THE IMMUNE DEFICIENCY FOUNDATION AND
AMERICAN ACADEMY OF ALLERGY, ASTHMA AND IMMUNOLOGY
IMMUNOLOGIST SURVEY REGARDING IVIG TREATMENT

THE IMMUNE DEFICIENCY FOUNDATION
40 W. CHESAPEAKE AVE., SUITE 308
TOWSON, MARYLAND 21204
800.296.4433
WWW.PRIMARYIMMUNE.ORG

APRIL 11, 2007
ABOUT THE IMMUNE DEFICIENCY FOUNDATION

Founded in 1980, the Immune Deficiency Foundation (IDF) is the national non-profit health organization dedicated to improving the diagnosis and treatment of primary immunodeficiency diseases through research, education and advocacy. IDF is governed by a Board of Trustees, has an active Medical Advisory Committee comprised of prominent clinical immunologists, a nationwide volunteer support network and a dedicated professional staff.

This survey was conducted with the cooperation of the American Academy of Asthma, Allergy and Immunology, and funded in part by an educational grant from Baxter Healthcare Corporation, Octapharma, Talecris Biotherapeutics, and CSL Behring.
# Table of Contents

**Executive Summary** .......................................................................................................................... 1  
**Survey Methodology** ......................................................................................................................... 2  
**Respondent Practice Characteristics** .................................................................................................. 2  
**IVIG Supply and Demand** .................................................................................................................... 3  
**Purchase of IVIG** ................................................................................................................................. 5  
**Administration of IVIG** ....................................................................................................................... 7  
**Impact of Product Availability and Reimbursement on Treatment** .................................................... 9  
**Conclusions** ......................................................................................................................................... 13  
**Figures (Charts & Tables)** .................................................................................................................... 14  
**Appendix I: Monthly Administration for IVIG** ............................................................................... 46  
**Appendix II: Survey Questionnaire** .................................................................................................... 47
EXECUTIVE SUMMARY

The Immune Deficiency Foundation, in collaboration with the American Academy of Asthma, Allergy and Immunology (AAAAI), conducted a national survey of the AAAAI membership concerning the treatment of patients with primary immunodeficiency diseases (PID) and other conditions with intravenous immunoglobulin (IVIG). The physician survey was conducted by Internet with e-mail invitations, and was conducted between October 13 and November 17, 2006. This physician survey was conducted in parallel with national surveys of patients with primary immunodeficiency diseases and hospital pharmacists who dispense IVIG.

A total of 230 immunologists completed the IDF physician survey. More than seven out of ten (71%) of these specialists were currently following patients with primary immunodeficiency diseases. Almost all of the doctors who followed any patients with primary immunodeficiency diseases reported that some of their PID patients were being treated with IVIG. A total of 152 physicians reported 2388 of their PID patients being infused with IVIG in an average month. This relatively large national sample of physicians, following an even larger sample of PID patients being treated with IVIG, provides a unique perspective on current treatment issues related to IVIG.

Availability of IVIG does not currently appear to be a widespread problem for these physicians. More than four out of five physicians reported that during the past 12 months they had been able to obtain enough IVIG to treat all (64%) or almost all (18%) of their PIDD patients. Only three percent of physicians reported that they could only obtain enough IVIG to adequately treat some (2%) or none (1%) of their PID patients.

Physician respondents reported an average purchase price for liquid IVIG per gram of $67.47. The average purchase price for liquid IVIG is ten percent higher than the 2006 fourth quarter Medicare reimbursement rate of $60.65 at ASP plus six percent. Nearly half (44%) of physicians who know the purchase price of their liquid IVIG reported paying more for it than the Medicare reimbursement rate of ASP plus six percent.

Similarly, physicians reported an average purchase price for lyophilized IVIG per gram of $60.25. This average purchase price for lyophilized IVIG is twenty percent higher than the 2006 fourth quarter Medicare reimbursement rate of $50.53 at ASP plus six percent. More than four out of five (81%) physicians who know the purchase price of their lyophilized IVIG reported paying a higher price for lyophilized IVIG than the current Medicare reimbursement standards.

Physicians with contracts reported an average price for liquid ($66.40) and lyophilized ($57.87) IVIG quite similar to that reported by hospitals for liquid ($63.17) and lyophilized ($58.00) products. Physicians with no contracts reported a much higher average price from liquid ($71.80) and lyophilized ($67.75) products.
Even ignoring other costs associated with the infusion of IVIG, the current Medicare reimbursement standard covers, on average, only 80-90% of the doctors’ purchase price for the product. Only 9% of physicians who knew exactly what their offices or facilities pay for liquid IVIG and 7% of those who know exactly what they pay for lyophilized IVIG say that Medicare provides adequate reimbursement for the purchase price of IVIG.

Intravenous immunoglobulin is the standard of care and only effective treatment for most patients with primary immunodeficiency disease. These physicians have experienced patients being forced to change optimal treatment location, infusion intervals and/or dosing amount as a result of reimbursement issues, in some case foregoing treatment for extended periods. As a result, some of these vulnerable patients have experienced additional or more severe health effects.

**Survey Methodology**

Between October 13 and November 17, 2006, the Immune Deficiency Foundation, in collaboration with the American Academy of Asthma, Allergy (AAAAI) and Immunology, conducted a national survey of the AAAAI membership concerning the treatment of patients with primary immunodeficiency (PID) diseases and other conditions with intravenous immunoglobulin (IVIG). AAAAI members were invited to participate in a web-based survey designed jointly by the membership of the AAAAI Primary Immunodeficiency Committee and the Immune Deficiency Foundation. The participants were recruited via email and at the AAAAI 2006 annual meeting. Data was collected over a six week period with a total of 230 unduplicated responses. This survey was conducted in parallel with national surveys of patients with primary immunodeficiency diseases and hospital pharmacists who dispensed IVIG.

**Respondent Practice Characteristics**

The sample of doctors was relatively evenly divided by primary practice location (Figure 1) between those who spent most of their patient care time in solo practice (28%), single specialty group practice (26%), multi-specialty group practice (17%) and hospital outpatient (21%). On average, these physicians reported seeing 106 patients, with a variety of conditions, per month on an out-patient basis (Figure 2). Those in solo practices see the most patients per month on an outpatient basis (141), while those who see most patients in a hospital outpatient setting saw the fewest (44) per month, on average.

A total of 164 of the responding immunologists, (71%) were currently following patients with primary immunodeficiency diseases (Figure 3). On average, these doctors report that they currently follow 33 patients with primary immunodeficiency diseases. The average number of PID patients currently followed is lowest for physicians in solo practice (14), and somewhat higher for physicians in single specialty group practice (18), and multi-specialty group practices (21). By contrast, physicians who saw most of their
patients in hospital outpatient settings followed an average of 73 patients with primary immunodeficiency diseases (Figure 4).

The 164 doctors from the survey who followed any patients with primary immunodeficiency diseases reported a total of 5521 PID patients being followed. Approximately half of these patients (51%) were being followed by physicians who see most of their patients in hospital outpatient settings (Figure 5). Another 14% of patients are followed by physicians in other care settings, which are predominantly academic medical centers. The rest of the patients with primary immunodeficiency diseases are relatively evenly dispersed between doctors in solo practice (11%), single specialty group practice (14%), and multi-specialty group practice (10%).

Physicians who followed one or more PID patients were asked how many of their PID patients were infused with IVIG in an average month. More than nine out of ten physicians reported that some of these patients were being infused with IVIG. Overall, physicians who followed IVIG-using PID patients, reported an average of 16 who infused with IVIG in an average month (Figure 6). The average number of IVIG infusing PID patients was about the same for physicians in solo practice (10), single specialty group practice (11), and multi-specialty group practices (10). There was a considerably larger average number of IVIG infusing PID patients (30) among physicians who see most of their patients in hospital outpatient settings or other patient care settings (25).

Overall, the average number of PID patients infusing IVIG per month (16) is only half of the average number of PID patients being followed (33) by these doctors. However, the proportion of IVIG infusing PID patients is seventy percent among physicians in solo practice, which is consistent with the proportion of primary immune deficient patients reporting current IVIG use (69%) in the 2003 IDF Treatment Experience Survey. The lower proportions of IVIG using PID patients compared to all PID patients followed in larger practices, particularly the hospital outpatient setting, suggests that doctors in larger practices, particularly hospital settings, may be familiar with the infusion practices of only a portion of those patients they follow.

In total, the 152 physicians with PID patients being infused with IVIG reported 2,388 PID patients being infused with IVIG in an average month (Figure 7). This relatively large national sample of physicians, following an even larger sample of PID patients being treated with IVIG, provides a unique perspective on current treatment issues related to IVIG.

**IVIG Supply and Demand**

As noted earlier, the survey includes 152 physicians with a reported 2,388 PID patients who are being infused with IVIG in an average month. These physicians also report an average of 269 of their non-PID patients being infused with IVIG per month. In addition, these doctors also report that an average of 358 of their PID patients receive subcutaneous immunoglobulin therapy. In total, among all patients being treated with immunoglobulin therapy in this physician sample, 79% are patients with primary
immunodeficiency diseases who are infusing IVIG. A small, but significant proportion (12%) of patients with primary immunodeficiency diseases is being treated with subcutaneous immunoglobulin. Less than one of ten (9%) are non-PID patients being treated with IVIG (Figure 8).

The physicians who were following IVIG infusing PID patients were asked the total number of grams of IVIG infused in their patients in an average month. Less than one in ten physicians (9%) reported that their patients infused less than 35 grams a month (Figure 9). Another 21% of physicians reported that their patients infused 35-99 grams per month. At the other extreme, nearly three in ten physicians reported that their patients infused more than 500 grams per month, with 12% infusing patients with 500-999 grams per month, 11% infusing patients with 1000-1999 grams, and 6% infusing patients with more than 2000 grams per month.

