Immune Deficiency Foundation

Improving the diagnosis and treatment of
primary immune deficiency disease for 25 years

Presentation to Advisory Committee on Blood Safety and Availability

Michelle B. Vogel, MPA

Vice President, Government Affairs & Reimbursement Services

May 16, 2005

Reimbursement Impact on PIDD Community

- IDF has received over 300 calls from Medicare patients since January 1, 2005 not being able to receive their IVIG infusions at their physicians' offices, outpatient infusion suites, home care settings and hospitals.
  - The patients that have been shifted to hospitals need to be admitted for 23 hours and are not receiving the most appropriate brand of IVIG, but the brand the hospital has accessible.
  - Patients who have not been successfully transferred to hospitals are on waiting lists, are denied access, or are being treated with prophylactic antibiotics.
- IVIG infusion suites have shut down, outpatient hospital clinics have shut down or are in the process of closing their doors. Some examples include: Ohio State University, Mt. Sinai Medical Center (NYC), Ambulatory Care in Texarkana, Arkansas, Northridge Hospital Medical Center (Los Angeles)…

Primary Immune Deficiency Community on Medicare

- Based on past surveys for the Immune Deficiency Foundation by Schulman, Ronca and Bucuvalas, Inc.
  - Approximately 7,000 Medicare patients (majority on disability)
  - 67% receive IVIG infusions in non-hospital settings
    - Physicians' offices, independent infusion centers, homecare settings
  - 32% receive IVIG infusions in outpatient hospital settings
    - Infusion clinics located in the hospital and admitted as an outpatient
      - Many of the infusion clinics located in the hospital do not bill under HOPPS.

IVIG Reimbursement Rates 2005

IVIG Reimbursement Changes:

- January 1, 2005, CMS implements new ASP formula, IVIG reimbursement is reduced from $66 to $40.02 per gram in non-hospital provider settings.
- January 14, 2005, CMS increases reimbursement for IVIG to $56.72 per gram retroactive to January 1, 2005
- April 1, 2005, CMS implements new "Q" codes for IVIG separating lyophilized vs. non-lyophilized (liquid).
  - Lyophilized is $39.138
  - Liquid is $56.355

RESULTS:

- **PRODUCTS CANNOT BE PURCHASED AT REIMBURSABLE RATES.**
- **PATIENTS LOSE ACCESS TO LIFESAVING THERAPY IN MOST, IF NOT ALL, SITES OF CARE.**

IGIV Administration Payments 2004-2005 - Liquid

			TYPICAL ADULT PIDD PATIENT (75 KG) TREATED AT 0.4 G/KG BODY WEIGHT						APRIL 1, 2005 NON-I	
			PHYSICIAN'S OFFICE			HOPPS			HOME ADMINISTRATION	
YEAR			2004		2005	2004		2005	2004	2005
Reimbursement Per Gram ($)			66.00		56.36	72.60		80.68	66.00	56.36
Administration Fee										
	First Hour		117.79		76.93	104.29		111.80		
	Each Additional Hour		33.02		25.77					
	For 30 GM		1980.00		1690.65	2178.00		2420.40	1980.00	1690.65
	3.5 hours Admin		200.34		141.36	104.29		111.80		
		TOTAL	2180.34		1832.01	2282.29		2532.20	1980.00	1690.65
Per Cent Change				Decrease	15.98		Increase	10.95	Decrease	14.61

IGIV Administration Payments 2004-2005 - Lyophilized

	TYPICAL ADULT PIDD PATIENT (75 KG) TREATED AT 0.4 G/KG BODY WEIGHT						APRIL 1, 2005 LYOPHILIZED RATES	
	PHYSICIAN'S OFFICE		HOPPS		HOME ADMINISTRATION			
YEAR	2004	2005	2004	2005	2004		2005	
Reimbursement Per Gram ($)	66.00	39.14	72.60	80.68	66.00		39.14	
Administration Fee								
First Hour	117.79	76.93	104.29	111.80				
Each Additional Hour	33.02	25.77						
For 30 GM	1980.00	1174.14	2178.00	2420.40	1980.00		1174.14	
3.5 hours Admin	200.34	141.36	104.29	111.80				
TOTAL	2180.34	1315.50	2282.29	2532.20	1980.00		1174.14	
Per Cent Change		Decrease 39.67		Increase 10.95		Decrease	40.70	

DO YOU EVER FEEL LIKE YOU ARE BEING BOUNCED AROUND?

- Unfortunately, I feel that I need to use this picture to demonstrate how I feel lately when I am trying to fix the IVIG reimbursement crisis, almost like a ping pong ball.
- Everyone seems sympathetic and realizes there is a problem, but no one has been able to fix it.

  - I have met with CMS, and they have been extremely receptive and I would like to thank Herb Kuhn, Amy Bassano and Don Thompson for all of their hard work on this issue, but we still have a serious problem with no solution.
  - I have met with Members of Congress and the staff on the key committees and we know that the Medicare bill needs to be fixed.
  - I have met with FDA due to reported concerns that reimbursement may not be the only problem occurring.
  - So, here I am today with the number of patients not being treated increasing every day and not knowing what to tell them as they get sicker and knowing that time is running out before we start losing lives.

What can be done to get patients treated

- Declare a Public Health Crisis or Reimburse IVIG as a "Blood Product"
  - If CMS took either one of these actions today, IVIG could go back under the old reimbursement system of Average Wholesale Price (AWP), which would help stabilize the system.
    - Is this a perfect, long-term solution? NO
    - Will this get patients back in the physicians offices, infusion centers, and home-care settings? Yes
  - The percentage of AWP needs to be adjusted and does not need to be reimbursed as high as 95%, as the law could allow, but should be reimbursed at least equal to the current hospital reimbursement rate at 83% of AWP and should remain at this reimbursement level for the next 2 years.
  - Additionally, hospitals, should not switch over to the new reimbursement methodology on January 1, 2006, and should remain at the current reimbursement formula of 83% of AWP for 2 years, as well.

Longer-Term Recommendations

- During the 2 year period that IVIG is reimbursed under the AWP system:
  - Study to determine best payment methodology
    - Participants: CMS, Congress, manufacturers, distributors, providers, and patient groups
    - Goal: to ensure access to all brands of IVIG in all sites of care.
    - Develop surveillance system to ensure that reimbursement never eliminates access to a lifesaving product as well as dictate site of care again.
- Longer-term recommendations:
  - Separation of all of the “J” codes for all of the IVIG products, since all of these products are unique by formulation, effectiveness and tolerability.
    - Plus an add-on payment, similar to the clotting-factor add-on payment would cover the distribution costs of IVIG and allow all products to be affordable to all providers.
  - IVIG administration codes/coverage for all sites of care.

Adequate Reimbursement for IVIG Administration in All Sites of Care

- Immediate Action:
  - CMS needs to recognize that IVIG is a biologic response modifier (BRM) therapy; therefore it should be covered under the chemotherapy administration code (increase of 20%):
    - Included in the chemotherapy administration code is coverage for BRM therapy, as well as monoclonal antibody therapies, such as: Embrel and Remicade. *According to the U.S. National Library of Medicine, the definition of BRM therapy is the treatment to stimulate or restore the ability of the immune system to fight infection and disease.*
- Long-term Fix:
  - Develop a fee schedule specifically for IVIG administration for the physicians office, home care setting, and hospital.
    - Needs to include: specialized/trained nursing services, coverage for infusions that can last for over 8 hours, adverse events, pre and post medication, DME, etc.

Questions and Discussion

Thank You.