



**Advisory Committee
Blood Safety and Availability
U.S. Department of Health and Human Services
Twenty-sixth Meeting, May 16 and 17, 2005**

**Update on IgIV Supply and Reimbursement
By Patrick M. Schmidt, FFF Enterprises Inc.**

The FFF Mission



The employees of the FFF family of companies are dedicated to serving patients by Helping Healthcare Care: We are accelerating the availability of lifesaving products and services, from innovation to delivery, with commitment to integrity, safety and cost containment.

IVIG Average Selling Prices

2003

2004

2005 YTD

\$39.55

\$40.32

\$46.29



FFF ASP Compared to Part B Rates

Non-lyophilized (liquid)

<u>FFF</u>	<u>Part B Rate</u>
\$54.04	\$56.355

Lyophilized (powder)

<u>FFF</u>	<u>Part B Rate</u>
\$41.65	\$39.138

1Q 2005

FFF ASPs 2002–2005 (Q1)

Non-lyophilized (liquid)

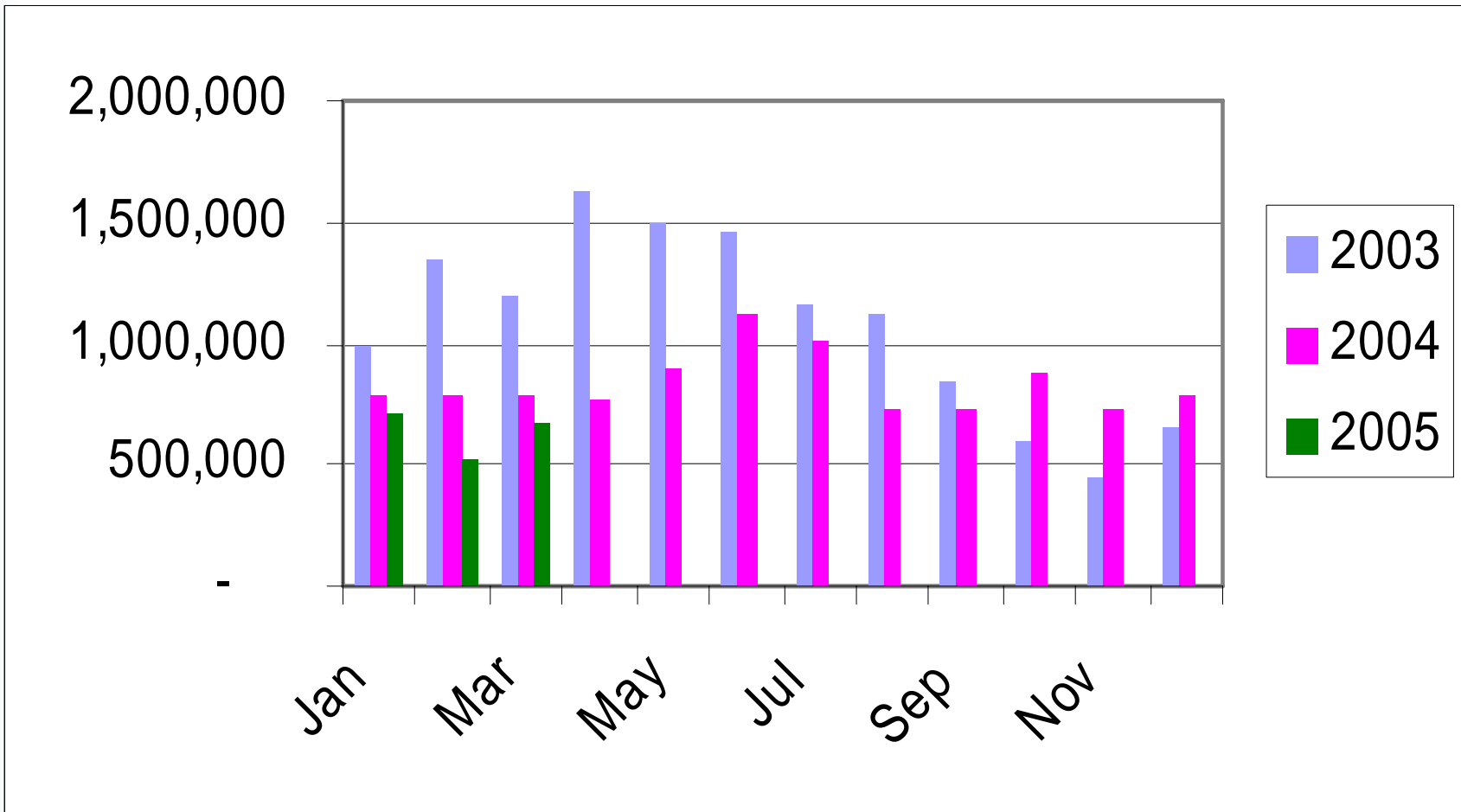
<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005 Q1</u>
\$53.66	\$48.32	\$51.48	\$54.04

Lyophilized (powder)

<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005 Q1</u>
\$44.57	\$37.88	\$37.70	\$41.65