As noted earlier, the vast majority of patients of these doctors who are being treated with immunoglobulin are IVIG using PID patients. Indeed, three quarters of these doctors (76%) say that 100% of the IVIG infused in their patients is for primary immunodeficiency diagnoses (Figure 10). Another 10% report that 90-99% of the IVIG they infuse is for PID diagnoses. Another 10% report that 50-89% of the IVIG they infuse is for PID diagnoses. Only a handful of physicians in this sample (4%) report that less than half of the IVIG they infuse is for patients with primary immunodeficiency diseases.

The majority of these physicians (64%) report that during the past 12 months they had been able to obtain enough (100%) of the IVIG needed to treat all of their PID patients (Figure 11). Another 18% report that the amount of IVIG they were able to obtain was sufficient to adequately treat almost all (90-99%) of their PID patients. At the same time, 16% of physicians reported that they had been only able to obtain enough IVIG to adequately treat most of their PID patients. Only three percent of physicians reported that they could only obtain enough IVIG in the past 12 months to adequately treat some (2%) or none (1%) of their PID patients.

Those physicians who reported that they were not able to get 100% of the amount of IVIG needed to adequately treat all of their PID patients were asked how many more grams of IVIG per month they needed. Nearly four in ten physicians (37%) who reported being able to get 100% of the IVIG needed to treat all of their PID patients said that the shortfall was less than 50 grams per month. An equal proportion (37%) reported that the shortfall was between 50 and 150 grams. Only about one in ten doctors who had not been able to get enough IVIG to adequately treat all of their patients reported a shortfall of 151 to 300 grams (6%), 301-500 grams (4%), or more than 500 grams (2%). However, 15% of doctors who said they could not get enough IVIG to treat all of their PID patients were not sure of the amount or did not answer the question.

As a check, physicians who stated they could adequately treat 100% of their PID patients with the amount of IVIG were also asked how many more grams of IVIG were needed per month. Ten percent of those who said they had enough to adequately treat all
patients said they needed between 1 and 49 grams additionally per month, while 2% said they needed an additional 50-150 grams, and 1% said they needed an addition 150-300 grams per month.

While more than four out of five doctors (82%) report sufficient availability of IVIG to adequately treat all or almost all PID patients, this does not mean that doctors are able to obtain specific brands that they need or prefer. Nearly half of these physicians are on a restricted formulary – some of which are satisfied with the products they can get (25%) but some of whom want other products (17%). A third of the doctors (33%) say they can get all of the specific brands that they need or prefer, while a quarter (25%) say they are not able to get all the specific brands they want (Figure 13).

More specifically, physicians treating IVIG using PID patients were asked whether they had to change a patient’s IVIG product in the past 12 months due to lack of availability of the patient’s primary product. Nearly three quarters (72%) say they had to change a patient’s IVIG product in the past 12 months because of lack of availability of that patient’s primary product (Figure 14). Hence, while relatively few doctors treating patients with PID have experienced a product shortage sufficient to interfere with adequate treatment of PID patients with IVIG, most have experienced a sufficiently tight market for IVIG such that preferred products may not be available for their patients.

PID patients are infused in a variety of sites. Most commonly, physicians report that many (44%) or some (34%) of their PID patients receive their IVIG in hospital outpatient settings. However, nearly a third (32%) say that many of their PID patients are infused in their office, while 11% say that some of their patients are infused in their offices. Nearly three out of ten physicians say that many of their PID patients (29%) are infused at home by a nurse, while 41% say that some of their PID patients are infused at home by a nurse. Self-infusion is reported for many patients by 13% of doctors, and some patients by 32% of doctors. Least commonly, 12% of doctors say that many of their patients receive their IVIG in hospital in-patient settings, while another 12% say that some of their PID patients are infused in hospital in-patient settings (Figure 15).

**PURCHASE OF IVIG**

Doctors with IVIG using PID patients were asked whether their practice or patient care setting had a contract for IVIG. Approximately one third (34%) said they had a contract for the purchase of IVIG (Figure 16). About the same number of doctors (35%) said they did not have a contract for IVIG. The remainder said they were not sure whether their practice or facility had a contract (16%) or chose not to answer the question (15%).

Those who said their practice or facility had a contract for the purchase of IVIG were asked the types of organizations with whom they had a contract. More than a third of those with a contract (37%) said the contract was with a group purchasing organization (Figure 17). Three out of ten (31%) said that they had a contract directly with a distributor. Less than a quarter (23%) said that they had a contract with a manufacturer.
Nearly one in five doctors who said that their practice or facility had a contract for the purchase of IVIG was not sure of the type of organization with whom they had a contract. The physicians who had a contract for the purchase of IVIG were asked what their total monthly allocation was. About one in five doctors with a contract (21%) had an allocation of 120 grams or less (Figure 18). At the other extreme, about one in five doctors with a contract (21%) had a monthly allocation of more than 1800 grams.

Most physicians who follow PID patients using IVIG are not aware of the current purchase price that their office or care facility pays for IVIG. However, those who were aware of the average purchase price for liquid IVIG reported an average purchase price per gram of $67.47 (Figure 19). The average purchase price for liquid IVIG is ten percent higher than the 2006 fourth quarter Medicare reimbursement rate of $60.65 at ASP plus six percent. Nearly half (44%) of physicians who know the purchase price of their liquid IVIG reported paying more for it than the Medicare reimbursement rate of ASP plus six percent. Most of the physicians who knew the price they paid for liquid IVIG had a contract. There was no significant difference in the price reported between those with a contract with a GPO, distributor or manufacturer (Figure 20). However, physicians without a contract reported a substantially higher average price per gram for IVIG ($71.80) than those with a contract ($66.44).

Similarly, those physicians who were aware of the average purchase price for lyophilized IVIG reported an average purchase price per gram of $60.25 (Figure 21). This average purchase price for lyophilized IVIG is twenty percent higher than the 2006 fourth quarter Medicare reimbursement rate of $50.53 at ASP plus six percent. More than four out of five (81%) physicians who know the purchase price of their lyophilized IVIG reported paying a higher price for lyophilized IVIG than the current Medicare reimbursement standards. As with liquid IVIG, most of the physicians who knew the price they paid for lyophilized IVIG had a contract. Among those with a contract for IVIG, those who had a contract with a manufacturer reported a higher average price ($72.33) than those with a contract with a GPO ($54.63) or a distributor ($59.45). (Figure 22) Similarly to liquid IVIG, physicians without a contract reported a substantially higher average price per gram for lyophilized IVIG ($67.75) than those with a contract ($57.87).

Even ignoring other costs associated with the infusion of IVIG, the 2006 fourth quarter Medicare reimbursement standard covered, on average, only 80-90% of the doctors’ purchase price for the product. Not surprisingly, less than half of the physicians with IVIG using PID patients (47%) responding to the question said that Medicare provides adequate reimbursement for the purchase price of IVIG (Figure 23). The proportion of doctors who report that Medicare provides adequate reimbursement for the purchase price of IVIG increases from 42% of those in solo practice to 52% of those seeing patients in hospital outpatient settings. More doctors (59%) say that Medicare with supplement provides adequate reimbursement for the purchase price of IVIG. The perception that Medicare with supplement provides an adequate reimbursement for the
purchase price of IVIG is most widely held among doctors seeing their patients in hospital outpatient settings (73%).

However, many of those responding to the question about the adequacy of Medicare reimbursement for the purchase price of IVIG did not know the price that their office was paying for IVIG. The majority of those with IVIG using PID patients who did not know what they were paying for liquid (64%) or lyophilized (62%) IVIG said that Medicare reimbursement was adequate (Figure 24). By contrast, only 9% of physicians who know what their office or facility pay for liquid IVIG and 7% of those who know what they pay for lyophilized IVIG say that Medicare provides adequate reimbursement for the purchase price of IVIG.

ADMINISTRATION OF IVIG

The purchase price of IVIG is only one component of the treatment cost of IVIG infusions for private physicians. While a typical office visit to see a physician may average about fifteen minutes, the average time that PID patients are on site for their infusions is much longer. Only seven percent of physicians report that the average time on site for an infusion is 90 minutes or less, not counting time in the waiting room (Figure 25). By contrast, nine percent of physicians report that the average time on site for a PID patient is more than 240 minutes. The average time on site is 189 minutes, or more than three hours. This estimate of the average infusion time for PID patients by the physicians closely matches the average length of infusion reported by patients (207 minutes) in the 2003 IDF Survey of Treatment Experiences and Preferences of Patients.

Many PID patients are treated with other medications, in addition to the IVIG, prior, during or after the infusion. More than a third of physicians (37%) report that all or most PID patients receive pre-medication prior to infusion, while most of the rest (36%) say that some PID patients receive pre-medication (Figure 26). Only 9% of physicians following PID patients using IVIG report that none of them receive pre-medication prior to their infusion. In addition, physicians report that all or most (9%), some (18%) or a few (30%) PID patients receive other non-IVIG medications DURING their infusions (Figure 27). Finally, doctors report that all or most (2%), some (14%) or a few (24%) of PID patients receive medication after the infusion while still at their infusion suite (Figure 28).

More than a third of physicians report that PID patients receive a physical examination prior to the infusion at their facility on every visit or most visits (36%). Another third of physicians (32%) report PID patients are given physical examinations prior to infusion for some visits. Only a minority of physicians report that PID patients are given physical examinations prior to infusion only rarely (17%) or never (15%) at their facility (Figure 29).

