of IVIG among the Premier membership. If it is determined that one member does not need all of their IVIG allocation for a given month, a communication is sent out to other field-based representatives regarding what is available in the total Premier supply. As members' monthly needs change IVIG is shifted within the Premier membership. This Interactive Allocation process applies to all classes of trade in the acute and non-acute provider segments. In addition, FFF Enterprises tracks the movement of each vial of IVIG from the manufacturer to the member purchasing that specific IVIG vial.

By employing a detailed tracking and interactive IVIG allocation system, Premier believes that more IVIG gets to more patients each month. Changes in allocation requirements can be the result of a physician who uses IVIG for treatment that is either added or deleted from a practice or hospital staff, patients moving to second homes for a portion of the year in a different location, new patients diagnosed, patient deaths, patient illness preventing a monthly infusion, or a new choice or designation of new treatment site. Based on the patient and physician movement and variability from month to month, Premier feels that it is imperative to employ allocation methods that move available IVIG to where patient need exists.

### **IVIG Availability Concerns**

IVIG is currently in tight supply. Numerous factors, including decreased manufacturer capacity, increased IVIG demand, more sophisticated processing steps required to remove potential viral threats from human plasma, and lower demand for by-products from IVIG fractionation have affected the supply of IVIG. The demand for IVIG exceeds the supply for all patients that may benefit from IVIG treatment. Based on the current levels of manufacturing production there may be a perception that enough IVIG is being produced. The manufacturing capacity of all of the IVIG manufacturers, however, is not being used currently. Some manufacturers have closed production facilities. In addition, we believe the allocation and the distribution of IVIG from the manufacturers does not match the locations where patient demand has been identified. Premier members communicate their patient needs for IVIG. Premier totals all the member requests for IVIG and then requests this total from manufacturers. The total Premier needs are not currently met. It is our understanding that the manufacturers allocate IVIG between contracted customers and non-contracted customers. The portion of non-contracted IVIG is not directed to an identified patient need, but rather to a distributor which usually does not have any contracts for IVIG and will sell IVIG to any end user willing to pay the highest price. The price spikes evident in the IVIG market clearly indicate that there is an IVIG shortage.

Premier member requests for IVIG for this time period were consistently 25 percent higher than the level that could be supplied under Premier contracts. It is our understanding that, in order to cover the shortfall, Premier members purchase IVIG on the open market at prices that are significantly higher than Premier's contracted prices.

Based on the results of Premier's 2006 member IVIG needs survey, member needs for IVIG are 25 percent higher than Premier's 2006 contracted supply.

Due to the fact that Premier has members on the waiting list to access IVIG products under Premier contracts, Premier has asked the contracted manufacturers for additional volume to be added to Premier's contracted allocations in 2006. To date Premier has been told by the manufacturers that they have no more US supply available. The manufacturer's indicated that they will continue to monitor their production capabilities and the demand world-wide, and will inform us if they are able to increase Premier's IVIG allocations.

Premier believes the increases in IVIG volume that were provided under Premier's contracts were based on the manufacturer's acknowledgement that some of the demand in the contracted market segments was not being met. It is Premier's belief that IVIG volume now committed to Premier is volume that was once available in the unencumbered market or was previously committed to other contracts that have expired.

Premier members have consistently requested more IVIG over the 2004 and 2005 time period. Some of the members requests for additional IVIG above their usual order were able to be filled based on the FFF Enterprises Interactive Allocation system which allows the transfer of IVIG from members who no longer need their allocated IVIG product to members who have a documented need in excess of their usual order. These increases do not always translate to a permanent increase in member allocations or usual orders and can be a result of seasonal patient movement to different parts of the country, physicians being added or deleted from a treatment site, patient deaths, new patients diagnosed and/or treatments occurring in a different treatment site.

Premier adds new members on a regular basis. New members' IVIG requests are filled when possible based on the same process as outlined in Premier's interactive allocation system.

## **IVIG Pricing and Supply**

### **Shifts in member demand:**

The member demand was fairly constant in 2004 across all classes of trade for Premier's membership. The shift in member demand began early in 2005 with hospital members and members with hospital outpatient clinics having an increased demand and the physician office practices having a slight decrease in demand. The demands from the hospital and hospital outpatient clinic members exceeded the decrease in demand from the physician office members.

### **Average percent price increase for IVIG products in 2006:**

15 percent

### **Anticipated additional price increases in 2006:**

Price increases for IVIG totaling may be at least 10 percent above the 1-1-2006 price in 2006. Price increases on Albumin, which is a related product in the manufacturing of IVIG, that will be as high as 20 percent in 2006.

### **Medicare's reimbursement methodology and the impact on the IVIG market:**

We understand that Medicare patients have been moved from physician offices to outpatient clinics for their IVIG infusions during 2005 due to the decreases in reimbursement that physician offices experienced beginning January 1, 2005. However as of January 1, 2006, the IVIG reimbursement for hospital outpatient clinics has been reduced under the average sales price (ASP) methodology. These changes place unfair financial burdens on Premier member

hospitals. IVIG is needed by a unique, fragile patient population and Medicare patient access could be reduced over a period of time if the low reimbursement issue is not addressed.