Total Inventory on Hand

In Grams



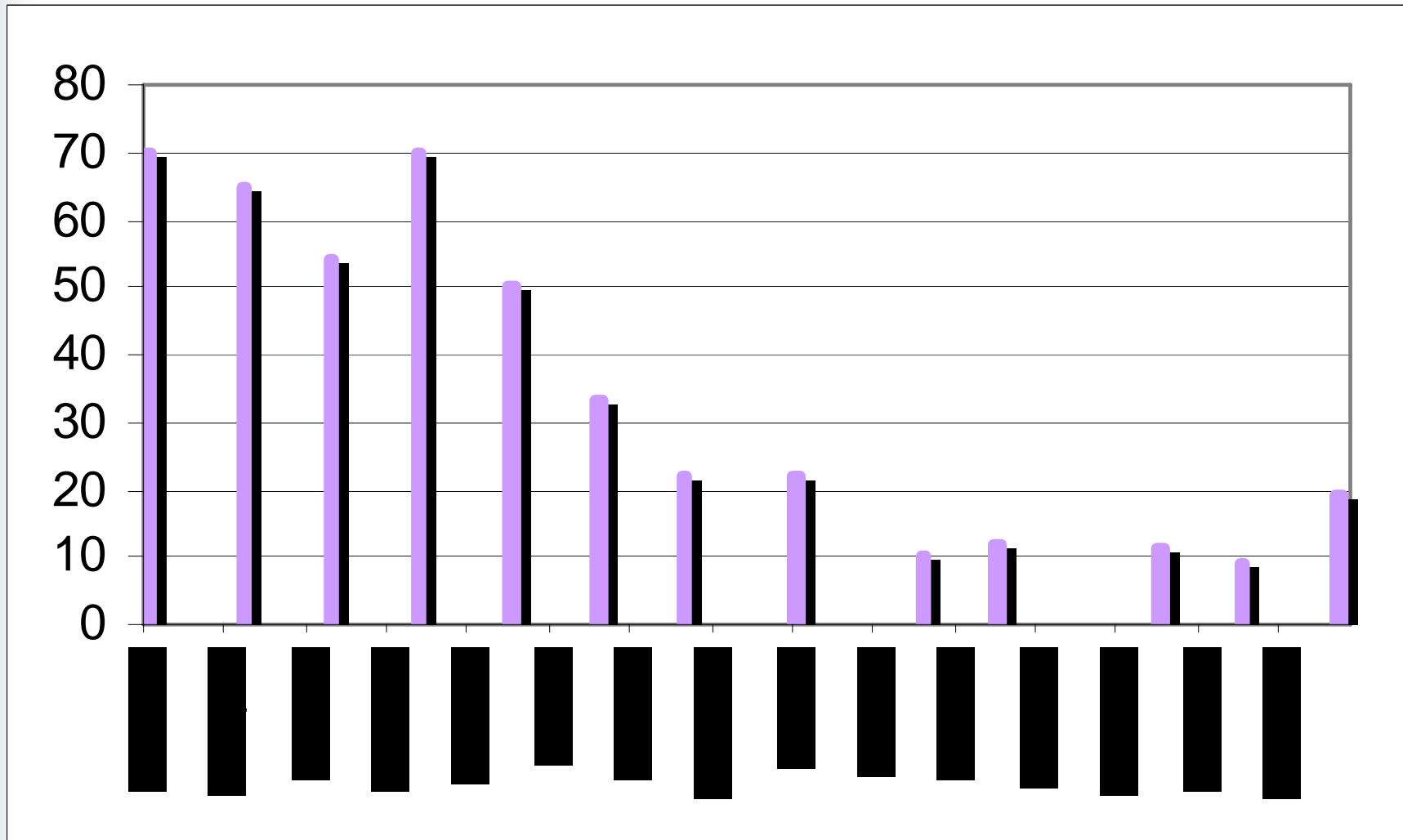
FFF Inventory v. Demand – IVIG

<u>Inventory on Hand</u>	<u>30-Day demand</u>
524,597	755,200

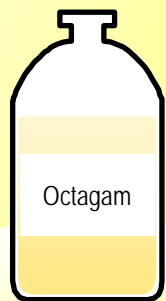
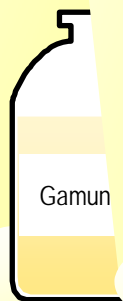
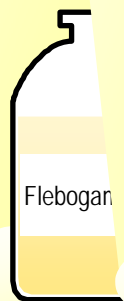
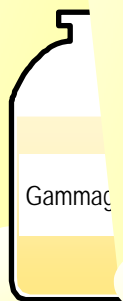
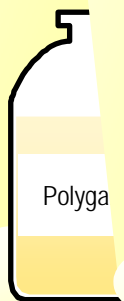
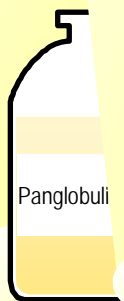
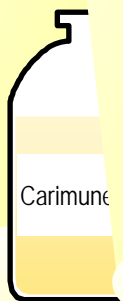
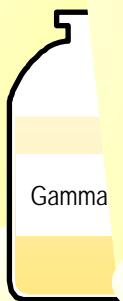
69.5%

* As of 10 May 2005

Panglobulin Days on Hand from BioSupply Trends



Lowest priced product always sells first!