During the average three hour infusion, physicians report that the patient’s vital signs and reactions are monitored on a regular basis. Nearly half of physicians report that their patients have vital signs and reactions monitored during the infusion four times an
hour (16%), more than four times an hour (22%) or continuously (7%). About an equal proportion say vital signs are monitored 2 times (30%) or three times (15%) an hour during an infusion. Only 10% of physicians report that vital signs and reactions are taken less than 1 time an hour during the infusion (Figure 30).

Aside from physical examinations and monitoring of vital signs, nearly two out of five physicians treating PID patients with IVIG (38%) say that all or most patients at their facility have additional face-to-face contact with the doctor during the infusion (Figure 31). About a third report that some (21%) or a few (13%) patients at their facility have additional face-to-face contact with the doctor during infusions. Only 28% say no patients have additional face-to-face contact with the doctor during the infusion.

The majority of physicians also report that at least a few patients have an examination or assessment with a physician in their office after the infusion. Only 17% of doctors say that all or most patients have a physician assessment after the infusion (Figure 32). However, 15% say that some patients have an examination or assessment by a doctor after the infusion while 28% say a few patients are examined by the doctor after the infusion.

There is also a certain amount of follow-up with patients after they have left the facility. Relatively few physicians say that there is a post-visit telephone call with the PID patient after every visit or most visits (4%) or some visits (21%). Almost half (49%) say that post-telephone are made only rarely with PID patients. But only 26% say that post-telephone visits are never made with PID patients (Figure 33). The frequency of post-visit telephone calls with PID patients corresponds to the frequency with which doctors report that their office has to deal with delayed post-infusion reactions. Only 1% of doctors say that they or someone else in their office often has to deal with delayed post-infusion reactions of patients, but 21% say that they occasionally have to deal with them, and 64% say that they seldom have to deal with them (Figure 34). Only 14% of physicians report that they never have to deal with delayed post-infusion reactions among their patients.

The examinations, medication and monitoring during an average PID infusion visit require a considerable amount of staff time. Overall, doctors estimate that physicians spend an average of 13 minutes of professional time during an average PID patient infusion visit (Figure 35). Doctors estimate that their registered nurses spend an average of 106 minutes during an average PID patient infusion visit. Practical nurses spend an average of 32 minutes during an average PID patient infusion visit. Technicians spend an average of 7 minutes per infusion visit, while other office staff spends an average of 8 minutes per PID patient infusion visit (see Appendix I: Monthly Administration of IVIG).

It should be noted that nurses who infuse patients with IVIG at these facilities are highly qualified. The average number of years of service for nurses who infuse patients with IVIG at these facilities is 12 years (Figure 36). In nearly half of these sites, either all (30%) or most (13%) nurses have advanced or specialized certifications (Figure 37). In
addition, all (18%) or most (47%) of the non-nursing staff who participate in the IVIG administration process have specialized or advanced training (Figure 38).

Aside from the time spent during the infusion visit, doctors report that a considerable amount of staff time is spent acquiring IVIG for the practice’s patients. On average, doctors report that they spend over two hours a month in acquiring IVIG for their patients (Figure 39). They estimate that their nurses spend an average of more than six hours a month acquiring product for the patients. In addition, doctors estimate that other office staff spends an average of more than four hours a month acquiring IVIG. Even among those practices which have a contract for IVIG, four out of five (80%) say that staff are still required to spend time acquiring an adequate amount of IVIG (Figure 40).

In addition to the time required to acquire IVIG and administer the infusion, physicians report that staff time is also required for support activities for patients being treated with IVIG. Doctors estimate that they spend more than three hours a month in these patient support activities (Figure 41). They estimate that their nurses spend an additional 10 hours per month in these support activities, while other office staff spends an average of almost 3 hours per month in these support activities.

In 2006, Medicare permitted a pre-administration related service fee for IVIG of $69 in a physician’s office and $75 in hospital outpatient settings, while hospital outpatient departments were also allowed a one time payment of $120.77 for the administration of IVIG. However, the survey finds that nearly half (47%) of physicians following PID patients being infused with IVIG said that Medicare reimbursement was not adequate for the cost of administering IVIG to patients (Figure 42). A majority of those in solo practice (60%) said it was not adequate, compared to a minority (40%) of those who see most of the PID patients in hospital outpatient settings. By contrast, 64% of doctors said that Medicare with supplement provided adequate reimbursement for the cost of administering IVIG to patients.

Physicians who reported that Medicare reimbursement was inadequate for the cost of the product or the cost of administering IVIG were asked what percentage increase in Medicare reimbursement would be necessary for a break-even level for purchase, acquisition and administration of IVIG in their office or primary care facility. Almost 80% of the doctors said that a sizeable increase, at least a 20% higher reimbursement, would be needed in order for them to break-even on the total cost for IVIG infusions (Figure 43). This translates into 28% who stated an increase of 20-34% would be needed, 17% who stated that a 35-49% increase would be necessary, and over a third (34%) who stated that reimbursement would have to be 50% higher than Medicare allowed for IVIG infusions.

**IMPACT OF PRODUCT AVAILABILITY AND REIMBURSEMENT ON TREATMENT**

A majority of physicians following IVIG using PID patients (53%) say that PID patients had changed their usual site of infusion since the beginning of 2005 because of
Medicare reimbursement (Figure 44). This was most common among physicians in solo practice settings (62%), single specialty group practices (55%) and multi-specialty group practices (50%). It was less common for physicians in hospital outpatient settings (40%). Among those physicians who report PID patients have changed their usual site of infusion due to reimbursement or availability, 13% say that many patients have been transferred, while 41% say several patients have been transferred and 18% say that one patient was transferred (Figure 45).

Physicians do not appear to distinguish well between reimbursement and availability as the reason patients have had to change their usual infusion since the beginning of 2005. Approximately the same proportion says that Medicare reimbursement (53%) and third party reimbursement (53%) have caused IVIG-using PID patients to change their usual site of infusion since the beginning of 2005 (Figure 46). Somewhat fewer (47%) say that unavailability of product at a reasonable price caused patients to change their usual site of care, while fewer (39%) say that unavailability of product at any price caused patients to shift their usual site of care. It should be noted that the inability to purchase IVIG at a price equal to or below reimbursement rates may be reported as unavailability of product at a reasonable price.

The shift in site of IVIG infusions for PID patients due to reimbursement or product availability is primarily towards the hospital. The majority of physicians who report infusion site transfers say that one (15%), several (25%) or many (13%) of their patients have been transferred to hospital outpatient settings (Figure 47). While 13% of physicians having to transfer patients to other infusion settings say that many patients have been transferred to hospital outpatient settings, only 3% say that many have been transferred to home nursing, 1% say many have been transferred to hospital inpatient and 1% say many have been transferred to their own office or facility. This pattern of transfer of patients to hospital outpatient infusion sites since the beginning of 2005 is consistent with changes reported by Medicare patients in the IDF patient survey.

The transfer of site infusion from doctors’ private offices and infusion suites to hospitals is not a treatment neutral process for patients with primary immunodeficiency diseases. When asked how much difficulty they have encountered in obtaining services for patients referred to hospital based infusion settings, only 27% of doctors treating these patients said they have encountered no difficulties. The majority say they have encountered some difficulty (52%) in obtaining service for these patients in the hospital setting, while 21% say they have encountered much difficulty (Figure 48).

According to their doctors, some of the patients who have had to change their site of infusion for non-medical reasons have had to forego treatment for an extended period. Half of the physicians reporting that any of their PID patients had to change their usual site of infusion due to reimbursement or availability say that at least one PID patient had to forego treatment for an extended period as a result of this transfer (Figure 49). Most commonly, doctors say that only one (18%) or several (28%) PID patients had to forego treatment for an extended period, rather than many patients (4%).
Nearly two in five physicians following IVIG using PID patients (39%) say that PID patients had to reduce their usual frequency of infusion since the beginning of 2005 because of Medicare reimbursement (Figure 50). Once again, physicians do not seem to distinguish well between reimbursement and availability as the causes for these treatment changes. The same proportion says that reductions in Medicare (39%) and reductions in third party payments (39%) have caused reduction in the usual frequency of IVIG infusions for PID patients since the beginning of 2005. Slightly fewer say that unavailability at a reasonable price (36%) or unavailability at any price (37%) has caused reductions in usual frequency of infusion.

The reported reduction of usual frequency of infusion among PID patients as a result of reductions in Medicare reimbursement was most common among physicians in solo practice settings (43%), single specialty group practices (45%) and multi-specialty group practices (41%). It was less common for physicians in hospital outpatient settings (32%) (Figure 51). Among those physicians who report PID patients have reduced their usual frequency of infusion due to reimbursement or availability, only 4% say that many patients have had their usual frequency of infusions reduced, while 39% say several patients have had their usual frequency of infusion reduced and 19% say that one patient was has had his or her usual frequency of infusion reduced (Figure 52). Finally, physicians were asked whether any of their PID patients who had their infusions reduced for reasons of reimbursement or availability had to forego treatment for an extended period. Among those physicians, only 24% said that none of their PID patients had been forced to forego therapy for an extended period (Figure 53). Most commonly, they said that one (32%) or several (38%) PID patients had been forced to forego therapy for an extended period due to these non-medical reasons.

Nearly three in ten physicians following IVIG using PID patients (29%) say that PID patients had to reduce their average dosage of IVIG since the beginning of 2005 because of Medicare reimbursement (Figure 54). Once again, physicians do not seem to distinguish well between reimbursement and availability as the causes for these treatment changes. Nearly the same proportion says that reductions in Medicare (29%) and reductions in third party payments (28%) have caused reduction in the average dosage for PID patients since the beginning of 2005. About the same say that unavailability at a reasonable price (27%) or unavailability at any price (28%) has caused reductions in dosage for PID patients in the past two years.