Hospital outpatient clinics and physician offices are now facing a situation where their IVIG purchase prices have been increased significantly in 2006, with price increase pressures expected to continue. The quarterly adjustment of the ASP reimbursement rate is 6 months behind today's IVIG selling price. This results in hospitals realizing a loss on almost all of the IVIG purchased for Medicare patient infusions based on the new 2006 ASP reimbursement rates. Specific cost and reimbursement information are set forth in the table below:

<b>IVIG FORMULATIONS AVAILABLE IN 2006</b>	<b>Contract Price Per Gram 12-31-05</b>	<b>Contract Price Per gram 5-1-2006</b>	<b>ASP reimbursement per gram 4-1-2006</b>
<b><i>Lyophilized IVIG</i></b>			<b>HCPSC CODE=J1566</b>
<b>Brand A</b>	<b>Not on contract</b>	<b>\$46.00</b>	<b>\$44.52</b>
<b>Brand B</b>	<b>\$41.08</b>	<b>\$47.75</b>	<b>\$44.52</b>
<b>Brand C</b>	<b>\$43.00</b>	<b>\$54.50</b>	<b>\$44.52</b>
<b>Brand D</b>	<b>\$43.99</b>	<b>\$54.50</b>	<b>\$44.52</b>
<b>Brand E</b>	<b>\$48.00</b>	<b>\$55.00</b>	<b>\$44.52</b>
<b><i>Liquid IVIG</i></b>			<b>HCPSC CODE=J1567</b>
<b>Brand F</b>	<b>Not on contract</b>	<b>\$55.50</b>	<b>\$58.18</b>
<b>Brand G</b>	<b>\$56.00</b>	<b>\$58.98</b>	<b>\$58.18</b>
<b>Brand H</b>	<b>\$51.00</b>	<b>\$59.00</b>	<b>\$58.18</b>
<b>Brand I</b>	<b>\$57.90</b>	<b>\$64.00</b>	<b>\$58.18</b>

Premier also believes the ASP reimbursement methodology may result in detrimental effects on the nation's health care costs. The ASP reimbursement methodology negatively impacts cost controls in contracting for all drugs that are reimbursed under the ASP methodology.

Premier tracks ASPs for IVIG reimbursement as well as IVIG pricing from each manufacturer on a quarterly basis in order to trend increases/decreases in drug expenditures for Premier members. IVIG pricing has escalated significantly since the ASP methodology was introduced. The IVIG manufacturers' 2006 price increases and the contractually permitted price increases under Premier's new 2006 contracts demonstrate that the manufacturers' price increases may be an effort to increase the ASP reimbursement rate. The current level of IVIG price increases will have an overall negative effect on controlling drug expenditure costs. This practice will raise the cost of healthcare for IVIG patients treated at all sites of care, not just for the Medicare patient.

Premier has communicated its comments to CMS-1501-FC (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates) and has recommended alternative reimbursement methodologies for IVIG in these comments for CMS to review and consider.

## Comments on Supply Chain Integrity

Premier advocates measures to support safety, encourage access and control the costs of drugs. Safety is breached when counterfeit products enter the marketplace. This often occurs because of a breakdown in supply chain integrity. Patients who vitally need care can lose access to products that are in short supply due to product diversion. Distributors in the secondary market will redirect product causing the price to escalate with items often being resold multiple times. Tracking methods need to be implemented that track each vial of IVIG product from each manufacturer to the distributor and then to the pharmacy that purchases and prepares the product and finally to the patient who receives the product. Premier believes that there are short term and long term options for improving supply chain integrity for all pharmaceuticals. One short term option for IVIG may be to implement the same ordering methods that are currently in place for controlled substances. Premier recommends as options for the long term that the federal government through regulation and/or legislation require standardized procedures for establishing licensing requirements for drug wholesalers and specialty distributors. This would assure a national standard for each state to apply consistently and raise fines/penalties for non-compliance and breach of supply chain integrity. We urge the federal government to support the development and standardization of a pedigree and pedigree tracing system, either paper or electronic, to ensure the integrity of the pharmaceutical product. We also recommend, in support of the FDA, the utilization of a chemical marker within the packaging and labeling.

The significant secondary market for IVIG product has grown out of unbridled access to IVIG by unauthorized distributors who have had no barrier to acquiring a distributor license to access IVIG. Further such distributors have no specialized training as to the handling and storage of IVIG. The secondary distributor market is supported by some of the IVIG manufacturers selling unencumbered IVIG into the secondary distributor market at a higher price than encumbered IVIG on contracts in order to meet their companies' financial goals. Manufacturers engage in selling to this market segment even when they are aware of the unmet patient needs with their contracted customers.