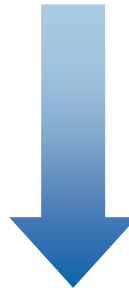
Supply Status by Product Type

Lyophilized – Inexpensive



All Products on Allocation

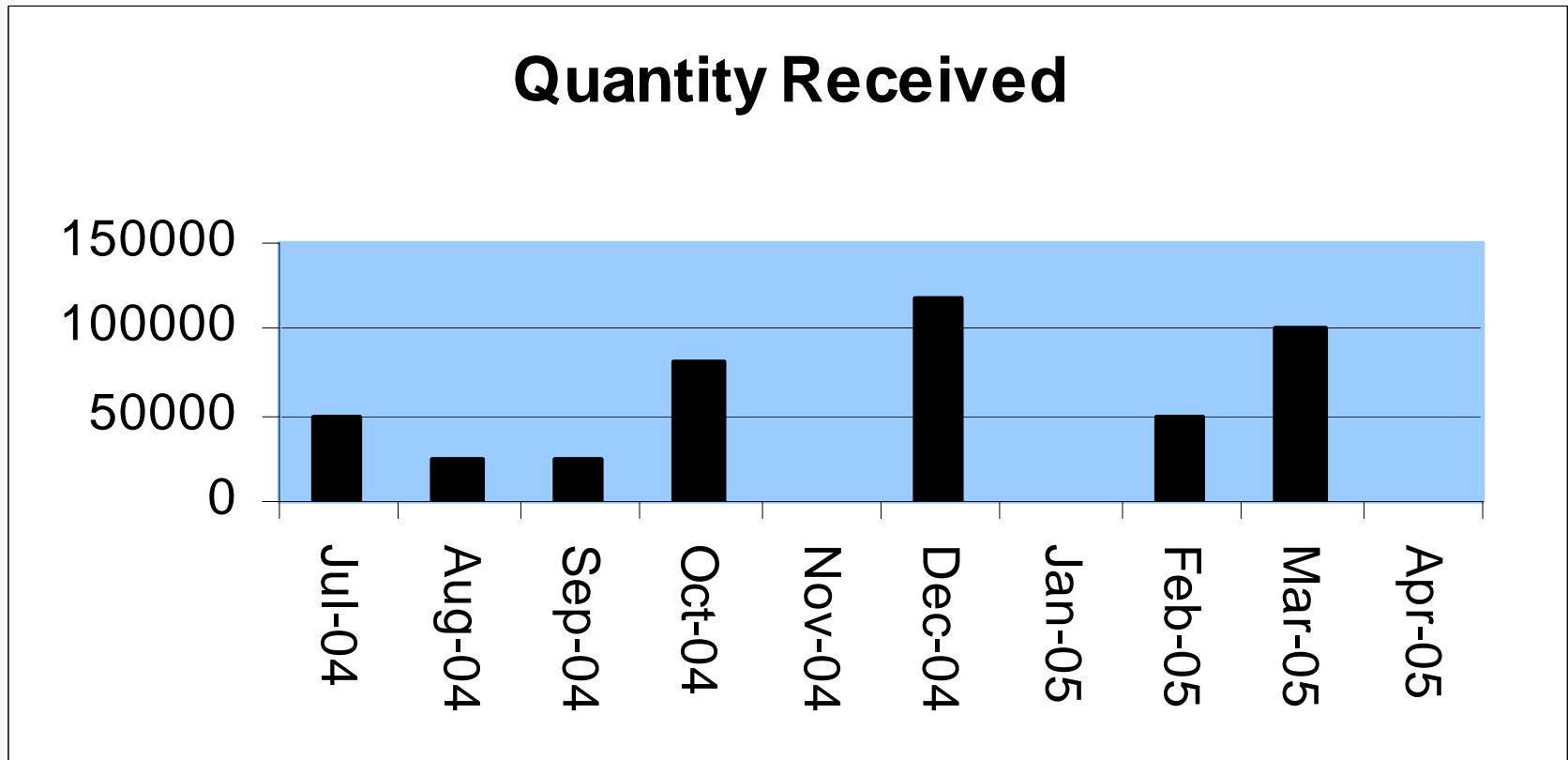
Liquid – Ready to Infuse



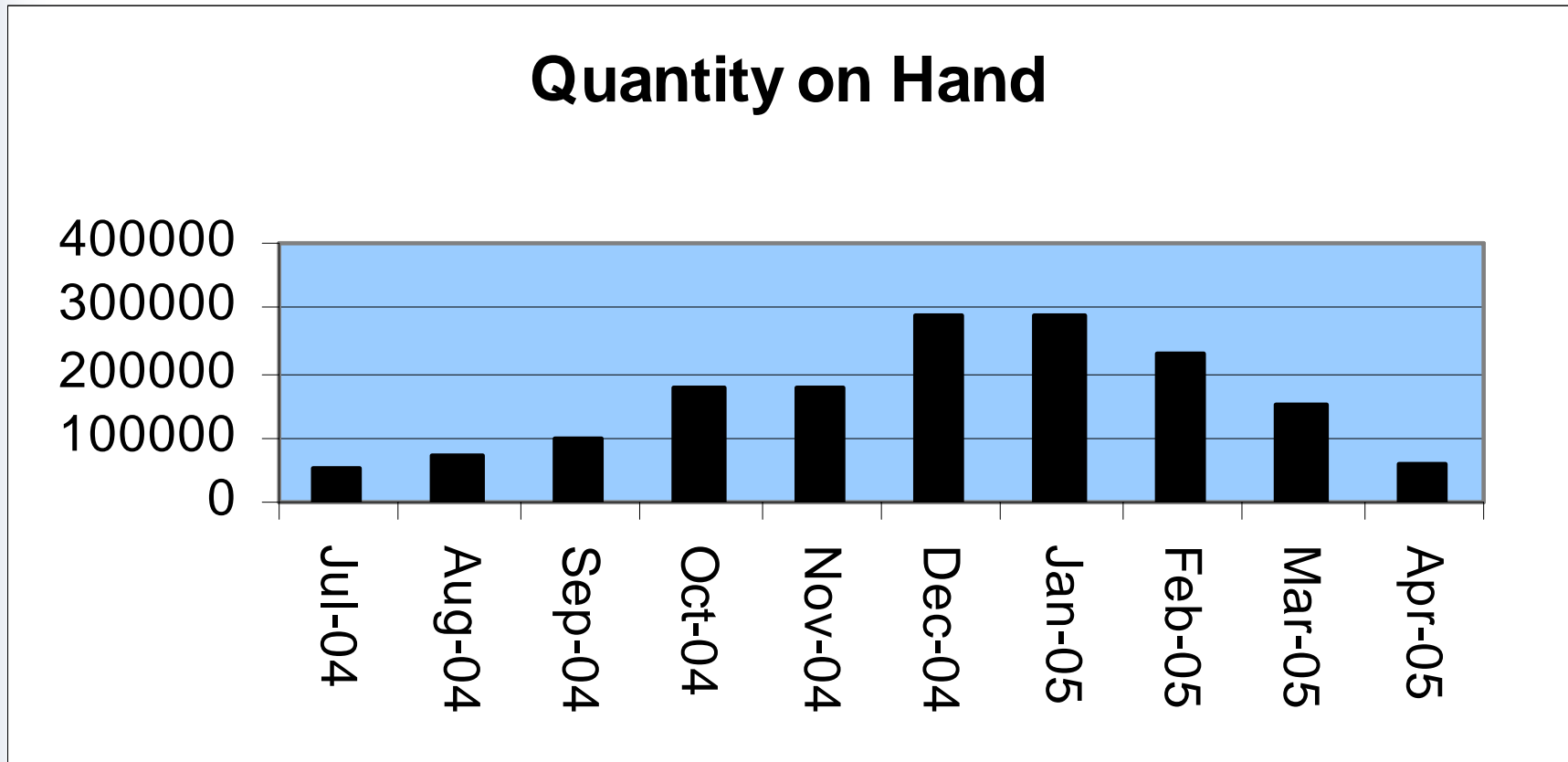
Limited Availability

Sept. 2004

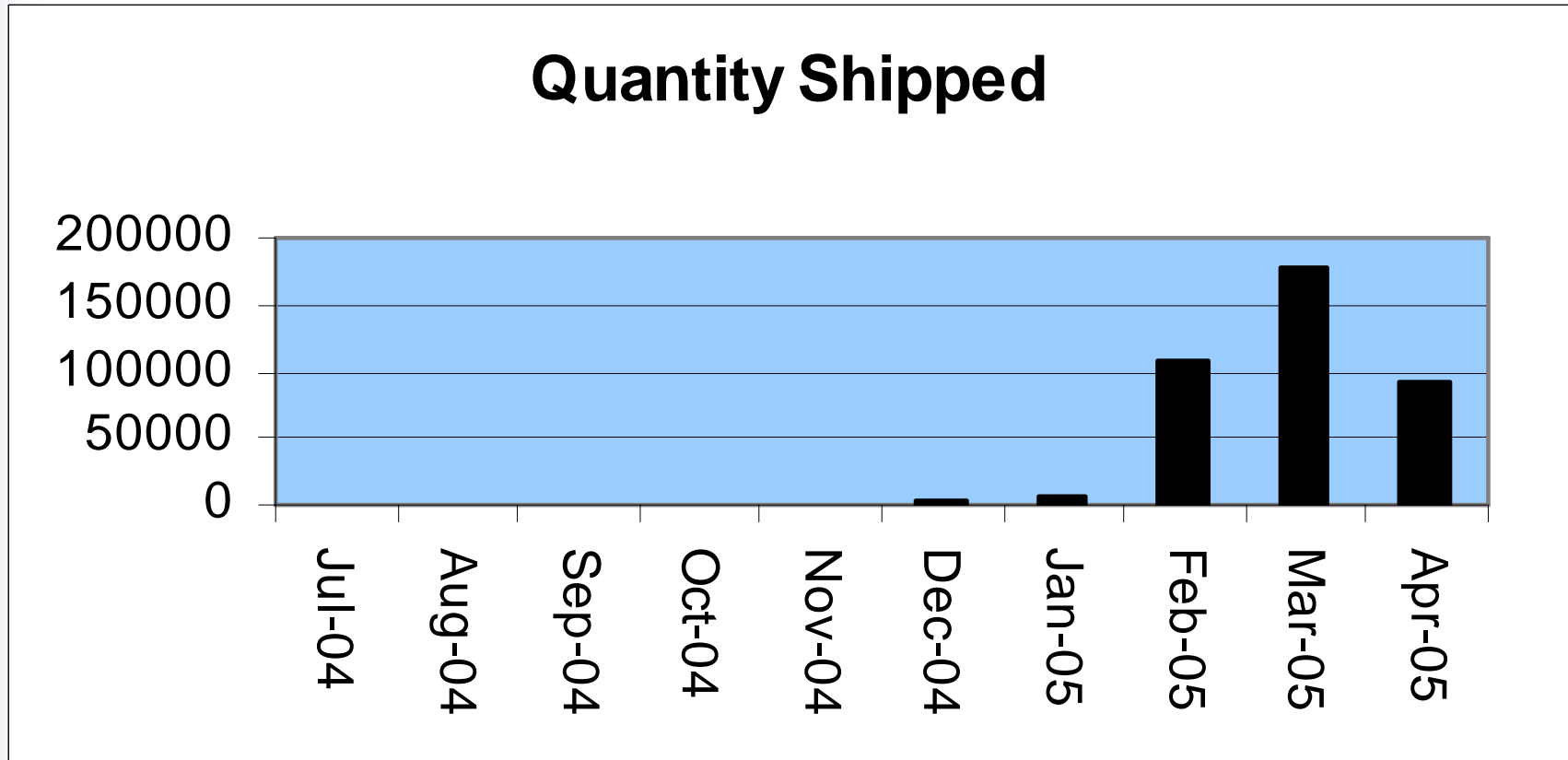
Octagam Receipts



Octagam Inventory Grows

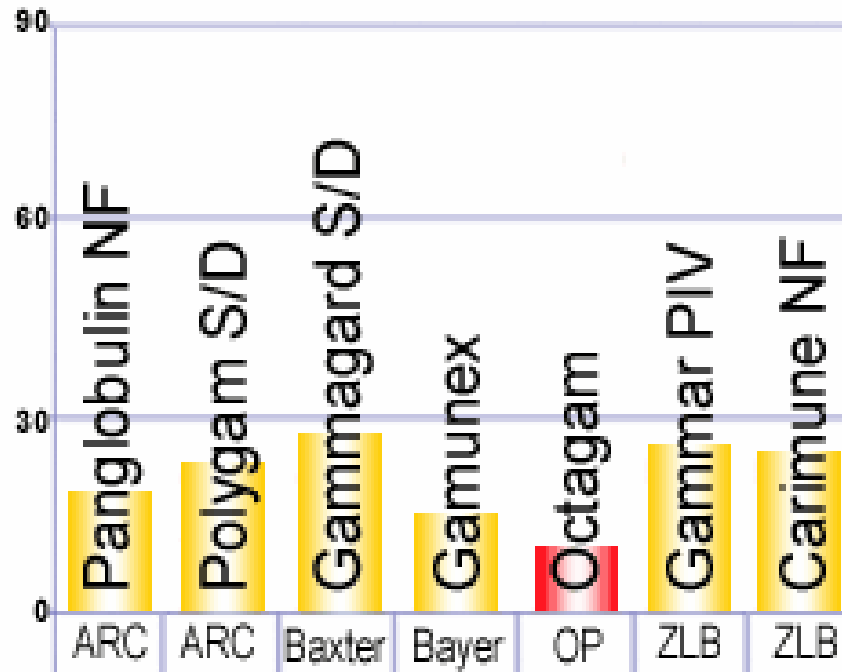


Sudden Uptake Begins



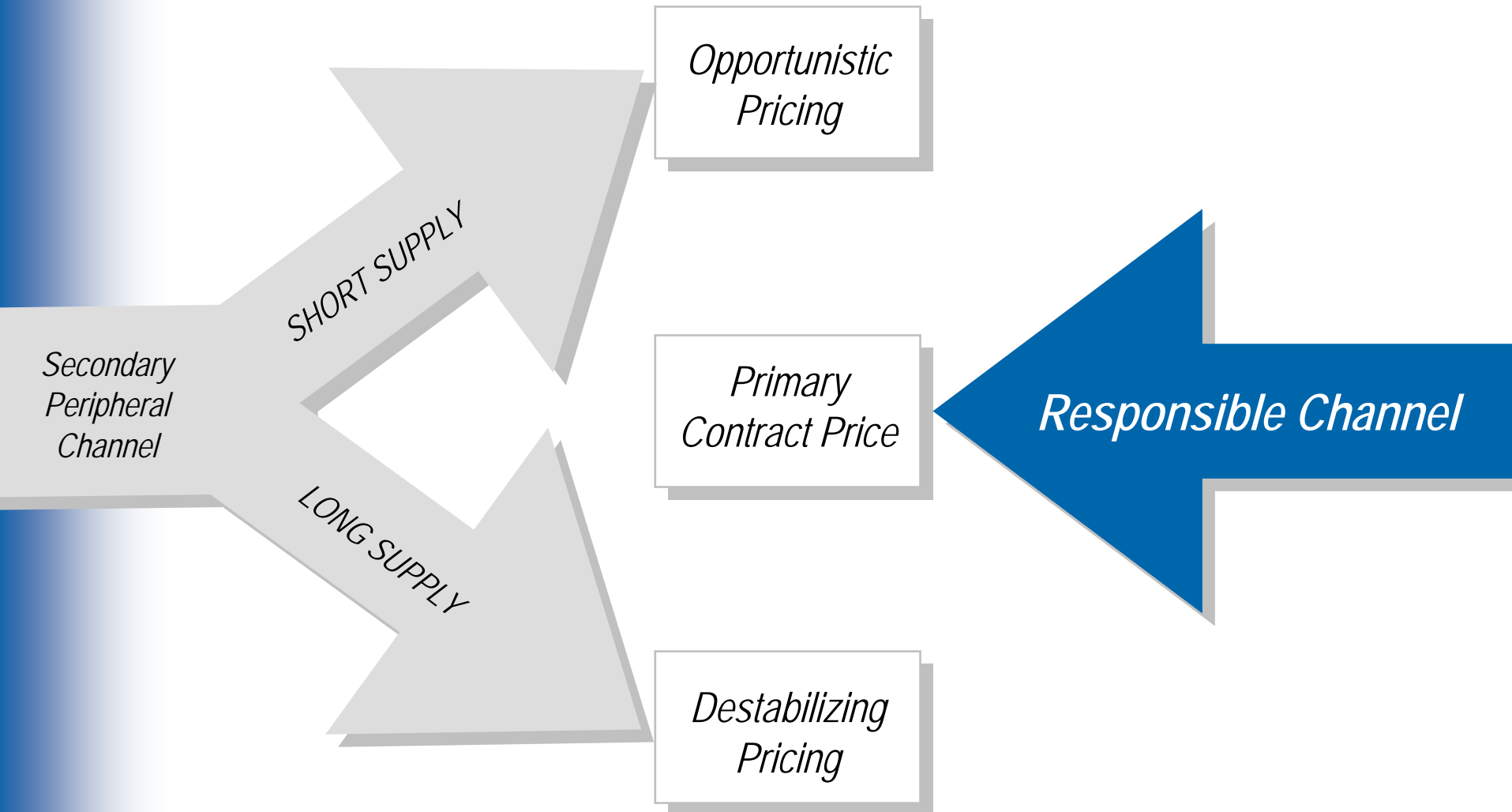
IVIG Supply Index

IVIG: Days On Hand



IVIG Supply Index represents on-hand supply at the nation's largest distributor of fractionated plasma products.

Market Turbulence



Open Market Product Flow

	<u>Annual</u>	<u>Monthly</u>
Company A	835,000	69,583
Company B	2,070,000	172,500
Company C	200,000	16,666