This reported reduction in average dosage for any IVIG-using PID patients was more common among physicians in solo practice settings (35%), single specialty group practices (33%) and multi-specialty group practices (32%) (Figure 55). It was less common for physicians in hospital outpatient settings (21%). Among those physicians who report PID patients have reduced their average dosage of IVIG due to reimbursement or availability, only 2% say that many patients have had their average dosage reduced, while 22% say several patients have had their average dosage reduced and 13% say that one patient has had his or her average dosage reduced (Figure 56).
Nearly two out of five physicians following IVIG using PID patients (38%) say that any of their PID patients have experienced additional or more severe health problems since the beginning of 2005 because of Medicare reimbursement (Figure 57). Nearly the same proportion says that reductions in Medicare (38%) and reductions in third party payments (40%) have caused additional or more severe health problems for IVIG-using PID patients since the beginning of 2005. Somewhat fewer say that unavailability at a reasonable price (32%) or unavailability at any price (32%) has caused additional or more severe health problems for IVIG-using PID patients in the past two years.

The experience of PID patients with additional or more severe health problems as a result of Medicare reimbursement was more common among physicians in solo practice settings (46%), single specialty group practices (41%) and multi-specialty group practices (36%). (Figure 58) It was less common for physicians in hospital outpatient settings (30%). Among all physicians who follow PID patients being treated with IVIG, 12% say that one patient, 15% say that several of their patients, and 2% say that many of their patients have experienced additional or more severe health problems as a result of reimbursement or availability (Figure 59).

Among all of the physicians following IVIG using PID patients, 13% report that one or more patients have experienced hospitalization as a result of reimbursement or product availability problems (Figure 60). Approximately the same proportion (14%) report one or more PID patients requiring emergency care as a result of these non-medical interferences with normal treatment. More than a quarter (28%) of all doctors following PID patient using IVIG therapy say that reimbursement and availability problems have caused one or more of their patients to need outpatient medical visits. The problems with product availability and reimbursement have also caused increased telephone contact with the physicians’ staff for one (9%), several (11%) or many (10%) patients.

Not surprisingly, the majority of doctors who are treating patients with primary immunodeficiency diseases with IVIG therapy feel that current reimbursement standards for IVIG pose a significant risk to health of their patients. More than half of doctors with IVIG using PID patients, who had an opinion about reimbursement standards, said that the current standards pose an extreme (9%) or serious (47%) risk to the health of PID patients. Most of the rest (33%) felt that current reimbursement standards posed a moderate risk to the health of PID patients. Few doctors who had an opinion about current reimbursement standards felt that current reimbursement standards posed only a slight risk (7%) or no real risk (4%) to the health of PID patients (Figure 61).

Medicare reimbursement standards, however, are not the only potential threat to the health and well-being of IVIG-using PID patients. Doctors were also asked how many of the third-party insurers with whom they had experience have not provided adequate reimbursement for the purchase and administration of IVIG. 12% of doctors said that more than half of third party payers have not provided adequate reimbursement for IVIG, while another 11% said that about half had not provided adequate reimbursement for the purchase and administration of IVIG (Figure 62). However, the
majority of doctors with IVIG-using PID patients (55%) report that some private insurers with whom they have experience do not provide adequate reimbursement for the purchase and administration of IVIG.

More specifically, doctors were asked whether their office had encountered any difficulties since the beginning of 2005 in obtaining third-party approval for PID patients who require IVIG. Only a third (35%) said that they had encountered no real difficulties in getting private insurance approval for PID patients needing IVIG in the past two years (Figure 63). About an equal number (37%) said that they had encountered problems in third-party approvals a few times since the beginning of 2005. Nonetheless, a significant proportion of doctors with IVIG-using PID patients reported a moderate number (17%) or often (11%) encountering difficulties with private insurers in getting approval for IVIG in the past two years. This is consistent with anecdotal reports that some third party payers were adopting Medicare reimbursement rules for IVIG.

**CONCLUSIONS**

In conclusion, the survey finds that doctors who treat patients with primary immunodeficiency diseases with IVIG therapy describe a labor intensive process involving highly trained specialists in the acquisition of product, administration of therapy and patient support between administrations. Current Medicare reimbursement rates for IVIG are ten to twenty percent below the cost of the product alone. The additional administration fee does not appear to cover the associated costs of acquisition, administration, and follow-up required for this therapy; much less say the shortfall in product price. Consequently, it is not surprising that physicians are warning that current reimbursement standards represent a significant risk to health of patients with primary immunodeficiency disease. Intravenous immunoglobulin is the standard of care and only effective treatment for most patients with primary immunodeficiency disease. These physicians have experienced patients being forced to change optimal treatment location, infusion intervals and/or dosing amount, as a result of reimbursement issues, in some case foregoing treatment for extended periods. As a result, some of these vulnerable patients have experienced additional or more severe health effects.
FIGURES (CHARTS & TABLES)

Figure 1

![Primary Ambulatory Care Setting](chart1)

**Primary Ambulatory Care Setting**

- Other: 6%
- Hospital Outpatient: 21%
- HMO: 2%
- Multi-specialty group: 17%
- Single-specialty group: 26%
- Solo practice: 28%

Q1. In what type of ambulatory care setting do you spend MOST of your patient care time? Is it...
Base: All doctors N=230

Figure 2

![Average Number of Outpatients Per Month by Setting](chart2)

**Average Number of Outpatients Per Month by Setting**

- Total: 106
- Solo practice: 141
- Single-specialty group: 130
- Multi-specialty group: 108
- HMO: 86
- Hospital Outpatient: 44
- Other: 56

Q3. In an average month, about how many patients do you see on an outpatient basis? Base: All doctors N=222
Figure 3

Patients with Primary Immune Deficiency Diseases

Q4. How many patients with primary immune deficiency diseases (PID) do you currently follow?
Base: All doctors N=200

Figure 4

Average Number of PID Patients by Setting

Q4. How many patients with primary immune deficiency diseases (PID) do you currently follow?
Base: Doctors who currently follow any PID patients N=164
Figure 5

**Distribution of PID Patients by Setting**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solo practice</td>
<td>11.1%</td>
</tr>
<tr>
<td>Single-specialty group</td>
<td>14.1%</td>
</tr>
<tr>
<td>Multi-specialty group</td>
<td>9.7%</td>
</tr>
<tr>
<td>HMO</td>
<td>1.0%</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>50.5%</td>
</tr>
<tr>
<td>Other</td>
<td>13.5%</td>
</tr>
</tbody>
</table>

Q4. How many patients with primary immune deficiency diseases (PID) do you currently follow?
Base: All PID patients followed by doctors N=552

Figure 6

**Average Number of PID Patients Infused with IVIG Per Month by Setting**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Average Infusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>16</td>
</tr>
<tr>
<td>Solo practice</td>
<td>10</td>
</tr>
<tr>
<td>Single-specialty group</td>
<td>11</td>
</tr>
<tr>
<td>Multi-specialty group</td>
<td>10</td>
</tr>
<tr>
<td>HMO</td>
<td>17</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td>25</td>
</tr>
</tbody>
</table>

Q5. In an average month how many of your PID patients are infused with IVIG?
Base: Doctors who follow IVIG-using PID patients N=152
Figure 7

Total Number of Patients Receiving IVIG or Sub-Q Ig Per Month

- PID Infused: 2388
- PID SubQ: 358
- Non-PID Infused: 269

Q5. In an average month how many of your PID patients are infused with IVIG? Q6. In an average month, how many of your PID patients receive subcutaneous immunoglobulin? Q7. In an average month, how many of your non-PID patients are infused with IVIG? Base: Doctors who follow PID patients. N=147.

Figure 8

Percentage of Patients by Type and Treatment

- PID Infused: 79%
- PID SubQ: 12%
- Non-PID Infused: 9%

Q5. In an average month how many of your PID patients are infused with IVIG? Q6. In an average month, how many of your PID patients receive subcutaneous immunoglobulin? Q7. In an average month, how many of your non-PID patients are infused with IVIG? Base: Doctors who follow PID patients. N=147.
Figure 9

Total Number of Grams of IVIG Infused into Patients Per Month

<table>
<thead>
<tr>
<th>Grams</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 35</td>
<td>9.1%</td>
</tr>
<tr>
<td>35-99 grams</td>
<td>21.0%</td>
</tr>
<tr>
<td>100-199 grams</td>
<td>16.1%</td>
</tr>
<tr>
<td>200-299 grams</td>
<td>15.3%</td>
</tr>
<tr>
<td>300-499 grams</td>
<td>9.1%</td>
</tr>
<tr>
<td>500-999 grams</td>
<td>11.8%</td>
</tr>
<tr>
<td>1000-1999 grams</td>
<td>11.2%</td>
</tr>
<tr>
<td>2000+ grams</td>
<td>6.3%</td>
</tr>
</tbody>
</table>

Q8. Provide your best estimate of the total number of grams of IVIG that are infused into your patients in an average month? Base: Doctors with IVIG using PID patients N=143 (excludes 9 no answers)

Figure 10

Percentage of Grams of IVIG Infused Per Month for PID Patients

<table>
<thead>
<tr>
<th>Percentage of Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 25%</td>
<td>2.7%</td>
</tr>
<tr>
<td>25-49%</td>
<td>1.3%</td>
</tr>
<tr>
<td>50-74%</td>
<td>4.1%</td>
</tr>
<tr>
<td>75-89%</td>
<td>6.0%</td>
</tr>
<tr>
<td>90-99%</td>
<td>10.1%</td>
</tr>
<tr>
<td>100%</td>
<td>75.8%</td>
</tr>
</tbody>
</table>

Q9. Approximately what percentage of this total is for patients with PID diagnoses? Base: Doctors with IVIG using PID patients N=143 (excludes 3 no answers)
Figure 11

Able to Obtain Amount of IVIG to Adequately Treat PID Patients

<table>
<thead>
<tr>
<th></th>
<th>Most (60-69%)</th>
<th>Almost all (90-99%)</th>
<th>All (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>16%</td>
<td>22%</td>
<td>10%</td>
</tr>
<tr>
<td>1-4 Patients</td>
<td>18%</td>
<td>6%</td>
<td>10%</td>
</tr>
<tr>
<td>5-9 Patients</td>
<td>63.6%</td>
<td>66.7%</td>
<td>76.6%</td>
</tr>
<tr>
<td>10-24 patients</td>
<td>53.6%</td>
<td>33%</td>
<td>80.0%</td>
</tr>
<tr>
<td>25 or more</td>
<td>33%</td>
<td>32%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Q10. Thinking about the last 12 months, how many of your PID patients could you adequately treat with the amount of IVIG you were able to obtain— all, almost all, most, some or none? Base: Doctors with PID (IVIG patients N=148 excludes 4 no answer)

Figure 12

Shortfall in Amount of IVIG Needed Per Month to Adequately Treat all PID Patients: In Grams

Q11. Please provide your best estimate of the shortfall about how many more grams of IVIG per month, on average, have you needed? Base: Doctors unable to obtain IVIG necessary to adequately treat all PID patients N=94
Figure 13

Able to Obtain All IVIG Brands Needed

- Yes, able (33%)
- Formulary restricted, but satisfied (25%)
- Formulary restricted, want others (17%)
- No, not able (25%)

Q12. Are you currently able to obtain all of the specific brands of IVIG that you need or prefer? Base: Doctors with IVIG using PID patients. N=150 (excludes 2 no answers)

Figure 14

Had to change Patient’s Primary IVIG Product due to Availability in Past Year

- Yes, had to change (72%)
- No, did not (28%)

Q13. In the past 12 months, have you had to change a patient’s IVIG product due to lack of availability of that patient’s primary product? Base: Doctors with IVIG using PID patients. N=149 (excludes 3 no answers)
Figure 15

Where PID Patients Receive their IVIG

Q14. How many of your PID patients receive their IVIG at the following sites - many, some or none?
Base: Doctors with PID IVIG patients N=150 (excludes 2 no answers)

Figure 16

Contract for Purchase of IVIG

Q33. Does your practice or patient care setting have a contract for the purchase of IVIG? Base: Doctors with IVIG
using PID patients. N=152
Figure 17

Types of Organizations with IVIG Contracts

- Group Purchasing Organization: 36.6%
- Manufacturer: 23.1%
- Distributor: 30.8%
- Not sure: 19.2%

Q34. Which of the following types of organizations do you have a contract? Base: Doctors with IVIG using PID patients with contracts for IVIG. N=52

Figure 18

Total Monthly Allocation

- 120 grams or less: 21%
- 121-320 grams: 25%
- 321-900 grams: 18%
- 901-1800 grams: 16%
- More than 1800 grams: 21%

Q34. What is your total monthly allocation? Base: Doctors with contract for IVIG. N=44
Figure 19

**Average Price for Liquid IVIG**

- ASP+6: $60.65
- Mean Price Paid: $67.47

Q35: What is the average price your office or care facility pays for 1 gram of liquid IVIG? Base: PID patients using IVIG (excludes not sure of price) N=96

Figure 20

**Average Price for Liquid IVIG**

- No contract N=10: $71.30
- Contract N=25: $66.44
- GPO N=9: $68.11
- Manufacturer N=9: $68.11
- Distributor N=11: $67.36

Q33: Does your practice or patient care setting have a contract for the purchase of IVIG? Q34: Which of the following types of organizations do you have a contract? Base: Doctors with IVIG using PID patients
Figure 21

**Average Price for Lyophilized IVIG**

Q36. What is the average price your office or care facility pays for 1 gram of lyophilized IVIG? Base: PID patients using IVIG (excludes not sure of price) N=32

Figure 22

**Average Price for Lyophilized IVIG**

Q33. Does your practice or patient care setting have a contract for the purchase of IVIG? Q34. Which of the following types of organizations do you have a contract? Base: Doctors with IVIG using PID patients
Figure 23

Average Price for Lyophilized IVIG

<table>
<thead>
<tr>
<th>Type of Organization</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>No contract N=8</td>
<td>$67.75</td>
</tr>
<tr>
<td>Contract N=23</td>
<td>$57.87</td>
</tr>
<tr>
<td>GPO N=8</td>
<td>$54.63</td>
</tr>
<tr>
<td>Manufacturer N=6</td>
<td>$72.33</td>
</tr>
<tr>
<td>Distributor N=11</td>
<td>$59.45</td>
</tr>
</tbody>
</table>

Q33. Does your practice or patient care setting have a contract for the purchase of IVIG? Q34. Which of the following types of organizations do you have a contract? Base: Doctors with PID IVIG patients

Figure 24

Medicare Reimbursement Adequate for Price of IVIG

<table>
<thead>
<tr>
<th>Form of IVIG</th>
<th>Adequate</th>
<th>Not Adequate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid IVIG</td>
<td>91%</td>
<td>9%</td>
</tr>
<tr>
<td>Lyophilized IVIG</td>
<td>93%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Q37a. Please indicate whether or not each of the following forms of insurance provides adequate reimbursement for the purchase price of IVIG – Medicare? Base: Doctors with PID IVIG patients who could answer the question N=136
Figure 25

**Time Patient on Site For Infusion**

Mean: 188.54 minutes

<table>
<thead>
<tr>
<th>Duration</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 minute or less</td>
<td>6.7%</td>
</tr>
<tr>
<td>120 minutes</td>
<td>9.9%</td>
</tr>
<tr>
<td>121-179 minutes</td>
<td>7.6%</td>
</tr>
<tr>
<td>180 minutes</td>
<td>20.4%</td>
</tr>
<tr>
<td>181-239 minutes</td>
<td>7.2%</td>
</tr>
<tr>
<td>240 minutes</td>
<td>13.8%</td>
</tr>
<tr>
<td>More than 240</td>
<td>8.7%</td>
</tr>
<tr>
<td>Not sure</td>
<td>18.4%</td>
</tr>
<tr>
<td>No answer</td>
<td>7.2%</td>
</tr>
</tbody>
</table>

Q15. How long on average are your practices PID patients on site for the infusion? (Do not count time waiting in the waiting room to begin the appointment. Base: Doctors with IVIG using PID patients N=152 (Mean excludes missing) 25

Figure 26

**Pre-Medication Prior to Infusion**

- None: 9%
- Only a few: 18%
- Some: 36%
- All or most: 37%

Q17. How many PID patients receive pre-medication prior to the infusion? Base: Doctors with IVIG using PID patients N=140 (excludes 12 not sure and no answers) 26
Figure 27

Other Medications During Infusion

Q20. How many PID patients receive non-IVIG medication during their infusion? Base: Doctors with IVIG using PID patients N=127 (excludes 25 not sure and no answers)

Figure 28

Medications After Infusion

Q22. How many PID patients receive medication after the infusion while still at your infusion suite? Base: Doctors with IVIG using PID patients N=152
**Figure 29**

Physical Examination Prior to Infusion

Q16. How often do PID patients receive a physical examination prior to the infusion at your facility? Base: Doctors with IVIG using PID patients N=124 (excludes 25 not sure and no answers)

**Figure 30**

Vital Signs Monitored During Infusion

Q19. How many times per hour do patients have their vital signs and reactions monitored during the infusion? Base: Doctors with IVIG using PID patients N=115 (excludes 37 not sure and no answers)
Figure 31

Contact with Doctor During Infusion

Q21. How many patients at your facility have additional face-to-face contact with the doctor during the infusion? Base: Doctors with IVIG using PID patients N=126 (excludes 25 not sure and no answers)

Figure 32

Physician Assessment after Infusion

Q23. How many patients have an examination or other assessment with a physician in your office after the infusion? Base: Doctors with IVIG using PID patients N=127 (excludes 25 not sure and no answers)
Figure 33

Post-Visit Telephone Call to Patient

Q24. How often is there a post-visit telephone call with the PID patient or other involved party? Base: Doctors with IVIG using PID patients. N=127 (excludes 25 not sure and no answers)

Figure 34

Frequency of Post-Infusion Reactions

Q25. How often is do you or someone in your office deal with delayed post-infusion reactions patients have? Base: Doctors with IVIG using PID patients. N=131 (excludes 21 not sure and no answers)
Figure 35

Average Minutes Spent during PID Infusion Visit

<table>
<thead>
<tr>
<th>Role</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors N=111</td>
<td>13.2</td>
</tr>
<tr>
<td>Registered Nurse N=102</td>
<td>105.7</td>
</tr>
<tr>
<td>Practical Nurse N=82</td>
<td>31.5</td>
</tr>
<tr>
<td>Technician N=79</td>
<td>6.9</td>
</tr>
<tr>
<td>Other Office staff N=90</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Q276 e. Please indicate for each staff member below how much time (in minutes) is spent during the average PID patient infusion visits? Base: Doctors with IVIG using PID patients (excludes no answers or not sure)

Figure 36

Years of Service for Nurses who Infuse Patients with IVIG

Mean years of service: 12.1

<table>
<thead>
<tr>
<th>Years of Service</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 or less</td>
<td>3.9%</td>
</tr>
<tr>
<td>2-4</td>
<td>4.0%</td>
</tr>
<tr>
<td>5</td>
<td>14.5%</td>
</tr>
<tr>
<td>6-9</td>
<td>10.5%</td>
</tr>
<tr>
<td>10</td>
<td>17.1%</td>
</tr>
<tr>
<td>11-14</td>
<td>6.9%</td>
</tr>
<tr>
<td>15-19</td>
<td>23.7%</td>
</tr>
<tr>
<td>20 or more</td>
<td>19.7%</td>
</tr>
</tbody>
</table>