Company D	2,000,000	166,666
Company E	<u>1,290,000</u>	<u>107,500</u>
	6,395,000	532,915



24% Market



FFF ENTERPRISES, INC.
 41093 COUNTY CENTER DRIVE
 TEMECULA, CA 92591
 (800) 843-7477
 FAX: (800) 418-4333

-REPRINT-

INVOICE
INVOICE

5266723

ORDER NO. 1303909

CUSTOMER NO. FFL05754

PAGE NO. 1 of 1

**** PLEASE REMIT PAYMENT TO ADDRESS BELOW ****

MAIL TO:

OPTION CARE
 ATTN: ACCOUNTS PAYABLE
 2880 SCHERER ROAD, #850
 ST. PETERSBURG, FL 33716
 USA



CUSTOMER: FFL05754
 OPTION CARE ST PETERSBURG

PAYER: FIL06000
 OPTION CARE

CARIMUNE-NF 6 GRAM VIAL
 45 VL 03609-00288 11/15/07

LN	QUANTITY	ITEM NUMBER/DESCRIPTION	LIST PRICE	UNIT PRICE	AMOUNT
1	270 GM	FFF Enterprises purchases 100% of FFF-distributed prescription drugs directly from the manufacturer, with no exceptions. IMM041706BR 44206-0417-06 CARIMUNE-NF 6 GRAM VIAL 45 VL 03609-00288 11/15/07		40.00	10800.00
Goods Value Total :					10800.00
Invoice Total :					10800.00

LOS ANGELES, CA 90084-0150

Thank You



110 CENTRUM DRIVE
 IRMO, SOUTH CAROLINA 29063
 803-732-1018 (FAX) 803-781-3349
 (800) 948-9834
 www.ivig.com

INVOICE

Date: 04/27/05 Inv. No.: 61757
 Due Date: 05/27/05 Page No.: 1
 Ship To/Remarks

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D
T
O



110 CENTRUM DRIVE
 IRMO, SOUTH CAROLINA 29063
 803-732-1018 (FAX) 803-781-3349
 (800) 948-9834
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INVOICE

Date: 04/27/05 Inv. No.: 61757
 Due Date: 05/27/05 Page No.: 1

DESCRIPTION ITEM NUMBER	ORDERED	SHIPPED		UNIT PRICE	EXTENDED PRICE
	UNIT MEASURE	BACKORDERED	ITEM DISCOUNT		
Carimune NF IVIG 12 gram vial (ZLB) 44206-418-12	50 VIAL	50 0	714.00 N	35700.00	
Lot No. 0361000115 QTY = 50					
Carimune NF IVIG 6 gram vial (ZLB) 44206-417-06	16 VIAL	16 0	357.00 N	5712.00	
Lot No. 0360900297 QTY = 9					
Lot No. 0360900193 QTY = 7					

NET TO PAY	41412.00
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Customer Original

REMIT TO:
 BLOOD DIAGNOSTICS, INC.
 P.O. BOX 65938
 CHARLOTTE, N.C. 28265-0938



Pharmaceutical
Distributors

3/28/2005

Polygam SD \$84.00/g

Here are our current prices for the following brands of IVIG:

Carimune NF	\$58.00/g
Gammagard SD	\$75.00/g
Gamunex 10%	\$75.00/g
Polygam SD	\$84.00/g

We can honor these prices through 3/31/05, though prices are subject to fluctuate.