Q30 On average, about how many years of service do your nurses have who infuse patients with IVIG? Base: Doctors with IVIG using PID patients N=76 (excludes 76 no answers or not sure)
Figure 37

Nurses with Advanced or Specialized Certifications

- All: 30.1%
- Most: 13.8%
- Some: 10.6%
- Only a few: 18.7%
- None: 27.8%

Q31: How many of these nurses have advanced or specialized certifications? Base: Doctors with IVIG using PID patients N=123 (excludes 29 no answers or not sure)

Figure 38

Advanced or Specialized Training for Non-Nursing Staff in IVIG

- All: 18%
- Some: 36%
- Most: 47%

Q32: Do any of your non-nurse staff who participate in the IVIG administration process have specialized or advanced training? Base: Doctors with IVIG using PID patients N=119 (excludes 33 not sure and no answers)
Figure 39

Average Hours Spent Per Month in Acquiring IVIG

<table>
<thead>
<tr>
<th></th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors N=102</td>
<td>2.3</td>
</tr>
<tr>
<td>Nurse N=101</td>
<td>6.3</td>
</tr>
<tr>
<td>Other Office Staff N=81</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Q23a-c. Please indicate how much time is spent, in hours per month, in acquiring IVIG for your practices' patients?  
Base: Doctors with IVIG using PID patients (excludes no answers or not sure)

Figure 40

Staff Time Required to Acquire IVIG

- Yes 80%
- No 20%

Q34b. Even though you have a contract are staff still required to spend time acquiring an adequate amount of IVIG?  
Base: Doctors with contracts for IVIG N=49 (excludes no answers)
Figure 41

Additional Hours Spent Per Month in Support Activities for Patients being treated with IVIG

<table>
<thead>
<tr>
<th>Role</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors (N=92)</td>
<td>3.4</td>
</tr>
<tr>
<td>Nurse (N=87)</td>
<td>10.4</td>
</tr>
<tr>
<td>Other Office Staff (N=77)</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Q29a-c. In addition to the infusion, please estimate how much time is spent, in hours per month, by each staff position in other support activities of your practice's patients being treated with IVIG? Base: Doctors with IVIG (those PPS patients who do not answer do not count).

Figure 42

Reimbursement Adequate for Cost of Administering IVIG

<table>
<thead>
<tr>
<th>Category</th>
<th>Medicare</th>
<th>Medicare with supplement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>55%</td>
<td>64%</td>
</tr>
<tr>
<td>Solo practice</td>
<td>89%</td>
<td>99%</td>
</tr>
<tr>
<td>Single-specialty group</td>
<td>51%</td>
<td>65%</td>
</tr>
<tr>
<td>Multi-specialty group</td>
<td>59%</td>
<td>69%</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>60%</td>
<td>74%</td>
</tr>
<tr>
<td>Other</td>
<td>57%</td>
<td>57%</td>
</tr>
</tbody>
</table>

Q33a/b. Please indicate whether or not each of the following forms of insurance provides adequate reimbursement for the cost of administering IVIG to patients? Base: Doctors with IVIG PPS patients who could answer the question.
Figure 43

Increase in Medicare Reimbursement Needed

- Less than 10%: 2%
- 10-19%: 19%
- 20-34%: 28%
- 35-49%: 17%
- 50% or more: 34%

Q39: What percentage increase in Medicare reimbursement would be necessary for a break-even level for purchase, acquisition, and administration of IVIG infusions in your office or primary care facility? Base: Doctors with IVIG using PID patients who wax Medicare reimbursement not adequate. N=192. Does not include “not sure” and “no answer.”

Figure 44

Changed Site of Infusions due to Medicare

- Total: 52.6%
- Solo practice: 62.2%
- Single-specialty group: 54.8%
- Multi-specialty group: 50.0%
- HMO: 33.3%
- Hospital Outpatient: 39.5%
- Other: 70.0%

Figure 45

Number of Patients who Changed Sites for Non-Medical Reasons

- No answer: 24%
- One: 18%
- Not sure: 4%
- Many: 13%
- Several: 41%

Q45: How many of your PID patients had to change their infusion site because of these non-medical reasons? Base: Doctors with IVIG using PID patients who have changed site of infusion due to reimbursement or availability N=101

Figure 46

Changed Usual Site of PID Infusions

- Medicare reimbursement: 52.6%
- Third Party Reimbursement: 53.3%
- Unavailability at reasonable price: 46.7%
- Unavailability at any price: 38.8%

Q44a-d: Did any IVIG-using PID patients change their usual site of infusion since the beginning of 2005 because of ...? Base: Doctors with IVIG using PID patients. N=152
Figure 47

Infusion Site Transfers Since 2005

- **Hospital Outpatient**: 15%
- **Hospital Inpatient**: 6%
- **At home with nurse**: 5%
- **Self-infused at home**: 19%
- **Your office/facility**: 5%
- **Other site**: 5%

46a-f. About how many of these infusion site transfers since the beginning of 2005 have been to...? Base: Doctors with IVIG PID patients who have had to transfer infusion sites due to Medicare reimbursement N=80

Figure 48

Difficulty in Obtaining Services for PID Patients Referred to Hospitals

- **Much difficulty**: 21%
- **No difficulties**: 27%
- **Some difficulty**: 62%

Q47. Thinking about your patients referred to a hospital-based infusion settings since the beginning of 2005, how much difficulty have you encountered, if any, in obtaining service for these patients in the hospital setting? Base: Doctors with IVIG using PID patients. N=73. (excludes 76 not sure and no answer)
Figure 49

PID Patients Had to Forego Treatment

Q48: How many of your PID patients who had to change their infusion site for because of these non-medical reasons have had to forego treatment for an extended period, if any? Base: Doctors with IVIG using PID patients who have changed site due to reimbursement or availability. N=152

Figure 50

Reduced Frequency of Infusions

Q49a-d: Did any IVIG-using PID patients whom you have treated have to reduce their usual frequency of infusions since the beginning of 2005 because of ...? Base: Doctors with IVIG using PID patients N=152
Figure 51

Reduced Frequency of Infusions due to Medicare

<table>
<thead>
<tr>
<th>Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>38.8%</td>
</tr>
<tr>
<td>Solo practice</td>
<td>43.2%</td>
</tr>
<tr>
<td>Single-specialty group</td>
<td>45.2%</td>
</tr>
<tr>
<td>Multi-specialty group</td>
<td>40.9%</td>
</tr>
<tr>
<td>HMO</td>
<td>33.3%</td>
</tr>
<tr>
<td>Hospital outpatient</td>
<td>31.6%</td>
</tr>
<tr>
<td>Other</td>
<td>20.0%</td>
</tr>
</tbody>
</table>

Q-49e. Did any IVIG using PID patients whom you have treated have to reduce their usual frequency of infusions since the beginning of 2005 because of reductions in Medicare reimbursement? Base: Doctors with IVIG using PID patients N=152

Figure 52

Number of Patients Had Frequency Reduced

- No answer: 30%
- None: 7%
- One: 19%
- Not sure: 1%
- Many: 4%
- Several: 39%

Q50. How many of your PID patients had the frequency of their infusions reduce because of these non-medical reasons? Base: Doctors with IVIG using PID patients who had frequency reduced due to reimbursement or availability N=81
Figure 53

Number of Patients Had to Forego Treatment

Q51: How many of your PID patients who had the frequency of their infusion reduced because of these non-medical reasons have had to forego treatment for an extended period, if any? Base: Doctors with IVIG using PID patients who had their usual frequency reduced due to reimbursement or availability. N=196.

Figure 54

Reduced Dosage of Infusions

Q52a. Have any of your IVIG-using PID patients had their average dosage reduced since the beginning of 2005 because of ________? Base: Doctors with IVIG using PID patients. N=192.
Figure 55

Reduced Dosage of Infusions due to Medicare

<table>
<thead>
<tr>
<th></th>
<th>Yes, reduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>28.9%</td>
</tr>
<tr>
<td>Solo practice</td>
<td>35.1%</td>
</tr>
<tr>
<td>Single-specialty group</td>
<td>33.3%</td>
</tr>
<tr>
<td>Multi-specialty group</td>
<td>31.8%</td>
</tr>
<tr>
<td>HMO</td>
<td>33.3%</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>21.1%</td>
</tr>
<tr>
<td>Other</td>
<td>10.0%</td>
</tr>
</tbody>
</table>

Q59a. Have any of your IVIG-using PID patients had their average dosage reduced since the beginning of 2005 because of reductions in Medicare reimbursement? Base: Doctors with IVIG using PID patients N=152

Figure 56

Number of PID Patients Had Dosage Reduced

- No Answer: 57%
- One: 13%
- Several: 22%
- Not sure: 6%

Q53. How many of your PID patients had their average dosage reduced because of these non-medical reasons, if any? Base: Doctors with IVIG using PID patients who had dosage reduced due to reimbursement or availability N=54
Figure 57

**Experienced Health Problems**

- Reductions in Medicare reimbursement: 38.2%
- Reductions in third party reimbursement: 39.5%
- Unavailability at reasonable price: 32.2%
- Unavailability at any price: 31.6%

Q54a-d. Have any of your IVIG-using PID patients experienced additional or more severe health problems since the beginning of 2005 because of ....? Base: Doctors with IVIG using PID patients N=152

Figure 58

**Experienced Health Problems due to Medicare**

- Total: 36.2%
- Solo practice: 45.9%
- Single-specialty group: 40.5%
- Multi-specialty group: 36.4%
- HMO: 33.3%
- Hospital Outpatient: 29.7%
- Other: 40.0%

Q54a. Have any of your IVIG-using PID patients experienced additional or more severe health problems since the beginning of 2005 because of reductions in Medicare reimbursement? Base: Doctors with IVIG using PID patients N=152
Figure 59