Daniel@biomedplus.com



BioMed Plus, Inc.
 6855 S.W. 81st Street
 Miami, Florida 33143
 Tel: 305/666-0389 Fax 305/666-8097
 Toll Free: 1-800-809-2308
 FL LICENSE# 22:00813

invoice

DATE
03/21/2005

INVOICE #
90057674



BioMed Plus, Inc.
 6855 S.W. 81st Street
 Miami, Florida 33143
 Tel: 305/666-0389 Fax 305/666-8097
 Toll Free: 1-800-809-2308
 FL LICENSE# 22:00813

invoice

DATE
03/21/2005

INVOICE #
90057674

ITEM	NDC #	DESCRIPTION	QTY	UOM	RATE	AMOUNT
2010402	00944-2620-03	Gammagard 5 grams Lot # LE080121AA Exp. Date 12/10/2006	20	G	75.00	1,500.00
100030	00000-0000-00	Freight	1	EA	15.07	15.07

Please remit payments only to:
 BioMed Plus, Inc.
 P.O. Box 101146
 Atlanta, GA 30392-1146

A friendly reminder. Blood and pharmaceutical products are non-returnable. Thank you.

Total 1,515.07



Corporate Headquarters: 11403 Bluegrass Parkway, Suite 400

Corporate Headquarters: 11403 Bluegrass Parkway, Suite 400
Louisville, Kentucky 40299
Phone: (800) 304-0123
Fax: (502) 266-9023

DATE: APRIL 26, 2005

Product	Vial sizes	Price Quote	Your Current Cost/Gm	Currently Available
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IVIG PRICING

We can provide IVIG in the manufacturer's original packaging for the Following prices:

Product	Vial sizes	Price Quote	Your Current Cost/Gm	Currently Available
Carimune NF	6/12 Gm	Acquisition Cost + 10%	\$59.40	Yes
Gammagard	5/10 Gm	Acquisition Cost + 10%	\$68.20	Yes
Gamunex	5/10/20 Gm	Acquisition Cost + 10%	\$60.50	Yes
Panglobulin	6/12 Gm	Acquisition Cost + 10%	\$93.50	Not readily
Polygam	5/10 Gm	Acquisition Cost + 10%	\$93.50	Not readily

Integrity Healthcare Services
Columbus, St. Louis and Wexford offices.



Effects of IVIG Reimbursement and Supply

“It is very frustrating trying to find an adequate supply of a safe and effective IVIG at a reasonable price. The cost has risen out of hand, while reimbursement has been lowered. The average price for IVIG is anywhere from \$75.00 to \$92.00 per gram! We are sending many patients to an acute care setting where I know they are not receiving the same quality care.

We are literally days away from sending all Medicare patients to their local hospital where we can only hope they can and will be treated; unfortunately with that comes increased infusion times and additional time off from work for the patient. I would love to see my patients be able to stay in a comfortable, safe and well-known environment; however, this cannot be unless the reimbursement increases in the physician setting.”

– Judy Back, RN, BSN, Innovative Infusions, Benbrook, TX

Effects of IVIG Reimbursement and Supply

“IVIG is on allocation, therefore, whenever a new patient needs to get the drug, I have a very difficult time finding it. There are other suppliers, but the cost of the drug is higher. Medicare will only pay a certain amount for these infusions, so any extra cost is incurred by the practice. If this does not change, many patients will be forced to the hospital for their infusion. That will be more costly for the patient.

This very serious issue will, in the end, be a barrier to care, considering the cost/reimbursement for the drug. This is very serious, and the one who will suffer the most for the decisions made by others will be the sick patient who needs IVIG.”

– Angie Brinegar, RN BSN OCN

Coastal Cancer Center

Myrtle Beach, SC

Effects of IVIG Reimbursement and Supply

“Dear Patients:

For the past year, there has been a nationwide shortage of IVIG. Over the past 2 months, the situation has become critical and our office cannot guarantee that we will have enough for all of our patients. We have been contacting the manufacturers directly and until now, they were able to allocate IVIG to us from their emergency inventories. These are becoming exhausted. The manufacturers are trying their best to replenish their stocks, however this will take some time; the shortage is worldwide.”

– R.H. Kobayashi, M.D.
UCLA School of Medicine

Effects of IVIG Reimbursement and Supply

“I am writing a quick note to express my concerns regarding IVIG with respect to Medicare patients. The reimbursement is now below cost for us to purchase the medication. IVIG is very useful in a variety of diagnosis. We are having a difficult time treating these patients both from a reimbursement aspect as well as obtaining product. One clinic we deal with is now sending all Medicare patients (particularly IVIG) to the hospital and hoping for the best.

There simply is no product to use for treatment. I would hope that the leaders in this arena could understand that we can provide IVIG therapy in the home or even in an infusion center at a tremendous cost savings over the hospital admission.”

– Todd E Thompson, RPh

InfuCare

Effects of IVIG Reimbursement and Supply

“Due to the changes in Medicare reimbursement at the doctors’ offices for IVIG, Tri-City Medical Center has been impacted by a 300% increase per month. There are also the following increased labor considerations:

- Pharmacy buyer time to obtain product in an extremely short-supply environment. Time spent contacting several distributors for availability of product and price comparisons.
- Increased pharmacy staff time to mix and prepare more IV solutions (while continuing to do other required tasks).
- Increased nursing time to administer IV, along with increased time to schedule for the outpatient department.”