**PID Patients Had Health Problems**

Q55. How many of your PID patients experienced additional or more severe health problems due to these non-medical reasons?  Base: Doctors with IVIG using PID patients  N=152

Figure 60

**Experienced Adverse Health Outcomes**

Q55a. How many of your PID patients experienced one or more of the following adverse health outcomes as a result of these non-medical reasons?  Base: Doctors with IVIG PID patients  N=152
Figure 61

How Serious a Risk to Patients’ Health are Current Reimbursement Standards

- Total: 53%
- 1-4 Patients: 47%
- 5-9 Patients: 60%
- 10-24 Patients: 40%
- 25 or more Patients: 28%

Q43. In your opinion, how much risk, if any, do current reimbursement standards for IVIG pose to the health of PID patients – extreme, serious, moderate, slight or no real risk? Base: Doctors with PID IVIG patients answering the question N=108

Figure 62

Adequacy of Private Insurance for IVIG

- More than half: 12%
- About half: 11%
- None: 22%
- Some: 55%

Q40. Thinking about third-party (private) insurers with whom you have some experience, how many of them have not provided adequate reimbursement for the purchase and administration of IVIG? Base: Doctors with IVIG using PID patients N=73 (excludes 79 not sure and no answer)
Figure 63

Problems with Approval from Private Insurance for PID use of IVIG

- No real difficulties: 36%
- A few times: 37%
- A moderate number: 17%
- Often: 11%

Q34: Have you or has your office encountered any difficulties since the beginning of 2005 in obtaining third-party approval for PID patients requiring IVIG? Base: Doctors with IVIG using PID patients N=101 (excludes 61 out of 101 who don't know or not sure).
APPENDIX I: MONTHLY ADMINISTRATION FOR IVIG

MONTHLY ADMINISTRATION FOR IVIG: IDF/AAAAI SURVEY

<table>
<thead>
<tr>
<th>Labor category</th>
<th>Minutes During Visit</th>
<th>Average # per Month</th>
<th>Minutes Administering</th>
<th>Minutes Aquiring</th>
<th>Minutes Other Support</th>
<th>Total Minutes Per month</th>
<th>Minutes Per Infusion</th>
<th>Hours Per Infusion</th>
<th>Hourly Rate</th>
<th>Cost Per Infusion*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>14.2</td>
<td>20.3</td>
<td>288.26</td>
<td>138</td>
<td>204</td>
<td>630.26</td>
<td>39.4</td>
<td>0.66</td>
<td>$0.00</td>
<td></td>
</tr>
<tr>
<td>RN</td>
<td>106.48</td>
<td>20.3</td>
<td>2161.544</td>
<td>378</td>
<td>624</td>
<td>3163.544</td>
<td>197.7</td>
<td>3.30</td>
<td>$0.00</td>
<td></td>
</tr>
<tr>
<td>PN</td>
<td>34.86</td>
<td>20.3</td>
<td>707.658</td>
<td>0</td>
<td>0</td>
<td>707.658</td>
<td>44.2</td>
<td>0.74</td>
<td>$0.00</td>
<td></td>
</tr>
<tr>
<td>Technician</td>
<td>7.61</td>
<td>20.3</td>
<td>154.483</td>
<td>0</td>
<td>0</td>
<td>154.483</td>
<td>9.7</td>
<td>0.16</td>
<td>$0.00</td>
<td></td>
</tr>
<tr>
<td>Office staff</td>
<td>7.85</td>
<td>20.3</td>
<td>159.355</td>
<td>270</td>
<td>162</td>
<td>591.355</td>
<td>37.0</td>
<td>0.62</td>
<td>$0.00</td>
<td></td>
</tr>
</tbody>
</table>

Total Administrative Costs per Infusion $0.00

Hospital-based outpatient reimbursement
Pre-Administration $75.00
Infusion Administration $120.77 (2006 data)
Total

Office-based
Pre-Administration $69.00
Infusion Administration, first hour $77.31
Infusion Administration, additional hours (189 minute/3 hour average infusion) $25.77

PRODUCT COSTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Average paid</th>
<th>Medicare rate</th>
<th>Difference</th>
<th>Average grams</th>
<th>Average loss per infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIQUID IVIG</td>
<td>$67.47</td>
<td>$60.65</td>
<td>$6.82</td>
<td>30</td>
<td>$204.60</td>
</tr>
<tr>
<td>LYOPHILIZED</td>
<td>$60.25</td>
<td>$50.53</td>
<td>$9.72</td>
<td>30</td>
<td>$291.60</td>
</tr>
</tbody>
</table>
APPENDIX II: SURVEY QUESTIONNAIRE
Dear Colleague:

We request your participation in an important survey to determine the extent to which recent changes in IVIG supply, cost, and reimbursement has affected treatment of primary immune deficiency patients and the effects on patients' health. It will also be used to document the level of effort required of medical staff in providing treatment.

This survey covers five general areas. These are
1) Information about your practice and your patients with PID
2) Information about how PID patients are treated in your practice
3) Information about the direct services required by PID patients in your practice
4) The costs of and insurance support of PID patients in your practice
5) The effects the current reimbursement environment on your patients

Responding to this survey as accurately and completely as possible is extremely important. In order to provide the best information, you might want to print out the survey in advance and share it with non-physician members of your office/staff to get their input on questions 27-29, 35-43,and possibly several others. To do this, use the link below to download a PDF file of the survey to print. After obtaining the input of other staff, you will then need to enter your answers into the online document. Completing the online survey will take about 30 minutes and should be done in one session.

Your participation in this research is important. The information being collected is essential to our advocacy efforts.

The questionnaire can be accessed at: http://www.aaaai.org/professionals/survey/idf0906/default.asp

With great appreciation,
Jordan Orange, Chair, Primary Immunodeficiency Diseases Committee
American Academy of Allergy, Asthma & Immunology

[AAAAI: Something like the text in the above box should be sent or e-mailed to sampled doctors along with the link (URL) to the online questionnaire.]

Please answer as accurately as possible, even if you currently see few or no patients who receive IVIG treatment. Some answers might be improved by consultation with others in your office. Mark “Don’t Know” only for those questions you are unable to answer with reasonable accuracy or confidence.
A. Your Patients and Practice Setting

1. In what type of ambulatory care setting do you spend MOST of your patient care time?
   - Solo practice
   - Single-specialty group practice
   - Multi-specialty group practice
   - Infusion clinic
   - HMO
   - Hospital outpatient
   - Other (Please specify:) ___________________________________________________

2. In what state is your practice located? ________, City: ________________________

3. In an average month, about how many patients in total do you see on an outpatient basis?
   ________ patients per week

4. How many patients with primary immune deficiency diseases (PID) do you currently follow?
   ________ PID Patients

   *** IF YOU CURRENTLY FOLLOW NO PATIENTS WITH PID DIAGNOSES (0 TO Q4), GO TO END ***

5. In an average month, how many of your PID patients are infused with IVIG?
   _____ PID patients/mo

6. In an average month, how many of your PID patients receive subcutaneous immunoglobulin?
   _____ PID patients/mo

7. In an average month, how many of your non-PID patients are infused with IVIG?
   _____ non-PID patients/mo

   *** IF YOU DO NOT CURRENTLY TREAT PATIENTS WITH IVIG (0 TO Q5 AND Q7), GO TO END ***
8. Provide your best estimate for the total number of grams of IVIG that are infused into your patients in an average month, (Base your answer on the past 12 months.)

   Total grams/mo: __________________

9. Approximately what percentage of this total is for patients with **PID** diagnoses? (Base your answer on the past 12 months.)

   ____________%

10. Thinking about the past 12 months, how many of your **PID patients** could you adequately treat with the amount of IVIG you were able to obtain?

    All (100%) → **GO TO Q12**
    Almost all (90-99%)
    Most (50-89%)
    Some (25-49%)
    Few (10-24%)
    Almost none (1-9%)
    None (0%)

11. Please provide your best estimate of the shortfall: About how many more grams of IVIG per month, on average, have you needed?

    Less than 50 grams
    50-150 grams
    151-300 grams
    301-500 grams
    More than 500 grams
    Don’t know

12. Are you currently able to obtain all of the specific brands of IVIG that you need or prefer?

    Yes
    No
    I am restricted to the use of specific brands by my hospital formulary, but want others
    I am restricted to the use of specific brands by my hospital formulary, but I am satisfied with my options

13. In the past 12 months, have you had to change a patient’s IVIG product due to lack of availability of that patient’s primary product?

    Yes
    No
14. How many of your PID patients receive their IVIG at the following sites? (Mark one answer for each site listed:)

   Many  Some  None  Don't Know

   a. Your office or primary care facility
   b. Hospital outpatient infusion suite
   c. Hospital inpatient
   d. Home with a nurse
   e. Home via self-infusion
   f. Any other site? (Specify: ____________)

B. Questions About how PID Patients are Treated in Your Practice

15. How long, on average, are your practice's PID patients on site for the infusion? (Do not count time waiting in the waiting room to begin the appointment.) Please take a moment to estimate the average patient time on site as carefully as you can. Do not enter a range.

   __________ minutes  □ Don't know

16. How often do PID patients receive a physical examination prior to the infusion at your facility?

   Every or most visits
   Some visits
   Only rarely
   Never
   Don't know

17. How many PID patients receive pre-medication prior to the infusion?

   All or most
   Some
   Only a few
   None
   Don't know

18. How long does an IVIG infusion take for your average PID patient, from venous access to discontinuation of the infusion?

   Less than 2 hours
   2-4 hours
   4-6 hours
   6-8 hours
   More than 8 hours
   Don't know
19. How many times per hour do patients have their vital signs and reactions monitored during the infusion?

   Less than 1 time
   2 times
   3 times
   4 times
   More than 4 times
   Continuously
   Don’t know

20. How many PID patients receive non-IVIG medication during their infusion?

   All or most
   Some
   Only a few
   None
   Don’t know

21. How many patients at your facility have additional face-to-face contact with the doctor during the infusion?

   All or most
   Some
   Only a few
   None
   Don’t know

22. How many PID patients receive medication after the infusion while still at your infusion facility?

   All or most
   Some
   Only a few
   None
   Don’t know

23. How many patients have an examination or other assessment by a physician in your office after the infusion?

   All or most
   Some
   Only a few
   None
   Don’t know
24. How often is there a post-visit telephone call with the PID patient or other involved party?

   Every or most visits
   Some visits
   Only rarely
   Never
   Don’t know

25. How often do you or someone in your office deal with delayed post-infusion reactions patients have?

   Often – after many visits
   Occasionally – after some visits
   Seldom – after few visits
   Never
   Don’t know

26. What is the average nurse to patient ratio at your facility when infusing IVIG?

   1 nurse for every _______ patients
   □ Don’t know

27. Please indicate for each staff member below how much time is spent during the average PID patient infusion visit? (In calculating these average times, be sure to include those visits when 0 minutes is spent.) Do not enter ranges or fractions.

   a. Doctor:   __________ minutes/infusion
   b. Registered nurse:  __________ minutes/infusion
   c. Practical nurse:  __________ minutes/infusion
   d. Technician:   __________ minutes/infusion
   e. Other office staff:  __________ minutes/infusion

C. IVIG Treatment Support Activities and Credentials

28. Please estimate how much time is spent, in hours per month, on average, in acquiring IVIG for your practice’s patients. Do NOT count time included in the previous answers. DO count: communication with patients, distributors, manufacturers, and specialty pharmacies; inventory management and record keeping; and insurance pre-certification. Please estimate as accurately as possible; avoid “Don’t know” unless you are unable to provide an estimate. Do not enter ranges or fractions.

   a. Average hours/month spent by MD:   ________hours/mo
   □ Don’t know
   b. Average hours/month spent by Nurse:   ________hours/mo
   □ Don’t know
   c. Average hours/month spent by Other Staff:  ________hours/mo
   □ Don’t know
29. In addition to the infusion, please estimate how much time, in hours per month, on average, is spent by each staff position in **other support activities** of your practice’s patients being treated with IVIG. Do NOT count time included in the previous answers. DO Include time spent ordering, obtaining, and monitoring blood studies; administration of non-IVIG medication after infusion, record-keeping, equipment/space preparation and space recycling. Please estimate as accurately as possible; avoid “Don’t know” unless you are unable to provide an estimate. Do not enter ranges or fractions.

   a. Average hours/month spent by MD:   ________hours/mo   □ Don’t know

   b. Average hours/month spent by Nurse:   ________hours/mo   □ Don’t know

   c. Average hours/month spent by Other Staff:  ________hours/mo   □ Don’t know

30. On average, about how many years of service do your nurses have who infuse patients with IVIG?
   
   _______ average years of service   □ Don’t know

31. How many of these nurses have advanced or specialized certifications?
   
   All
   Most
   Some
   Only a few
   None
   Don’t know

32. Do any of your non-nurse staff who participate in the IVIG administration process have specialized or advanced training?
   
   Yes
   No
   Don’t know

33. Does your practice or patient care setting have a contract for purchase of IVIG?
   
   Yes
   No ➔ **GO TO Q35**
   Don’t know ➔ **GO TO Q35**

34. With which of the following types of organizations do you have a contract? (Mark all that apply or mark “don’t know”.)
   
   Group Purchasing Organization (GPO)
   Manufacturer
   Distributor
   Other type
   Don’t know
34a. What is your total monthly allocation?

____________________ g/mo

34b. Even though you have a contract, are staff still required to spend time acquiring an adequate amount of IVIG?

Yes
No
Don’t know

D. Operating Costs and Insurance Related Issues

35. What is the average price your office or care facility pays for 1g of liquid IVIG? Round to the nearest dollar. Do not enter a range.

__________ per gram □ Don’t know

36. What is the average price your office or care facility pays for 1g of lyophilized IVIG? Round to the nearest dollar. Do not enter a range.

__________ per gram □ Don’t know

37. Please indicate whether or not each of the following forms of insurance provides adequate reimbursement for the purchase price of IVIG?

Adequate    Not Adequate    Don’t Know

a. Medicare
b. Medicare with supplement
c. Medicaid

38. Please indicate whether or not each of the following forms of insurance provides adequate reimbursement for the cost of administering the IVIG to patients?

Adequate    Not Adequate    Don’t Know

a. Medicare
b. Medicare with supplement
c. Medicaid
39. **(IF EITHER “NOT ADEQUATE” IN Q37a OR Q38a:)** What percentage increase in Medicare reimbursement would be necessary for a break-even level for purchase, acquisition, and administration of IVIG infusions in your office or primary care facility?

- 1-- 9%
- 10 – 19%
- 20 – 34%
- 35 – 49%
- 50% or more
- Don’t know

40. Thinking of the third-party (private) insurers with whom you’ve had some experience, how many of them have NOT provided adequate reimbursement for the purchase and administration of IVIG?

- None – all reimburse adequately
- Some do not
- About half do not
- More than half do not
- Don’t know

41. Have you or has your office/facility encountered difficulties since the beginning of 2005 in obtaining third-party (private insurance) approval for PID patients who require IVIG?

- No real difficulties ➔ **GO TO Q43**
- Yes, a few times
- Yes, a moderate number of times
- Yes, often
- Don’t know ➔ **GO TO Q43**

42. Please list those third-party insurers that you or your office has had difficulty with since the beginning of 2005 in obtaining insurance approval. (If cannot recall name(s), write “Don’t Know” on the first line.)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

43. In your opinion, how much risk, if any, do current reimbursement standards for IVIG pose to the health of PID patients?

- Extreme
- Serious
- Moderate
- Slight
- No real risk
- Don’t know
E. Additional Questions About YOUR Patients (Not the Patients of Other MDs in Your Practice)

44. Did any IVIG-using PID patients whom you’ve treated have to change their usual site of infusion since the beginning of 2005 because of…?

- Yes
- No
- Don’t Know

   a. Reductions in Medicare reimbursement
   b. Reductions in third-party (private insurer) reimbursement
   c. Unavailability of the product at a reasonable price
   d. Unavailability of the product at any price

IF NO TO ALL IN Q44, GO TO Q49.

45. How many of your PID patients had to change their infusion site because of these non-medical reasons?

- One
- Several
- Many
- Don’t know

46. About how many of these infusion site transfers since the beginning of 2005 have been to… (Mark on answer for each site.)

- None
- One
- Several
- Many
- Don’t Know

   a. A hospital outpatient site
   b. Hospital inpatient
   c. Home with a nurse
   d. Home via self-infusion
   e. Your office/facility
   f. To another site (SPECIFY:) ___________________

47. (IF ONE OR MORE TO Q46a OR Q46b:) Thinking of your patients referred to a hospital-based infusion setting since the beginning of 2005, how much difficulty have you encountered, if any, in obtaining service for these patients in the hospital setting?

- No difficulty
- Some difficulty
- Much difficulty
- Don’t know

48. How many of your PID patients who had to change their infusion site because of these non-medical reasons have had to forego treatment for an extended period, if any?

- None
- One
- Several
- Many
- Don’t know
49. Did any IVIG-using PID patients whom you’ve treated have to reduce their usual frequency of infusions since the beginning of 2005 because of…?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Reductions in Medicare reimbursement  
b. Reductions in third-party (private insurer) reimbursement  
c. Unavailability of the product at a reasonable price  
d. Unavailability of the product at any price  

**IF NO TO ALL IN Q49, GO TO Q52.**

50. How many of your PID patients had their frequency of infusions reduced because of these non-medical reasons?  

<table>
<thead>
<tr>
<th>None</th>
<th>One</th>
<th>Several</th>
<th>Many</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

51. How many of your PID patients who had their infusion frequency reduced because of these non-medical reasons have to forego treatment for an extended period, if any? (For example, needing to change from every 4wks to every 5wks)  

<table>
<thead>
<tr>
<th>None</th>
<th>One</th>
<th>Several</th>
<th>Many</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

52. Have any of your IVIG-using PID patients had their average dosage reduced since the beginning of 2005 because of…?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Reductions in Medicare reimbursement  
b. Reductions in third-party (private insurer) reimbursement  
c. Unavailability of the product at a reasonable price  
d. Unavailability of the product at any price  

**IF NO TO ALL IN Q52, GO TO Q54.**

53. How many of your PID patients who had their average dosage reduced because of these non-medical reasons, if any?  

<table>
<thead>
<tr>
<th>One</th>
<th>Several</th>
<th>Many</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

54. Have any of your IVIG-using PID patients experienced additional or more severe health problems since the beginning of 2005 because of…?

Yes  No  Don’t Know

a. Reductions in Medicare reimbursement
b. Reductions in third-party (private insurer) reimbursement
c. Unavailability of the product at a reasonable price
d. Unavailability of the product at any price

IF NO TO ALL IN Q54, GO TO END.

55. How many of your PID patients experienced additional or more severe health problems due to these non-medical reasons?

One
Several
Many
Don’t know

56. How many of your PID patients experienced one or more of the following adverse health outcomes as a result of these non-medical reasons?

None  One  Several  Many  Don’t Know

a. Death
b. Illnesses requiring hospitalization
c. Illness requiring emergent care
d. Illness requiring outpatient medical visits
e. Increased telephone contact time with medical or support staff

Thank you very much for taking the time to complete this survey!