– Laura Ball, Pharmacy Buyer, Tri-City Medical Center
Oceanside, California

Effects of IVIG Reimbursement and Supply

“I am writing to address the issue of the IVIG shortage, allotments and outages that are being felt across the nation. It is a travesty to tell people that it is approved for their conditions, but we cannot obtain enough of the drug to take care of them.

I have had several patients contact me about trying to locate a supply of IVIG for their condition, because their doctor or other provider can no longer obtain enough to keep them going. This is sad, especially since some of these patients have just started having their quality of life restored to them.”

– James Mike Jones, R.Ph.

Christus St Michael

Effects of IVIG Reimbursement and Supply

“The cost of I.V.I.G. has risen, while reimbursement has been dramatically lowered by Medicare. We are seriously considering denial of this vital therapy to Medicare patients. They would be referred to a hospital for outpatient treatment and subsequently be exposed to a variety of pathogens while in a compromised immune state. Many would simply not go at all.

Either way, many would probably succumb to pneumonia and other illnesses requiring lengthy hospital stays and extensive treatment and possible disability.”

– Joan M. Nasr, R N

California Allergy & Asthma Medical Group

Los Angeles, California

Effects of IVIG Reimbursement and Supply

“We cannot obtain IVIG at a price lower than or equal to Medicare’s reimbursement rate. In the face of recent cutbacks, which have been devastating to physicians practices, we cannot continue to lose each time we treat a patient. Overall, the IVIG shortage, cost and reimbursement has created confusion, stress and frustrations for providers and patients.

Our plea is for someone in CMS to recognize the need to raise the reimbursement for both lyophilized and non-lyophilized product so that the providers can at least break even for IVIG administration in this financially disastrous year!”

– Cherie Moore RN, OCN, CCRP

Cancer Center of Boston

Effects of IVIG Reimbursement and Supply

“Just wanted to let you know that the Gamunex was on backorder. I called Blood Diagnostics: We delayed treatment for the patient, because their price was \$75.00/gram (they have the same price for Polygam). Our reimbursement for Medicare is ASP plus 6%. I think it is around \$56.00/gram, so we will lose money on all Medicare patients.”

– Glenda McGarrigle

SC Oncology

Effects of IVIG Reimbursement and Supply

“I am aware of the tight supply of Gamunex and that we do not have a permanent allocation for our patients. I have contacted Bayer to request an increase supply to FFF, so we can get Gamunex for our patients that have trouble tolerating IVIG. The patient [for whom we] ordered that Gamunex today is in that category, having to get hydrocortisone IV before treatment. I have told the staff we cannot get guarantee supply for this drug.

I hope the future is brighter so we can get the drugs we need to our pediatric patients.”

– Howard Fistel, RPh

Miami Children's Hospital

Effects of IVIG Reimbursement and Supply

“I am very concerned about the increase in usage I am seeing in this product. I am not sure if the trend is that physicians’ offices are finding it unprofitable to continue treatment or if the product availability is affecting them. I have noticed this product seems to be in the hands of 2nd generation distributors, which bothers me.

Though I have no definitive proof that this product is not safe, I personally would not buy it for my facility.”

– Carol Keegan, Pharmacy Supply Coordinator

Banner-Good Samaritan Regional Medical Center

Phoenix, Arizona

Effects of IVIG Reimbursement and Supply

Immune Globulin, Intravenous

Brand Names / Synonyms: IVIG, Sandoglobulin, Gamimune N, Polygam SID

Classes: SERUMS

Dosages: Injection: *preferably 10% solvent treated, 100 ml vials

Notes:

Order in grams or immune globulin; specify percent if necessary

Product is difficult to procure due to nation-wide supply shortage

– USAMEDDAC FORMULARY

Martin Army Community Hospital, Fort Benning, GA 31905

Updated February 2005

Effects of IVIG Reimbursement and Supply

“Cost of IVIG is higher by 5% than what Medicare reimburses. The infusion for patients will cost me an out of pocket loss of 35% for Medicare patients. There is a shortage and local hospitals, specifically SJH, have refused to accept them. The prediluted products, which are below or at Medicare reimbursement levels, are not available to me due to product allocation. The costs at secondary markets are at least 25% above Medicare reimbursement levels.

Although I continue to see Medicare patients I cannot take on any new patients for infusion, because of the above.

– Dr. Kumaraswamy Sivakumar

Scottsdale, Arizona

Conclusions

- Manufacturer inventory levels have decreased
- Primary Distribution Channel inventory levels have decreased
- Demand continues to grow steadily
- Revenue per liter must increase for mfg to increase supply
- Declining Reimbursement Trend

Conclusions

- Medicare Beneficiaries increasingly being denied care in setting of choice
- Opportunistic pricing from secondary distributors impacting affordable care in all settings
- Potential healthcare crisis
- Lives are being negatively impacted

Immediate Action Plan

- We need grams placed in a trusted, responsible channel–IDF Safety Net
- We need an interim fix to Medicare Part B Reimbursement Methodology
- We need industry collaboration for a permanent reimbursement solution

Immediate Action Plan

- We need to ask FDA to assist in education of safe and appropriate use of Albumin
- Appropriate utilization of albumin and any possible increase in demand will help produce additional affordable IGIV
- We need primary channel distributors to supply inventory and distribution data voluntarily
- I will volunteer our data to the appropriate agency.